Orange County District Office
RAP Session June 28, 2017
Presented by:

Jacqueline A. Lincer, Branch Chief
Hang Nguyen, District Manager
Kathleen Davidson, District Administrator (LTC)
Josefina Sabino, District Administrator (NLTC)
Porntip Athinan, Supervisor
Audrey Bui, Supervisor
Susan Seyboth, Supervisor
Kathleen Kirkpatrick, Supervisor
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Jane Sarmiento, Training Supervisor
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Lydia Vizcaino, AGPA
Zeandra Villa, SSA

Updates to Food & Nutrition Services in Long Term Care

Terri Blackwell-Goetz, MPH, RD
Nutrition Consultant Unit Chief
CDPH, Center for Healthcare Quality

Learning Objectives

- Will have an understanding of the recent changes in Food & Nutrition Services section of the State Operations Manual and how they impact your facility

Learning Objectives

- Will have an understanding of what constitutes compliance with F325 Nutrition Care

CMS Regulation Changes
Food & Nutrition Section

Final Rule

- S&C 17-07-NH
  November 9, 2016

- S&C 17-19-NH
  February 17, 2017
  March 10, 2017 (revised)

CMS S&C Letters

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

History

- Not comprehensively updated since 1991
- Significant changes in nursing homes
- Higher acuity residents

Themes of the Final Rule

- Person centered care
- Strengthening Regulatory Language
- Requiring that facilities provide more services
- Improving patient safety

3 Phase Process

Phase 1: existing requirements

Began Nov. 28, 2016

Phase 2: Includes all Phase 1 & Phase 2 requirements

Begins: Nov 28, 2017

Phase 3: Includes all Phase 1 & Phase 2 requirements & those that need more time

Begins Nov. 28, 2019

Name Changes

- Regulatory Groupings
- Sections

- Dietary Services
- Food and Nutrition Services

F150 Definitions

- Person Centered Care – to focus on the resident as the locus of control and support the resident in making their own choices and have control over their lives

F360 Food & Nutrition Service

- The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets *his or her* daily nutritional and special dietary needs, *taking into consideration the preferences* of each resident.

F361Food & Nutrition Service

- The facility must employ *sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service*

- Phased in regulatory requirement for DSS qualifications depending on the date of hire.

F361 §483.60(a)(2)

- If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services *who*:

F361 §483.60(a)(2)

- (A) A certified dietary manager; or
  (B) A certified food service manager; or
  (C) Has similar national certification for food service management and safety from a national certifying body; or
  (D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; and

F361 §483.60(a)(2)

…AND (ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and

(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

F361 §483.60(a)(2)

- (i) For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016,

- Or no later than 1 year after November 28, 2016 for designations after November 28, 2016, is:

F362 Support Staff

- The facility must provide sufficient support personnel to *safely and effectively* carry out the functions of the department

- *A member of the FNS staff must participate in interdisciplinary care planning*

F363 Menus

- Menus must meet *established nutrition guidelines*;
- *Reflect reasonable efforts to meet cultural, religious and ethnic needs as determined by residents;*
- *Be updated periodically;*
- *Be reviewed by the facility Registered Dietitian*

F364 Food and Drink

- The facility must provide food *and drink* that is prepared by methods that conserves nutritive value, flavor and appearance; and that is palatable, attractive and at a *safe and appetizing* temperature.

F366

- *Accommodate resident allergies, intolerances and preferences*
- Offer *appealing options* of similar nutritive value for residents who *choose not to eat* food that was *initially* served *or who request a different meal choice*
- *Drinks and other liquids consistent with resident needs and preferences sufficient to maintain resident hydration*

F367 Therapeutic Diets

- State of California prohibits Dietitians from prescribing Resident Diets!

F368 Frequency of Meals

- Facility must provide 3 meals/day…or *in accordance with resident needs, preferences, requests and plan of care*
- No more than 14 hours between breakfast and dinner
- *Suitable and nourishing meals must be provided to residents who choose to eat outside of non-traditional meal schedules*

F369 Assistive Devices

- The facility must provide special eating utensils *and appropriate assistance to ensure that the resident can use the assistive devices when consuming meals and snacks.*

F371 Food Safety

- *May use items obtained from local producers*
- *Facility Gardens*
- *Policy needed on use & storage of foods brought in by family/visitors*

Small Farm Food Safety Guidelines

- https://www.cdfa.ca.gov/is/i_&_c/pdfs/SFFSGbooklet-QuickPrintEnglish.pdf

F371 Food Safety

The facility must store, prepare, distribute and serve food in accordance *with professional standards of food service safety*.

Food Code

- F 371 guidance:
  - "CMS recognizes the **US FDA Food Code** and CDC food safety guidelines as national standards to procure, store, distribute and serve food in LTC facilities in a safe and sanitary manner."

Food Code

U.S. Public Health Service

FDA

2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

CDPH California Department of PublicHealth

F371 Food Safety

- Guidance
  - Nursing home residents risk **serious** complications from foodborne illness as a result of their compromised status
- Immediate Jeopardy Language…
  - Has caused or is likely to cause, **serious** injury, harm, impairment or death

Best Practices

- Network with other Supervisors
- Train, Train, then train again!
- Observe, watch your staff
  - If the DSS is not in the kitchen??
- Help staff understand how IMPORTANT they are!

F 325 Assisted Nutrition & Hydration

Based on a resident's comprehensive assessment, the facility must ensure that a resident maintains acceptable parameters of nutritional status, such as *usual* body weight or *desirable body weight range* and *electrolyte balance*, unless the resident's clinical condition demonstrates that this is not possible *or the residents preferences indicate otherwise*.

F325 Assisted Nutrition & Hydration

- *Is offered* a therapeutic diet when there is a nutritional problem *and the health care provider orders a therapeutic diet.*

F325 Assisted Nutrition & Hydration

- UNAVOIDABLE: the resident did not maintain acceptable parameters of nutritional status when the facility did all of the following:

F325 Assisted Nutrition & Hydration

- Evaluate the resident's clinical condition and nutritional risk factors

F325 Assisted Nutrition & Hydration

- Define and implement interventions that are consistent with the resident's needs, goals and recognized standards of practice.

F325 Assisted Nutrition & Hydration

- Monitor and evaluate the impact of the interventions
- Revise interventions as appropriate

F325 Assisted Nutrition & Hydration

- AVOIDABLE: means the resident did not maintain acceptable parameters of nutritional status and the facility did not do 1 or more of these

Questions

Pharmacy Survey Trends

Orange County CAHF Chapter
Annual CDPH RAP session
June 28, 2017

Robert Jackson, PharmD
Pharmaceutical Consultant II, Specialist
CDPH – Center for Health Care Quality
Licensing & Certification Program

Objectives

- Automated Drug Dispensing Devices (ADDS)
  - SB 1193 changes effective January 1, 2017
- Nuedexta
  - PBA or Psychoactive?
- Medical Marijuana
  - State vs. Federal

ADDS System Examples

- Cubex
- AlixaRx
- Talyst
- Omnicell
  - AcuDose-Rx
  - ~~MTS MedLocker~~
- MedSelect
- Phoenix LTC-StatSafe

ADDS H&SC 1261.6

- SNF/ICF
- Transaction records
- P&P

H&SC 1261.6(g)

- (g)(1 & 2) – stocking of ADDS must be done by a pharmacist UNLESS the ADDS utilizes removable pockets, cards, drawers, or unit of use or single dose containers, which are stocked by pharmacist/tech/intern outside the facility and delivered to facility in a secure tamper-evident container

- (g)(3) – P&Ps developed to ensure pockets, cards, drawers, unit of use or single dose containers are properly placed in ADDS

H&SC 1261.6(f)

- (7)(A) – Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed…if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an [ADDS] shall notify the department in writing prior to utilization of the system.
- (7)(B) – (discusses what will be reviewed)
- (7)(C) – ~~This paragraph shall remain in effect only until January 1, 2012, unless a later enacted statute is enacted on or before January 1, 2012, deletes or extends that date.~~

AFL 17-05

State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

EDMUND G. BROWN JR.
Governor

February 3, 2017 AFL 17-05

TO: Intermediate Care Facility
Nursing Facilities
Skilled Nursing Facilities

SUBJECT: Senate Bill (SB) 1193: Healing Arts (Chapter 484, Statutes of 2016)

All Facilities Letter (AFL) Summary

- This AFL notifies providers of the chaptering of SB 1193, that effective January 1, 2017, reinstates skilled nursing facilities' (SNF), nursing facilities' (NF), and intermediate care facilities' (ICF) ability to use automated drug delivery systems (ADDS) that allow personnel to have access to multiple drugs not patient specific in their design if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.
- Facilities must obtain authorization from the California Department of Public Health's Licensing and Certification Program (L&C) prior to using an ADDS that meets the aforementioned criteria.

Prior to January 1, 2012, HSC section 1261.6 permitted SNF, NF, and ICF personnel to access multiple drugs that are not patient specific only if an ADDS had both electronic and mechanical safeguards in place to ensure that the only drugs delivered to the patient were specific to that patient. This was initially a pilot program that sunsetted January 1, 2012. SB 1193 repeals the sunset provision, thereby reauthorizing the use of these devices in SNFs, NFs, and ICFs provided they meet all requirements.

This AFL notifies providers that effective January 1, 2017, SB 1193: Healing Arts reinstates SNFs, NFs, and ICFs ability to use ADDS that allow personnel to have access to multiple drugs not patient specific in their design if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

Center for Health Care Quality, MS 0512 • P.O. Box 997377 • Sacramento, CA 95899-7377
(916) 324-6630 • (916) 324-4820 FAX
Internet Address: www.cdph.ca.gov

NUEDEXTA®

(dextromethorphan HBr and quinidine sulfate) capsules 20 mg / 10 mg

CDPH California Department of PublicHealth

Nuedexta – what is it?

- Combination product
  - Dextromethorphan 20mg
  - Quinidine sulfate 10mg

- AWP = $907 for bottle of 60 capsules

CDPH California Department of PublicHealth

Dextromethorphan

- The “DM” in Robitussin DM
- Cough suppressant with ***dissociative anesthetic*** properties at high doses
  - Hallucinogenic state
  - Visual distortion
  - Loss of sense of time
  - Euphoria
- Typical cough suppressant dose is 10mg/5mL

CDPH California Department of PublicHealth

Quinidine Sulfate

- Antiarrhythmic – atrial fibrillation/flutter
- Typical oral dose is 200-300mg when used for arrhythmia
- Included mainly for CYP2D6 liver enzyme inhibition = increases dextromethorphan concentrations

CDPH California Department of PublicHealth

Nuedexta Indication/MOA

- Labeled (FDA approved)
  - Treatment of Pseudobulbar Affect (PBA)
- Unlabeled (non-FDA approved)
  - Agitation associated with dementia
  - Major depressive disorder
- Mechanism of Action
  - "The mechanism by which dextromethorphan exerts therapeutic effects in patients with pseudobulbar affect is unknown." – Nuedexta package insert

CDPH California Department of PublicHealth

What is PBA?

- Pseudobulbar Affect
  - **Neurological condition**
    - Not psychiatric
  - Emotional lability, labile affect, or emotional incontinence: characterized by involuntary crying and/or laughing.
  - Occurs secondary to a neurologic disorder or brain injury
    - Stroke, Alzheimer's Dz, MS, ALS, Parkinson's Dz
  - Episodes may also be mood-incongruent: a patient might laugh uncontrollably when angry or frustrated
  - Estimated to affect less than 1% of US population (no official studies)

CDPH California Department of PublicHealth

Nuedexta Dose

- One capsule daily by mouth for 7 days, then one capsule twice daily
  - Recommended to be 12 hour separation
  - May be taken with or without food
  - No official recommendation but reports indicate it may be opened up and the contents administered via alternative routes (e.g. GT)

Contraindications/Warnings

- Contraindications
  - Do not take with quinidine, quinine, mefloquine
  - Patients with prolonged QT interval/Torsades de Pointes
  - *Heart failure*
  - AV block

- Warnings
  - Thrombocytopenia
  - Hepatotoxicity
  - Increases risk for prolonged QT interval
  - Dizziness (10% of patients = falls)
  - Serotonin syndrome

CDPH California Department of PublicHealth

Adverse Reactions

- Diarrhea (13%)
- Dizziness (10%)
- Cough, vomiting, peripheral edema (5%)
- UTI, influenza (4%)
- Flatulence (3%)
- Also:
  - Muscle spasms
  - Abdominal pain
  - Physical weakness

Drug Interactions

- SSRIs
  - Especially Paxil (paroxetine)
  - 1.5 – 1.7x increase in paroxetine concentrations
  - Serotonin syndrome

- Digoxin
  - 2x increase digoxin levels
  - Digoxin levels should be closely monitored

CDPH California Department of PublicHealth

What are the concerns?

- Potential for use as chemical restraint
  - Similar concept for the use of antipsychotics in dementia patients
  - Produce dissociative affect in the patient in order to reduce negative behavior
- Not indicated for treatment of dementia
- PBA is not common
- Side effects of Nuedexta components can be serious
- Placing a lifelong diagnosis of PBA on a patient who does not have PBA

CDPH California Department of PublicHealth

Things to Consider

- Is the true diagnosis for use PBA or psych/dementia?
  - If PBA, is there evidence to support PBA diagnosis?
    - History (pre-admission) of PBA
    - Did the Neurologist prescribe (although not required)
    - Typical manifestations (laughing/crying)
- Does the resident have psychosis or dementia?
  - Other medications for treatment of dementia behavior?
  - Antipsychotics? Anxiolytics? Mood stabilizers?
- Is there benefit to the resident?
  - Documented evidence of improvement
  - Increased social interaction?
  - Happy vs. depressed?

CDPH California Department of PublicHealth

Deficiency?

- A deficiency may exist for the use of Nuedexta, at F329 Unnecessary Drugs, if it is determined:

  - Without adequate indications
    - A PBA diagnosis is placed on the resident's record with no history of PBA and no evaluation by qualified practitioner
    - No documented signs/symptoms of typical manifestations (uncontrolled laughing or crying)
    - Actual diagnosis for use is behavior control

  - Without adequate monitoring
    - Uncontrolled laughing or crying *or other behavior* is not monitored
    - Side effects are not monitored/documented
    - Presence of other indicators that medication is being used for psychiatric/dementia behavior control

  - In the presence of adverse consequences
    - Resident has evidence of Nuedexta side effects that should have indicated a reduction in dose or discontinuation
      - Diarrhea, dizziness (falls), cardiovascular events (QT interval), contraindicated use

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Required?

- Side effect monitoring
- Behavior monitoring
- GDR
- EKG
- Neurologist prescribed only
- Previous meds tried and failed?

- Nuedexta should not be used for dementia or psychiatric behavior control….MYTH!!
  - However, handle as psychoactive medication with behavior/SE monitoring and GDRs.

CDPH California Department of PublicHealth

Medical Marijuana

- The **Controlled Substance Act (CSA)** classifies both marijuana and marijuana extract as Schedule I drugs.
  - Substances in Schedule I have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Medical Marijuana

- Until CMS Central Office directs otherwise (regardless of California law or circumstances for use), **federal law prohibits use**.

- Any use (storage, administration, etc.) would jeopardize the provider agreement with the federal government regarding compliance with “all applicable federal laws” etc.

CMS Newsletter June 2011 Vol. 4 Issue 2

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

REGION IX
SURVEY AND
CERTIFICATION

Inside this issue:

Medical Marijuana 1

Best of the West

Volume 4 Issue 2 Newsletter Date June 2011

MEDICAL MARIJUANA

Region IX periodically receives questions from both providers and surveyors about the use of medical marijuana in long term care facilities. One of our finest lawyers, Randall Brooks, recently passed away. Just before he left the Region IX Office of General Counsel he provided us with the following comments:

"Section 1819(d)(4) of the Social Security Act (42 U.S.C. 1395i-e(d)(4)) provides that "[a] skilled nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations . . . ."

Marijuana is a Schedule I controlled substance under the Controlled Substance Act (CSA), 21 U.S.C. 801, 812. This classification renders the manufacture, distribution, or possession of marijuana a criminal offense. CSA sections 841(a)(1), 844 (a).

In Gonzales v. Raich et al., 545 U.S. 1 (2005), the Supreme Court held that application of CSA provisions criminalizing the manufacture, distribution, or possession of marijuana to intrastate growers and users for medical purposes (under the California Compassionate Use Act, Cal. Health & Safety Code Ann. Section 11362.5) did not violate the Commerce Clause. I.e., was constitutional. The court also observed that "[t]he Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail."

Given this legal context, we conclude that federal law prohibits a SNF from dispensing medical marijuana. As the court held, "even if respondents are correct that marijuana does have accepted medical uses and thus should be redesignated as a lesser schedule drug, the CSA would still impose controls beyond what is required by California law." They went on to hold that "the dispensing of new drugs, even when doctors approve their use, must await federal approval."

As more States consider the legalization of marijuana use for medicinal purposes, we expect our Central Office will provide some clarification. Until then, we will continue to follow the above counsel. J.Motter, CMS

Any Questions?

CDPH California Department of PublicHealth

Bedrails

Jane Sarmiento, HFES

Side rail, Bed rail Enabler

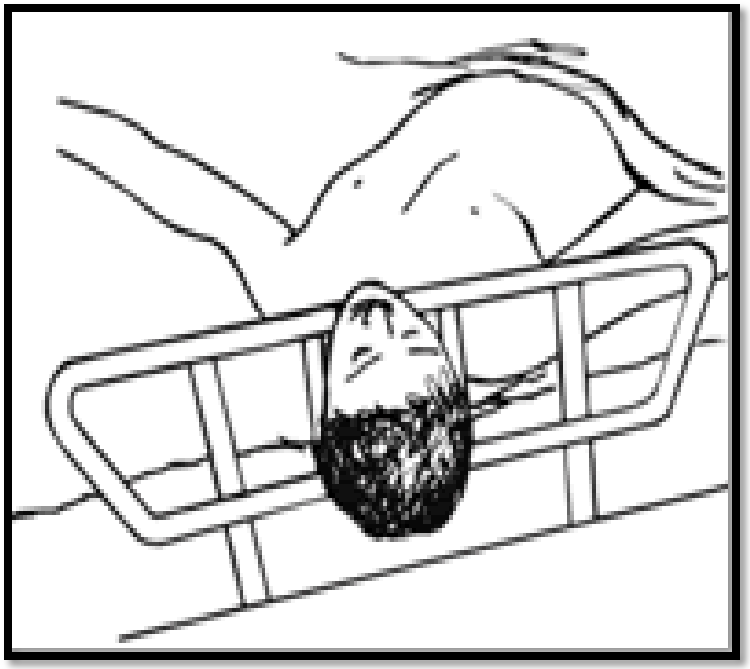
FDA definition of bed rails:

- Rigid bars that are attached to the bed and are available in a variety of sizes and configurations from full length to half, one-quarter, and one-eighth length and are used as restraints, reminders, or as assistive devices.

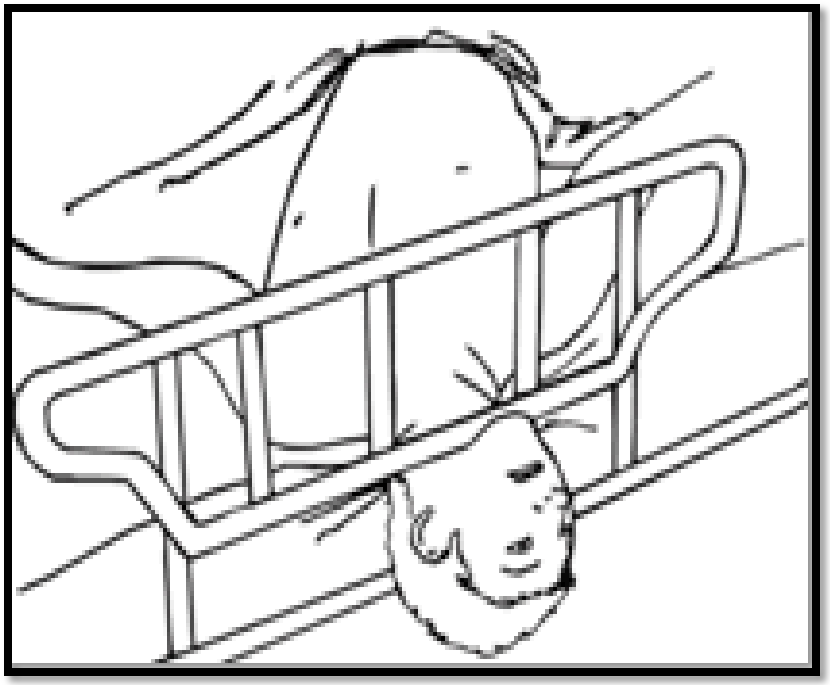
For 20 years, FDA has received reports, in which vulnerable patients have become entrapped in hospital type beds while undergoing care and treatment in health care facilities.

The term "entrapment" describes an event in which a patient is caught, trapped, or entangled in the space in or about the bed rail, mattress, or bed frame. Patient entrapments can result in deaths and serious injuries.

Zone 1 – Entrapment within the rail



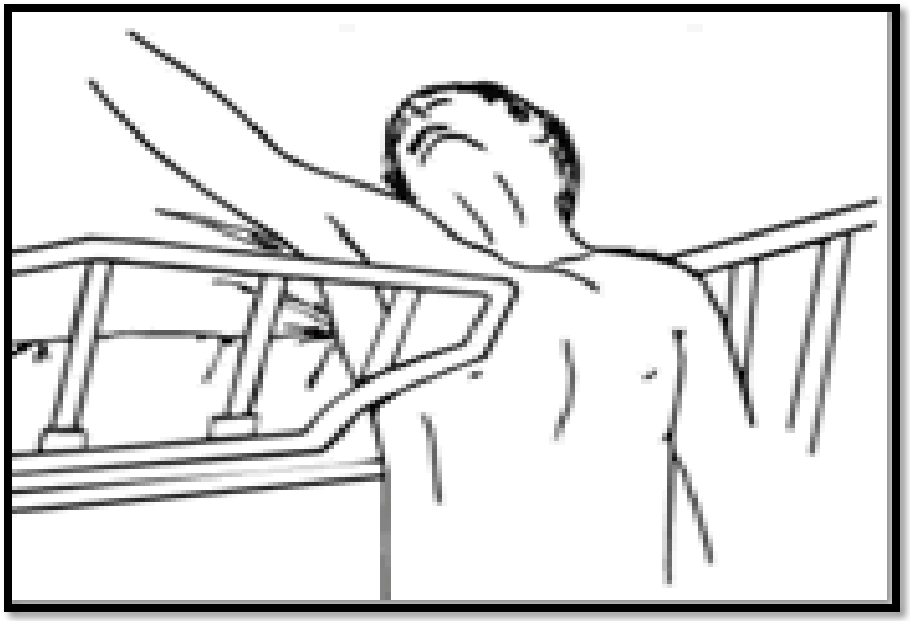
Zone 2 – Entrapment under the rail, between the rail supports or next to a single rail support



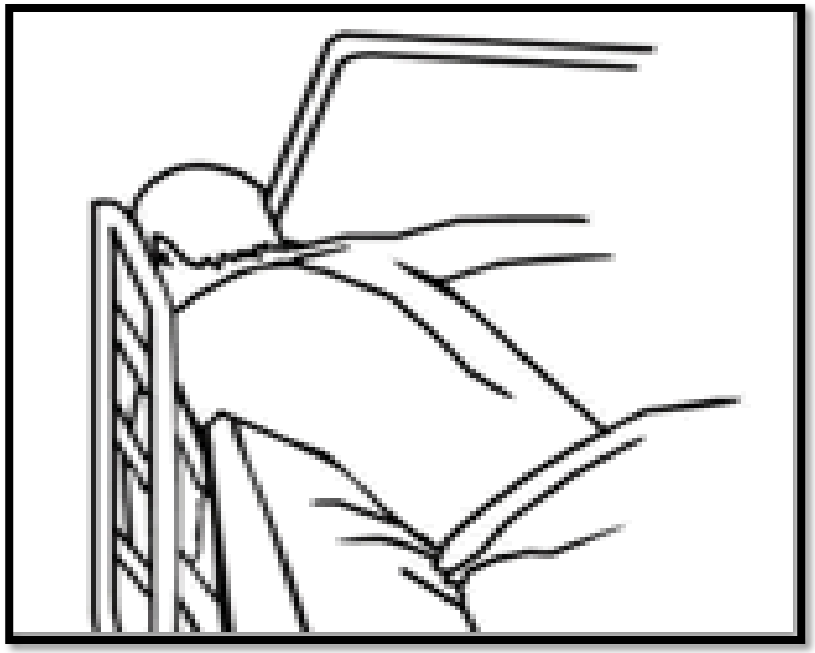
Zone 3 – Entrapment between the rail and mattress

Zone 4 – Entrapment under the rail, at the end of the rail

Zone 5 – Entrapment between split bed rails



Zone 6 – Entrapment between the end of the rail and the side edge of the head or foot board



Zone 7 – Entrapment between head or foot board and the mattress end the mattress

F323
483.25 (n) Accidents Bedrails.

"The facility must attempt to use appropriate alternative *prior* to installing a side or bed rail."

What are the alternatives for side or bed rail?

If a bed rail is used, the facility must:

- Ensure correct installation, use, and maintenance of bed rails including but not limited to:

- Assessing the risks for entrapment from bed rails ***prior*** to installation / implementation.

F323 cont.

- Review the risks and benefits of bed rails with resident or resident's representative and obtain informed consent ***prior*** to installation / implementation.

- Ensure that the bed's dimensions are appropriate to the resident's height and weight.

F461

483.25 (n)(4)

"Follow the manufacturer's recommendation and specifications for installing and maintaining bed rails."

F461 cont.

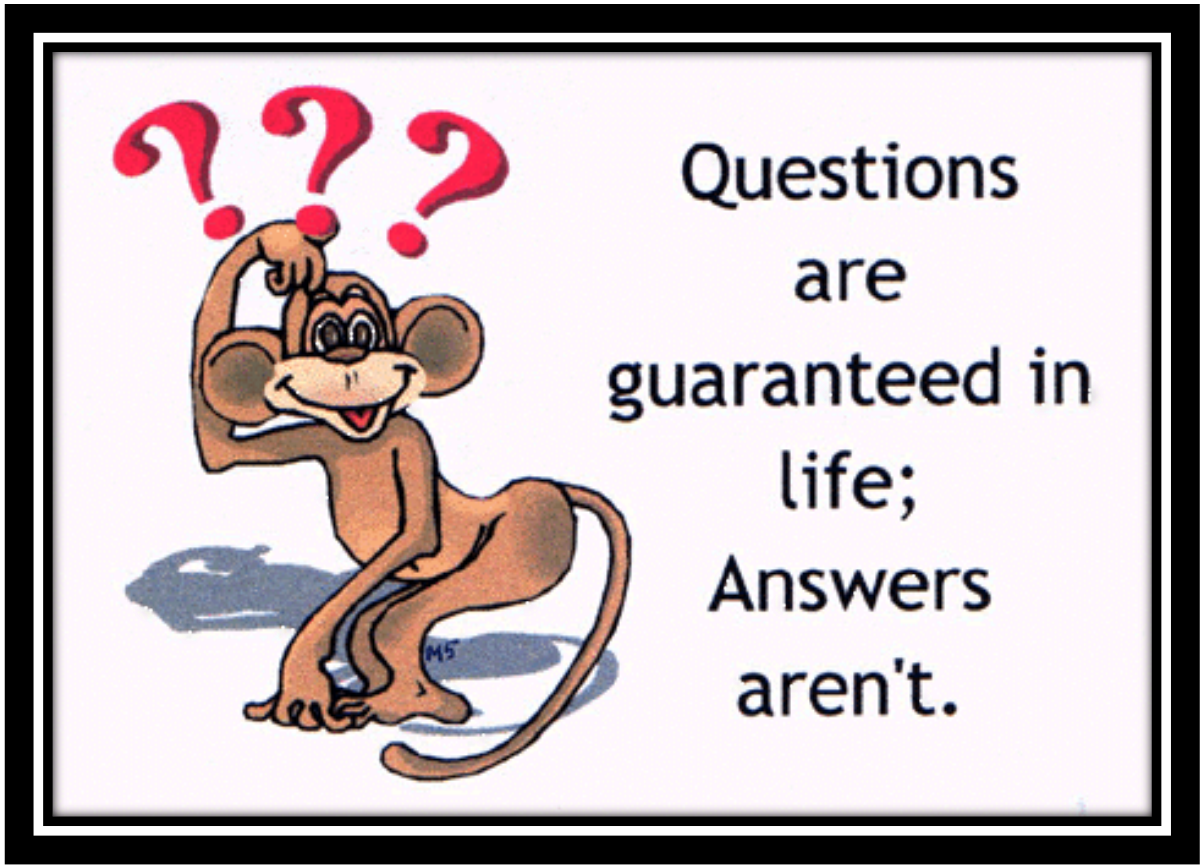
483.90(c)(3)

"Conduct regular inspection of bed frames, mattresses, and bed rails, if any as part of a regular maintenance program to identify areas of possible entrapment."

"When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure the bed rails, mattress, and bed frame are compatible. "

REFERENCE:

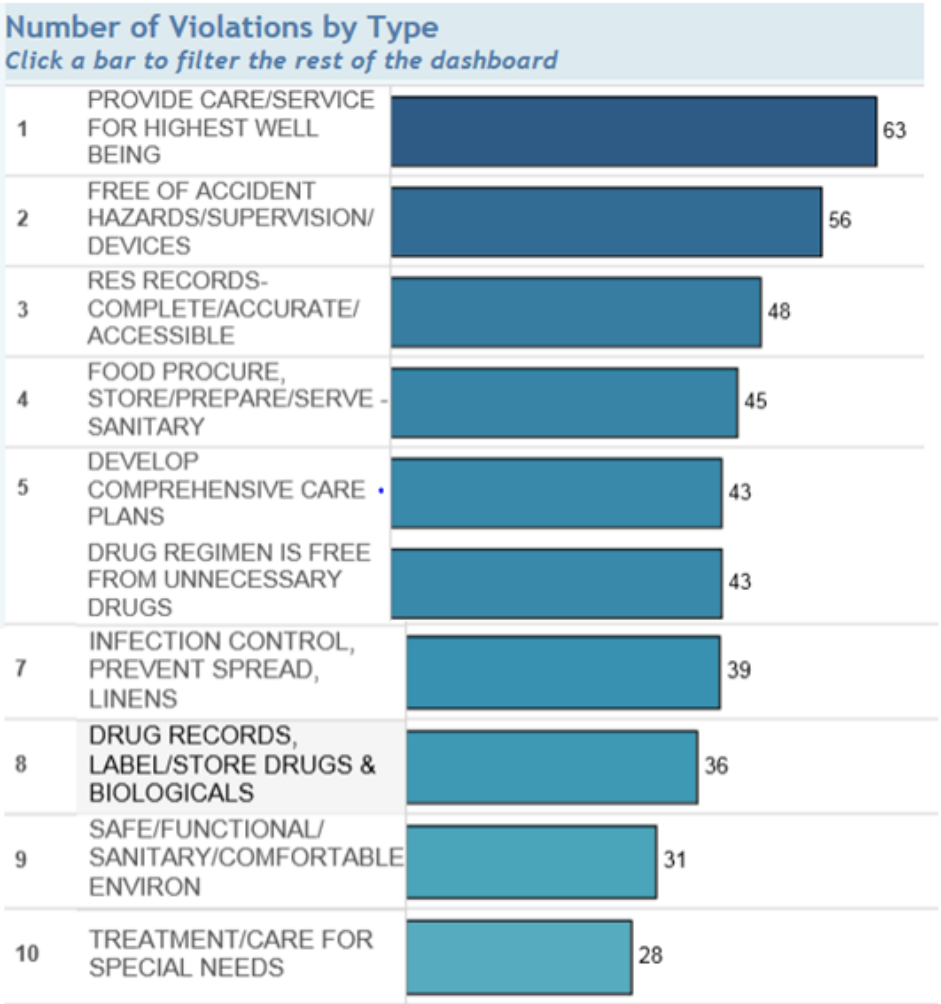
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm


Questions
are
guaranteed in
life;
Answers
aren't.

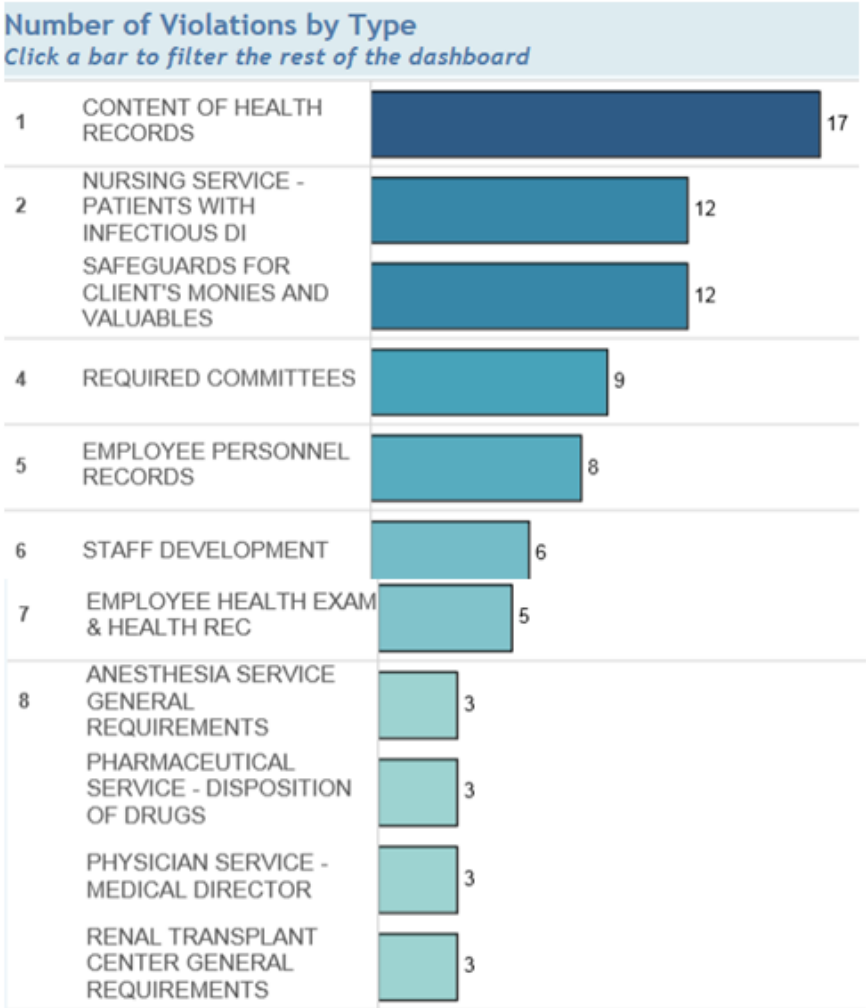
Orange DO Update:
Hang Nguyen

Top 10 most common violation

Federal Tags for Orange DO



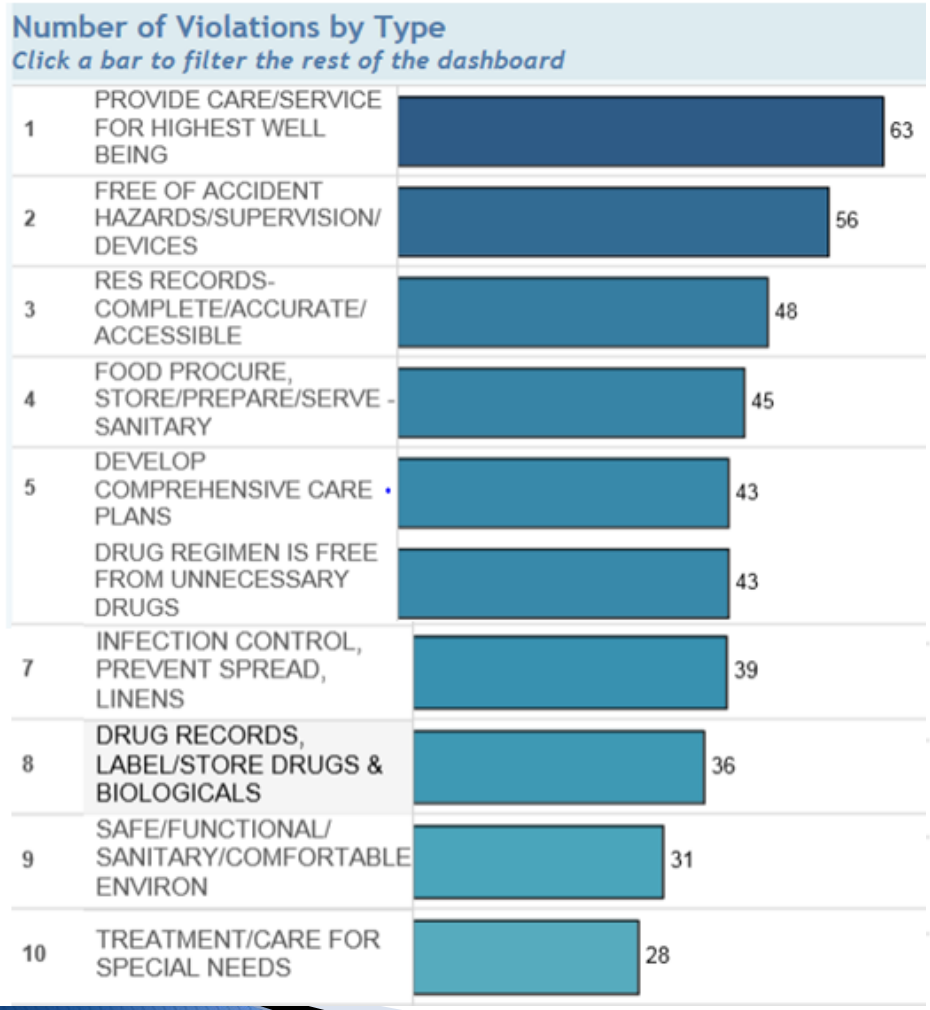
State Tags for Orange DO



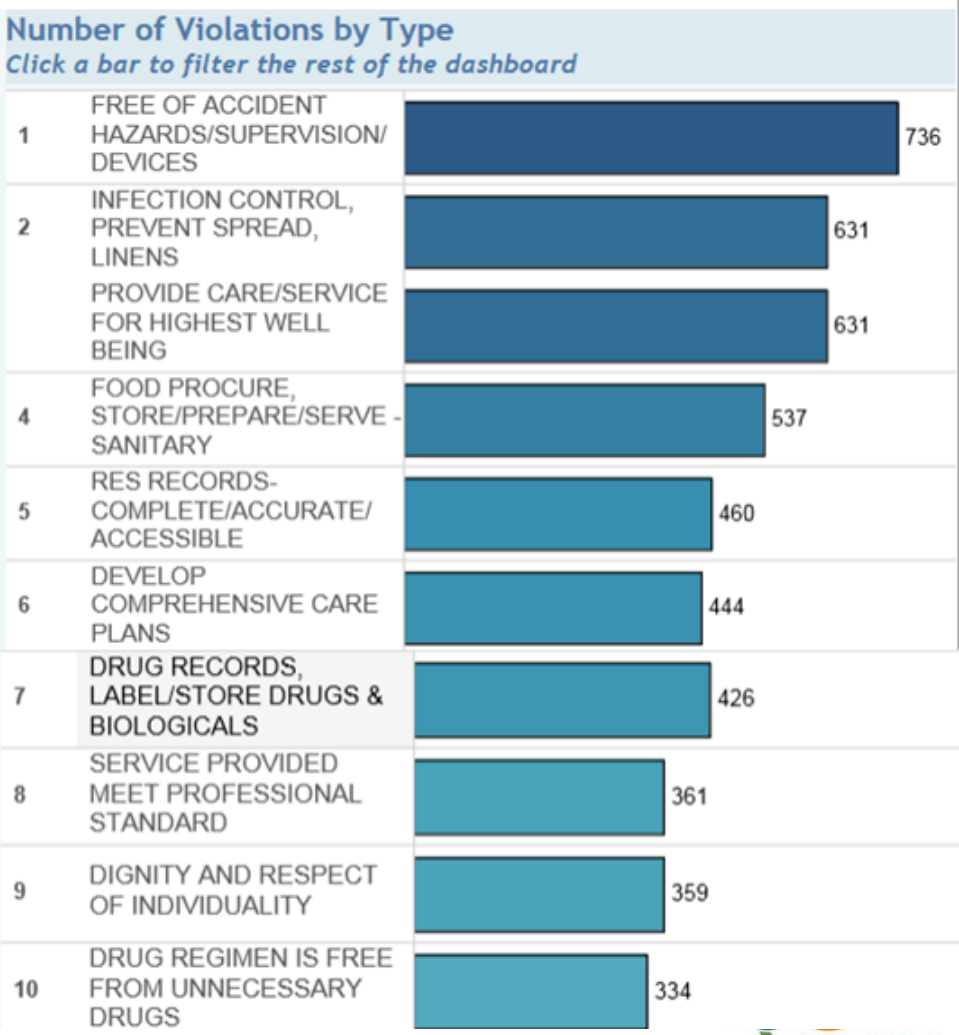
CDPH California Department of PublicHealth

Top 10 most common violation

Federal Tags for Orange



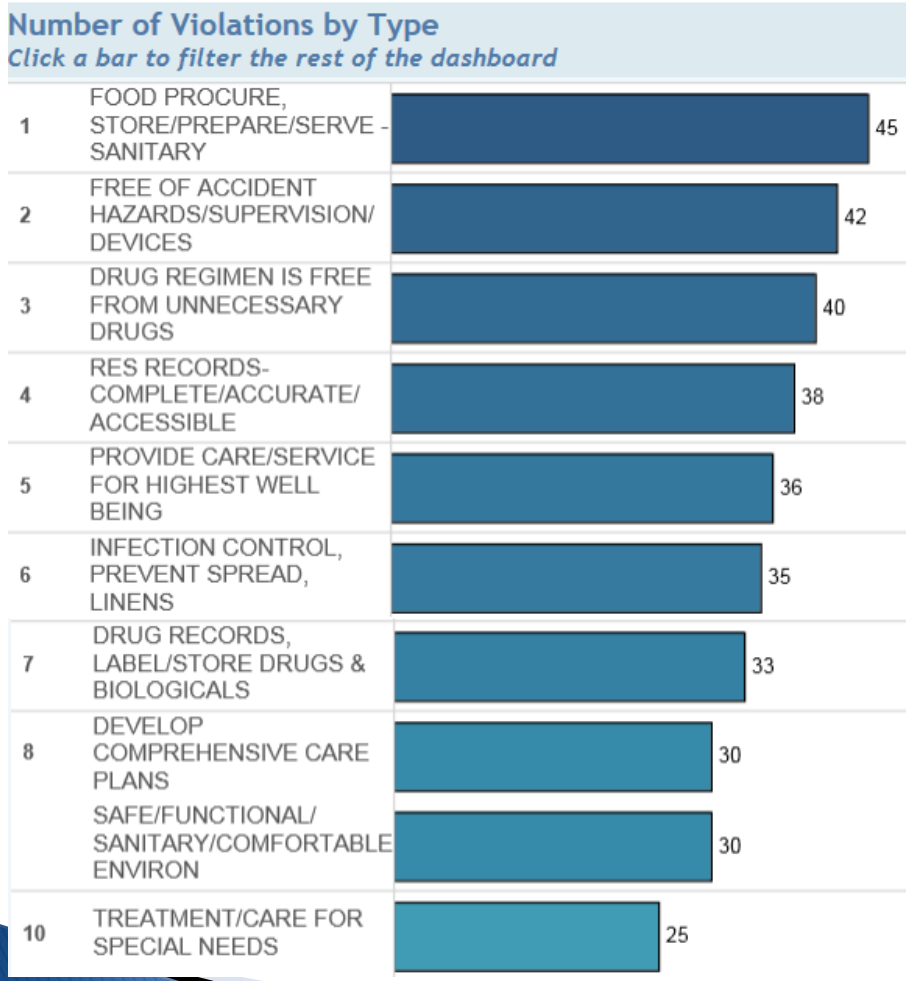
Federal Tags for State Wide



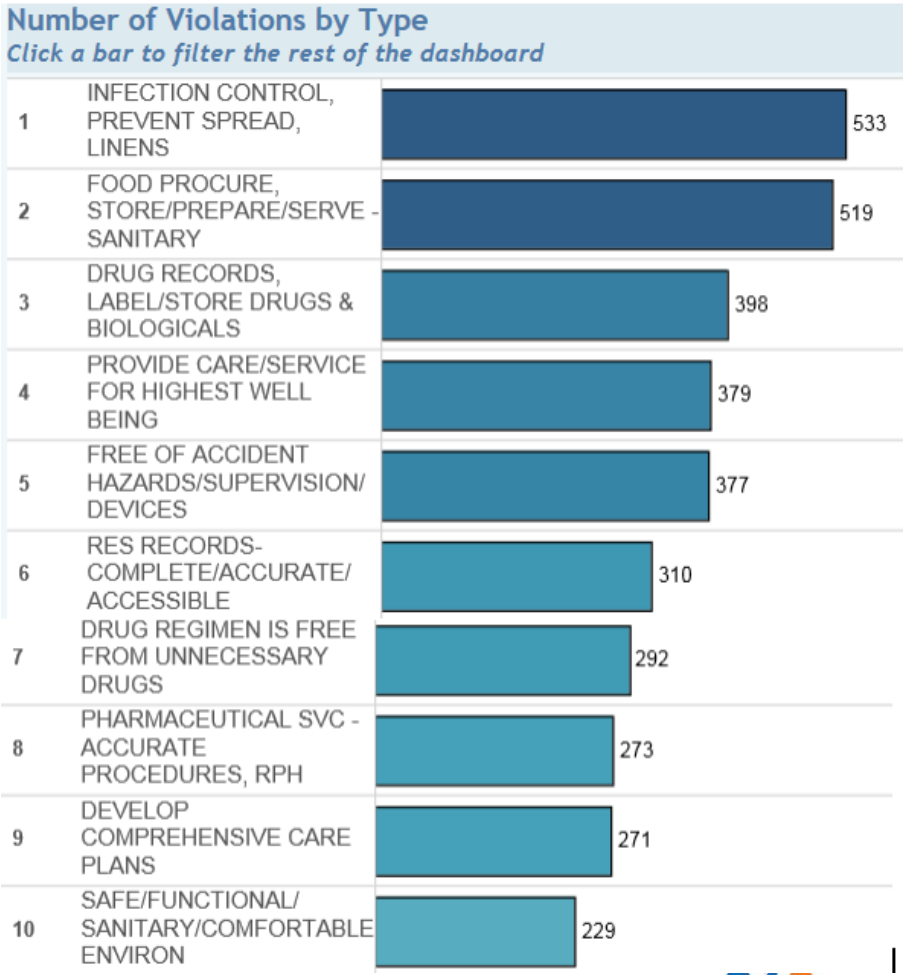
CDPH California Department of PublicHealth

Top 10 most common violation

State Tags for Orange

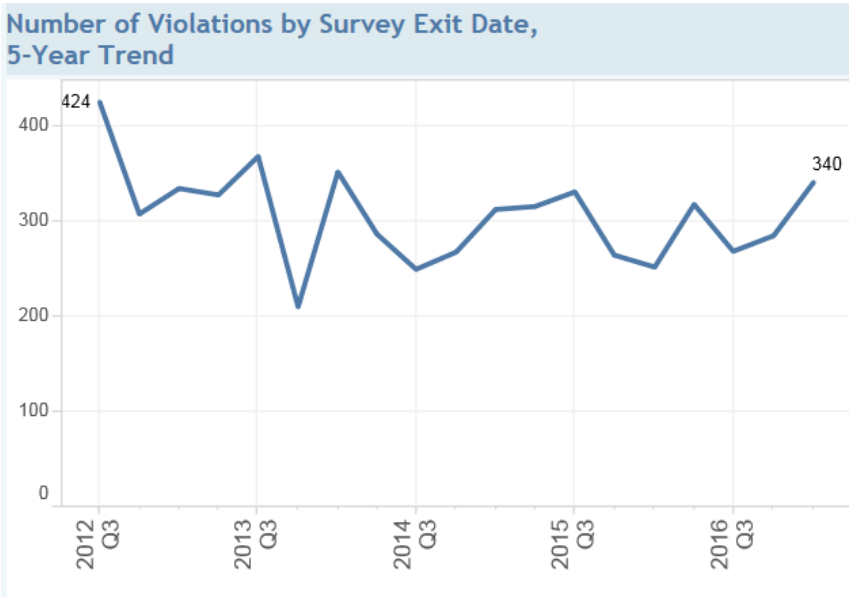


State Tags for State Wide



Top 10 most common violation

Federal Tag Trends for Orange DO



State Tag Trends for Orange DO

CMS Ref: S&C 17-34-ALL

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-34-ALL

DATE: **June 16, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: New Guidance for the Formatting of the Plans of Correction

Memorandum Summary

- **Format for Plans of Corrections (PoCs)/Allegations of Compliance (AOC)**: Providers/Suppliers and Clinical Laboratory Improvement Amendments (CLIA) Laboratories will no longer be required to write their PoC (for CLIA, this includes AOCs) on the right side of the CMS Form 2567. Providers/Suppliers or CLIA Laboratories may submit their PoC/AOC as a separate document attachment or may continue to document the PoC on the right side of the CMS Form 2567.
- **Signature on First Page:** The Laboratory Director or Provider/Supplier Representative's signature is still required on the first page of the CMS Form 2567 for the PoC/AOC. The PoC/AOC can be sent as an attachment to the signed first page of the CMS Form 2567.

Background

Section 2728B- *PoC* of the State Operations Manual (SOM) provides the expectations for an approved POC:

An acceptable plan of correction must contain the following elements:

- *The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited;*
- *The procedure for implementing the acceptable plan of correction for the specific deficiency cited;*
- *The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements;*
- *The title of the person responsible for implementing the acceptable plan of correction.*

Please see the SOM at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html

AFL 15-23

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health

EDMUND G. BROWN JR.
Governor

December 7, 2015 AFL 15-23

TO: Nursing Facilities (NF)
Skilled Nursing Facilities (SNF)

SUBJECT: Automated Survey Processing Environment (ASPEN) Web: Electronic Plan of Correction (ePOC) Implementation for Federally Certified Skilled Nursing and Nursing Facilities (SNF/NF) - Provider Access Request

AUTHORITY: Title 42 Code of Federal Regulations (CFR), section 488.402(d)

All Facilities Letter (AFL) Summary

- Providers are invited to participate in the ePOC web based application, which allows providers to receive their Statement of Deficiencies (CMS-2567) and submit their Plan of Correction (POC) electronically.
- Provides a general overview of the ePOC process, and describes the process for requesting access and enrolling in ePOC webinar training.

The Centers for Medicare and Medicaid Services (CMS) implemented an online ePOC web based application, which allows providers to receive their CMS-2567s and submit their POCs electronically. This software application is accessible by providers, the California Department of Public Health (CDPH), Licensing and Certification Program (L&C), the CMS Regional Office (RO) and the CMS Central Office (CO).

Pursuant to 42 CFR section 488.402(d), all federally certified skilled nursing facilities, and nursing facilities (SNFs/NFs) must submit a POC to L&C upon issuance of a deficiency(s). ASPEN Web: ePOC will streamline the POC submission, review, correction, and approval process by allowing information to be passed between providers and L&C electronically. CDPH is seeking 100 percent participation by SNFs/NFs.

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CDPH California Department of PublicHealth

Any Questions?

- OC Team will now answer questions email to OCDO.

- SNF Questions:

- A 48 hour baseline plan of care needs to be developed, and a comprehensive care plan needs to be developed 7 days after completion of the comprehensive assessment. Does this apply to NF-NF unit transfers as well as ICF-NF unit transfers?

- How many surveyors are supposed to be surveying about Infection Control? Is it only one or can it be multiple surveyor? When there are multiple surveyors, it feels overwhelming to the Infection Preventionist?

- With the upcoming new survey process, will you be adding more surveyors in the building? As it is Right now it already ranges from 8-9 surveyors during survey

- SNF Questions cont.:

- When surveying care plans, is it possible for the surveyors to be more understanding about it. A lot of times, the problems, goals and interventions all measurable are there but just because they're not orderly written, or not the way they want them written, the facility still gets a deficiency.

- Emergency Preparedness Regulations – Will the Health Surveyors or the LSC be reviewing these for compliance on surveys?

- SNF Questions cont.:

- What will the DPH expect from facilities related to comprehensive facility assessments.

- What other comments can you provide related to the new requirements?

- Discuss how you are training surveyors related to notifying the Ombudsman regrading discharges.

CMS Ref: S&C: 17-27-NH

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-27-NH

DATE: May 12, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Implementation Issues, Long-Term Care Regulatory Changes: Substandard Quality of Care (SQC) and Clarification of Notice before Transfer or Discharge Requirements

Memorandum Summary

- **New Definition for SQC**: A new regulatory definition was published in the Centers for Medicare & Medicaid Services (CMS) 2016 Final Long-term Care Rule and became effective on November 28, 2016.
- **Implementing SQC**: The new regulatory definition will affect which F-tags and regulatory groupings are considered to be SQC in both Phase 1 and Phase 2 of the Final Rule implementation process.
- **Notice Before Transfer or Discharge Requirements:** CMS is also providing clarification in advance of formal interpretive guidance of 42 CFR §483.15(c)(3)(i) which requires facilities to send a copy of the notice of transfer or discharge to the Office of the State Long-Term Care Ombudsman.

New Definition for SQC

A new definition of SQC was added to 42 CFR 488.301 by the Final Rule to reform the requirements for long-term care facilities that went into effect on November 28, 2016 (81 FR 68688). There were no substantial or substantive changes to the content of what types of deficient practices would result in SQC, however, the regulatory citations to the relevant requirements have changed. The new definition reflects this general reorganization of the regulations. Also, some regulations may have been moved from their previous regulatory grouping to a new regulatory group.

The new definition of SQC in §488.301 provides that substandard quality of care means one or more deficiencies which constitute either immediate jeopardy to resident health or safety; a

CDPH California Department of PublicHealth

- **ICF Questions**:

For ICF II/DD §483.475 Condition of participation: Emergency preparedness.

- The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal, State, and local emergency preparedness requirements. The ICF/IID must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

  - Emergency plan. The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

- ICF Questions cont.:

- (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, ***including missing clients***. Please clarify if the wording about missing clients means that for each hazard in the ICF II/DD facility based risk assessment, the issue of missing clients must be addressed. I see this as a very different issue for the instance when a client living at an ICF II/DD, goes AWOL during the course of a normal day.

- Regarding the new Requirements of Participation related to emergency preparedness; what will you be expecting from facilities related to community exercises by this coming this November?

The Green House Project: Susan Ryan, Senior Director

Thank you