

FMDA's 31st Annual Conference and Trade Show

AHCA Regulatory Update

November 5, 2022

2:55PM-3:55PM

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Division of Health Quality Assurance

Objectives

Identify

- Identify the top federal tags cited in Florida

Discuss

- CMS Memos, including new changes and State legislative updates

Describe

- What is Immediate Jeopardy and Other Agency Updates



Highlights of Top 10 Florida Nursing Home Federal Tags

- The 10 top tags are the same as last year, but different ranking
- Top ranking tag for 2022 is the same as last year
- Three of the top 10 tags relate to Quality of Care
- Two of the top 10 tags relate to Quality of Life
- F880 citations are decreasing since the beginning of the COVID-19 pandemic



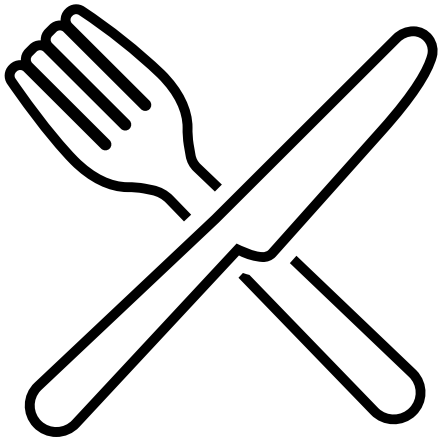
Top Ten Florida Nursing Home Federal Tags

January 2022
to
October 2022

Rank	Tag	Tag Title
1	F812	Food Safety Requirements
2	F684	Quality of Care
3	F761	Label/Storage of Drugs and Biologicals
4	F695	Respiratory/Tracheostomy care
5	F689	Free of Accident Hazards/Supervision/Devices
6	F656	Develop/Implement Comprehensive Care Plan
7	F584	Safe/Clean/Comfortable/Homelike Environment
8	F842	Resident Records - Identifiable Information
9	F677	ADL Care Provided to Dependent Residents
10	F880	Infection Prevention & Control



F812 – §483.60(i) Food Safety Requirements



The facility must –

§483.60(i)(1) - Procure food from sources approved or considered satisfactory by federal, state or local authorities.

- (i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.
- (ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.
- (iii) This provision does not preclude residents from consuming foods not procured by the facility.

§483.60(i)(2) - Store, prepare, distribute and serve food in accordance with professional standards for food service safety.





F684 – §483.25 Quality of Care

- Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices.....





F761 – Labeling/Storage of Drugs and Biologicals



F761 – §483.45(g) Labeling/Storage of Drugs and Biologicals

§483.45(g) Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

§483.45(h)(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

§483.45(h)(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.



Ways to Improve Regulatory Compliance

- Read the actual regulations and interpretive guidance several times
- Conduct daily care rounds
 - Use formalized checklists or forms to monitor, but remember they don't include everything
 - Have different staff conduct rounds to get a fresh perspective
- Conduct daily communication opportunities
 - Talk to staff, residents and families – really listen and ask them if they could make something better, what would that be
- Sufficient nursing staff is key to good outcomes and better compliance
- QAPI is your lifeline!
- Put your residents first, not your own self-interests – that is what ethics and compliance is all about!





Overview of CMS Memos

CMS QSO Memo 22-19 NH Revised Long Term Care Guidance

- Revisions to Surveyor Guidance for Phases 2 & 3, Arbitration Agreement Requirements, Investigating Complaints & Facility Reported Incidents, & Psychosocial Outcome Severity Guide
- **Effective October 24, 2022**
- References advanced copies of Appendix PP, Psychosocial outcome Severity Guide and Chapter 5 State Operations Manual Complaint Procedures
- Free CMS training available in the Quality Safety & Education Portal (QSEP) at <https://qsep.cms.gov/welcome.aspx>
- *Get started now!*



Links to QSO Memo & Advanced Copies of Revised Survey Guidance

- CMS QSO Memo 22-19-NH – <https://www.cms.gov/files/document/qso-22-19-nh.pdf-0>
- Appendix PP – <https://www.cms.gov/files/document/appendix-pp-guidance-surveyor-long-term-care-facilities.pdf>
- Psychosocial outcome Severity Guide – <https://www.cms.gov/files/document/psychosocial-outcome-severity-guide.pdf>
- Chapter 5 State Operations Manual Complaint Procedures – <https://www.cms.gov/files/document/som-chapter-5-complaint-procedures.pdf>
- SOM Exhibit 358- Sample Form for Facility Reported Incidents (PDF) – <https://www.cms.gov/files/document/som-exhibit-358-sample-form-facility-reported-incidents.pdf>
- SOM Exhibit 359- Follow-up Investigation Report (PDF) – <https://www.cms.gov/files/document/som-exhibit-359-follow-investigation-report.pdf>





Driving Healthcare Quality

Welcome to the Quality, Safety & Education Portal (QSEP)

Login

Sign Up

Select [here](#) for public access to the Training Catalog

Select [here](#) for instructions on how to access Targeted COVID-19 Training for Nursing Homes

Selecione [aquí](#) para obtener instrucciones para acceder Capacitación en COVID-19 para asilos de ancianos



QSEP is Your Friend!

www.qsep.cms.gov



16 Regulatory Group Guidance Revisions

Resident Rights

Abuse &
Neglect

Admission/
Transfer and
Discharge Rights

Quality of Life

Quality of Care

Physician
Services

Nursing
Services

Behavioral
Health

Pharmacy
Services

Food and
Nutrition
Services

Administration

Quality Assurance
& Performance
Improvement

Infection
Control

Compliance and
Ethics Program

Physical
Environment

Training
Requirements



Regulations with Major Guidance Revisions



483.70 Administration: Binding Arbitration Agreements

- New Guidance for **F847** Binding Arbitration Agreement and **F848** Arbitrator/Venue Selection and Retention of Agreements
 - Applies to binding arbitration agreements entered into **on or after September 16, 2019**



Key Revisions to Quality Assurance and Performance Improvement (QAPI)

- New guidance in F865 for the QAPI plan and program
- Requirements in F866 have been moved to F867
- New requirements for the QAPI program, feedback, data collection, analysis and monitoring, and improvement activities
- Expansion of required Quality Assessment and Assurance (QAA) required committee members
 - Infection Preventionist
- New QAPI training requirements



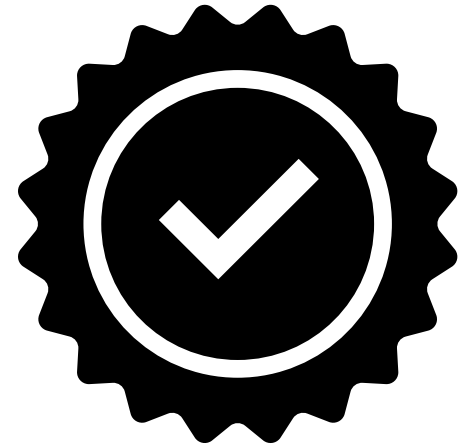
Compliance Program and Ethics – F895

- Requires the operating organization of each facility to have a compliance and ethics program
 - That is reasonably designed, implemented, maintained and enforced to be likely effective
 - For prevention and detection of *criminal, civil, and administrative* violations under the Act and in promoting quality of care



F895 Compliance Program and Ethics for *All Facilities*

- Compliance and Ethics Program guidance language includes –
 - Written standards, policies and procedures
 - High-level Personnel Oversight
 - Sufficient Resources and Authority
 - Delegation of Substantial Discretionary Authority
 - Effectively Communicating Program Standards, Policies, and Procedures
 - Reasonable Steps to Achieve Program Compliance
 - Consistent Enforcement through Disciplinary Mechanisms
 - Response to Detected Violations
 - Annual Review



F895 Compliance Program and Ethics for *Operating Organizations with 5 or More Facilities*



- Additional requirements –
 - Mandatory Annual Training
 - Designated Compliance Officer
 - Designated Compliance Liaison



Training Requirements with Revisions



Highlights of New Training Requirements and Guidance

- F941, Communication
- F942, Resident Rights
- F944, QAPI
- F945, Infection Prevention and Control
- F946, Compliance and Ethics
- F949, Behavioral Health



Highlights of Infection Prevention & Control Revisions

- Updated & clarified guidance for the COVID-19 pandemic related to PPE, environmental cleaning and disinfection, reporting to disease outbreaks to health authority, etc.
- Added guidance for Multi-drug Resistant Organisms (MDROs), Legionellosis, and facility water management.
- Updated guidance for Transmission-Based Precautions, contact precautions, droplet precautions, disinfection of blood glucose meters, and safe medication practices regarding insulin pen labels to warn against sharing devices.



Key Revisions for Infection Preventionist – F882

- Employed at least part-time and determined by facility assessment
 - Must work onsite at facility, be a member of QAA committee and report regularly on Infection Prevention & Control Program
- Responsible for IPCP includes IPCP & Antibiotic Stewardship Program
- Primary professional training –
 - Nursing, medical technology, microbiology, epidemiology or other related field (physician, pharmacist, PAs)
- Must stay current with IPC issues and be aware of national organizations' guidelines and national/state/local public health authorities guidelines



Resident Rights & Abuse/Neglect Revisions

- F557, Respect, Dignity/Right to have Personal Property – addresses mental health and substance use disorders throughout guidance
 - Facilities can't search resident belongings without permission and shouldn't act as the arm of law enforcement for resident illegal substance possession
- F600, Abuse & Neglect – added guidance related to neglect
- F608, Reporting of Reasonable Suspicion of a Crime, will be deleted, and guidance will be included in F607/F609
- F609, Reporting Alleged Violations – facility reported incidents must be submitted *timely and accurately*



Admission/Discharge & Behavioral Health Revisions

- F623, Notice Requirements Before Transfer/Discharge – transfer or discharge notice should contain the specific transfer or discharge location
- F626, Permitting Residents to Return to Facility –
 - Policies for bed-hold and permitting residents to return following hospitalization or therapeutic leave apply to all residents, regardless of their payment source
 - Not permitting a resident to return following hospitalization or therapeutic leave may constitute a facility-initiated discharge
 - If a resident was forced, pressured, or intimidated into leaving AMA, the discharge would be considered a facility-initiated discharge
- Behavioral Health, F740 & F741 – addresses residents with mental health, substance use disorders, trauma and PTSD

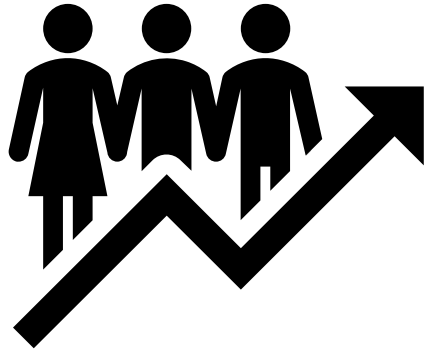


Quality of Care Revisions

- F689, Accidents/Supervision – addresses electronic cigarettes and safety of residents with substance use disorder
- F694, Pain Management –
 - Facilities should assess residents for history of past addiction and related treatment and employ strategies to address pain for residents with history of opioid use disorder
 - Addresses prevention of opioid overdoses by administering naloxone
- F700, Bed Rails –
 - Bedrails do not have to be removed or disabled when not in use
 - If bedrails are determined to be inappropriate for a resident, if left on the bed in the down position, raising the rail would be considered noncompliance



Payroll Based Journal & Nursing Services – F851



- F851, 483.70(q) Mandatory Submission of Staffing Information Based on Payroll Data in a uniform format (Payroll Based Journal or PBJ) is an *Administration* regulation, but affects Nursing Services
- Surveyors will be using PBJ data from CASPER report to identify concerns with nursing staffing
- F851 focuses on the submission of the staffing data which is now critical for the LTCSP
- Surveyors will cite F851 if facilities if they fail to submit complete, accurate, and timely data required for PBJ





Nursing Services, Sufficient Staff – F725 Revisions

- New guidance states compliance with State staffing standards is not necessarily determinative of compliance with Federal staffing standards that require a sufficient number of staff to meet all of the residents' basic and individualized care needs
 - Facilities may meet a state's minimum staffing ratio requirement, and still need more staff to meet the needs of its residents
 - Facilities are also required to provide licensed nursing staff 24 hours a day, 7 days a week
- The LTCSP process will alert surveyors of specific dates that require further investigation related to staffing and use the CE Pathway of Sufficient and Competent Staffing



Pharmacy Services Regulatory Group Revisions

- Addresses disposal of Fentanyl patches in relation to life threatening risks with exposure to or ingestion of hazardous waste
- Clarified other classes of drugs not listed in the regulation and how they are affected by the psychotropic medication requirements (i.e., use of anticonvulsants for mood disorders)
- Addresses potential misdiagnoses, such as schizophrenia, in order to prescribe antipsychotics
- Directs surveyors to evaluate if a resident experienced psychosocial harm related to side effects of medications



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Major Revisions to the Psychosocial Outcome Severity Guidance

- Psychosocial Outcome Severity Guide can help determine severity of an outcome when the impact on the resident may not be apparent or documented
- Provided examples of when a resident may experience a greater psychosocial harm when experiencing no physical harm from physical assault
- Severity of psychosocial outcome is determined by gathering evidence through observation, interview and record review and resident behavior
- New guidance on how surveyors should apply the reasonable person concept



CMS QSO Memo 23-01 NH Revisions to Special Focus Facility (SFF) Program –October 21, 2022

- Section I: SFF Candid List
 - Florida has 3 SFF's
- Section II: Initial Selection of SFF
- Section III: Progressive Enforcement
- Section IV: Graduation from the SFF Program



CMS QSO Memo 23-01 NH Revisions to Special Focus Facility (SFF) Program- October 21, 2022

- Section V: Termination
- Section VI: Factors Considered for Graduation or Termination
- Section VII: Post-Graduation
- Section VIII: Operational Procedures



The National Imperative to Improve Nursing Home Quality

- Statement of Task
 - Examine how our nation delivers, regulates, finances and measures the quality of nursing home care.
 - Delineate a frameworks and general principles for improving the quality of care in nursing homes.
 - Consideration of COVID-19 pandemic



Seven Goals

- 1- Deliver comprehensive, person-centered, equitable care that ensures residents' health, quality of life, and safety; promotes autonomy; and manages risks.
- 2- Ensure a well-prepared empowered, and appropriately compensated workforce.
- 3-Increase the transparency and accountability of finances, operations, and ownership.



Seven Goals, continued

4-Create a more rational and robust financing system.

5- Design a more effective and responsive system of quality assurance.

6-Expand and enhance quality measurement and continuous quality improvement.

7-Adopt health information technology in all nursing homes.



Immediate Jeopardy Discussions



IJ Definition

§488.301

Immediate Jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused or is likely to cause serious injury, harm, impairment, or death to a resident.



Immediate Jeopardy Numbers

July 2022	August 2022	September 2022
7	7	6



Core Appendix Q Guidelines for Immediate Jeopardy

- IJ must have 3 components
 - Noncompliance
 - Actual or *likely* serious injury, harm, impairment or death
 - Need for immediate action
- Psychosocial harm matters
- Immediate Jeopardy notification requires the IJ Template



Facility Response to Immediate Jeopardy Found

- Act quickly – procrastination extends the IJ duration, which increases impact of enforcement actions
- Be forthright in providing information to surveyors.
 - Remember you must abide by professional Code of Ethics
- Begin your investigation immediately and document what you are doing every step of the way
- Provide surveyors
 - Investigation documentation
 - Your interviews with all persons involved in the incident
 - Staff education/competencies
 - Documentation of anything you did to reduce the serious harm or likely serious harm and to correct the issues.
- Begin QAPI process & follow up on corrective actions to determine effectiveness



Immediate Jeopardy Removal Plan

- No longer called an “Allegation of Compliance” in LTC
 - Purpose of the plan is to removal of serious harm or likely serious harm, *not to achieve compliance*.
- IJ Removal Plan *is not* a Plan of Correction
 - Include only immediate actions necessary to remove the serious harm or likely serious harm
 - Plan of correction includes correcting the system that caused the issue
- Removing staff or residents does not necessarily remove the IJ
- If more than one IJ tag, the IJ Removal Plan must address each area of noncompliance and immediate actions will be different for each.



Final Thoughts –

- Read the Appendix PP Severity Guidance for each regulation (if applies)
 - Provides examples of Level 4 severity (IJ)
- Ensure that you have the necessary structures and processes (staff, supplies, services, policies, training, or staff supervision and oversight) to meet the resident's needs to prevent neglect
- Information about citations is available on CMS Survey & Certification's QCOR (Quality, Certification and Oversight Reports) and FloridaHealthFinder



State Legislation



SB 988- “No Patient Left Alone Act”

- 408.823 In-Person Visitation

- Establish visitation policies and procedures must at a minimum include;
 - Infection control and education policies for visitors;
 - Screening;
 - Personal protective equipment; and
 - Other infection control protocols for visitors;
 - Permissible length of visits; and numbers of visitors, which must meet or exceed the standards in ss. 400.022 (1) (b) and 429.28(1)(d), and;
 - Designation of a person responsible for ensuring that staff adhere to the policies and procedures.
 - Must allow consensual physical contact between resident, client, patient and the visitor.
 - May **NOT** require visitors to submit proof of any vaccination or immunization.



HB 1239 Nursing Home State Staffing

- **Direct Care Staff Definition**

- Persons who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being, including, but not limited to, disciplines and professions that must be reported in accordance with 42 C.F.R. s. 483.70(q) in the categories of direct care services of nursing, dietary, therapeutic, and mental health.



Direct Care Staff

- **Does not include** a person whose primary duty is maintaining the physical environment of the facility, including, but not limited to, food preparation, laundry, and housekeeping.
- **Does not include** time spent on nursing administration, activities program administration, staff development, staffing coordination, and the administrative portion of the MDS and care plan coordination for Medicaid.
- Determined by each facility based on the facility assessment and the individual needs of a resident based on the resident's care plan.



Minimum Requirements

- Weekly (Sunday through Saturday) average of 3.6 hours of care by **direct care staff** per resident per day
- **2.0** hours of direct care by a CNA per resident per day
- May not staff below one CNA per 20 residents
- 1.0 hour of direct care by a licensed nurse per resident per day
- May not staff below one licensed nurse per 40 residents



Failure to Comply

Facility that has failed to comply with state minimum-staffing requirements for **48 consecutive hours** is prohibited from accepting new admissions until the facility has achieved the minimum-staffing requirements for 6 consecutive days.




Agency Resources and Reminders



Sign up for Email Health Alerts

<http://ahca.myflorida.com/MCHQ/alerts/alerts.shtml>



AGENCY FOR HEALTH CARE ADMINISTRATION

HOME ABOUT US MEDICAID LICENSURE & REGULATION FIND A FACILITY REPORT FRAUD

Health Care Alerts

This service allows subscribers to receive an email alert to notify registered providers or interested parties of health care information.

To subscribe to the automated alert system, complete the online form below. A confirmation email will be sent to your mailbox to avoid fraudulent subscription requests. **Subscribers must click on the link "Confirm to list: HQA Alert" in the confirmation email to complete their subscription.**

Sign up for a free [FloridaHealthFinder.gov](#) webinar today!

The Agency for Health Care Administration also releases [Medicaid Alerts](#) notifying interested parties about Medicaid information.

NOTE: Please set the setting on your internet browser (Microsoft Internet Explorer, Firefox or Chrome) to 100% or less so the form below will display correctly.

Email* First Name Last Name Organization

* = Required Field



Agency Alert- September 20, 2022

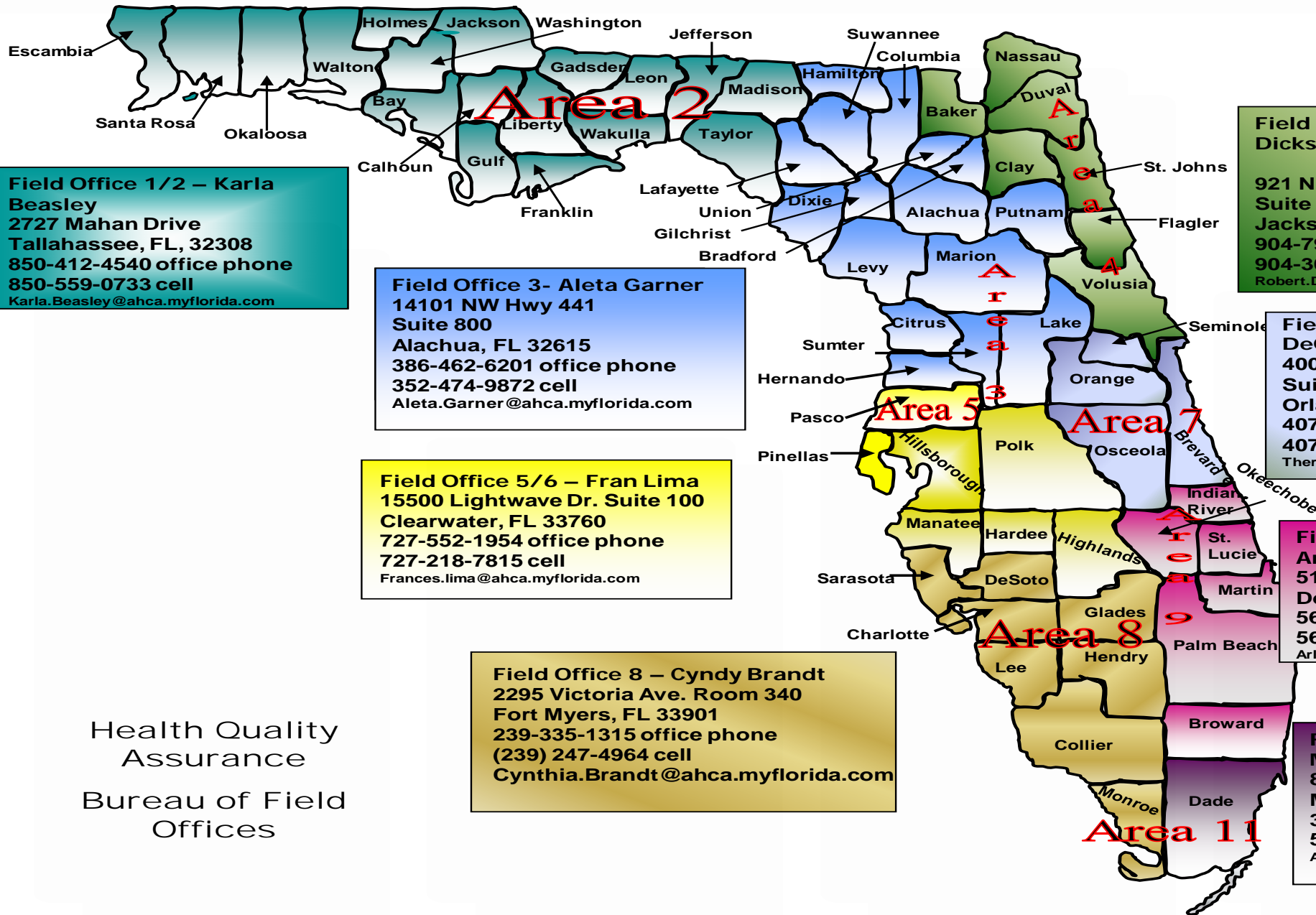
- Operational Updates: Hospitals & Long Term Care Facilities
- This health care alert is to remind Florida's hospitals and long-term care facilities (nursing homes, assisted living facilities, and intermediate care facilities for the developmentally disabled) of standard protocols, including recommendations against screening, masks, and other measure known as "source control" for COVID-19. Additionally, Providers are obligated to allow for robust visitation and must adhere to Florida's prohibition against blanket employer vaccine mandates for COVID-19.



Hurricane Ian Discussion

- Evacuations
- Power outages
- Damages
- Nursing homes and assisted living facilities out of service
- Communication





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