Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

New Mexico Health Care Association (NMHCA)

February 28, 2023

90 Minutes

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

C.A.R.E.S.™

HHI C.A.R.E.S. About Care

Compliance | Analysis | Audit | Regulatory | Rehabilitation

Reimbursement | Education | Efficiency | Survey

Harmony Healthcare International, Inc. (HHI)

"HHI C.A.R.E.S. about Care"

Harmony Healthcare INTERNATIONAL

About Kris

Kris Mastrangelo OTR/L, LNHA, MBA

President and CEO

Owns and operates
Harmony Healthcare International (HHI) a Nationally recognized, premier Healthcare Consulting firm specializing in C.A.R.E.S.
There are no nonfinancial disclosures to share.

"HHI C.A.R.E.S. About Care."

C Compliance ™
A Analysis Audit
R Regulatory Rehabilitation Reimbursement
E Education Efficiency
S Survey

HHI C.A.R.E.S. About Care

Harmony Healthcare INTERNATIONAL

Speaker and Planning Committee Disclosure

- Disclosures: The planners and presenters of this educational activity have no relationship with commercial entities or conflicts of interest to disclose.
- Planners:
  - Kris Mastrangelo, OTR/L, LNHA, MBA
  - Joyce Sadewicz, PT, RAC-CT
  - Pamela Duchene, PhD, APRN-BC, NEA, FACHE
- Presenters:
  - Kris Mastrangelo, OTR/L, LNHA, MBA

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Agenda

1. 483.70 Administration: Binding Arbitration Agreements
2. 483.15 Admission, Transfer, and Discharge
3. 483.40 Behavioral Health Services
4. 483.85 Compliance and Ethics Program
5. 483.60 Food and Nutrition Services
6. 483.12 Freedom from Abuse, Neglect, and Exploitation

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Agenda

7. 483.80 Infection Control
8. 483.45 Pharmacy Services
9. 483.90 Physical Environment
10. 483.60 Physician Services
11. Psychosocial Outcome Severity Guide and Citations at F600-Abuse
12. 483.75 Quality Assurance and Performance Improvement

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Agenda

13. 483.24 Quality of Life/483.25 Quality of Care
14. 483.10 Resident Rights
15. Staffing
16. 483.95 Training Requirements
17. Exhibit 358: Sample Form for Facility Reported Incidents
18. Exhibit 359: Follow-up Investigation Report

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.70 Administration
Binding Arbitration Agreements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Overview

- Requirements F847 and F848
- Intent
- Definitions and interpretive guidance (IG)
- Investigative protocol
- Guidance on review of Plan Correction (POC)

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70

- F847 - Entering Binding Arbitration.
- F848 - Arbitrator/Venue Selection and Retention of Agreements.
- F851 - Mandatory submission of staffing information based on payroll data in a uniform format.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)
- Binding Arbitration Agreements: F847 and F851
- Clarifies requirements to settle disputes.
  - Entering Binding Arbitration
  - Arbitrator/Venue Selection and Retention of Agreements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)

- On September 16th, 2019, CMS implemented revised regulations on the usage of arbitration agreements by facilities. The guidance clarified existing requirements for when arbitration agreements are used by nursing homes to settle disputes.
- This applies to any agreements entered on or after September 16th, 2019.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)

- Entering Binding Arbitration: F847
  - **Prevents** making entry into an arbitration agreement a **condition of admission** or **continued residency.**
  - Requires a facility to **explain the agreement** to a resident or their representative.
  - Requires a facility to **obtain an acknowledgement** of such understanding by the resident or they are representative.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)
  - Requires the agreement to provide a **30-Day Right of Rescission.**
  - **Prevents** the facility to include any language that **denies** or **discourages** the resident or anyone else from **communicating with government officials.**
- This **new tag** elaborates on how facilities should ensure that they properly communicate at the **literacy level** and **language proficiency** of the resident.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)

- Arbitrator/Venue Selection and Retention of Agreements: F848
- CMS implements requirements that arbitration agreements provide for the selection of a neutral arbitrator and a convenient venue.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)

- *"The facility should promptly be **disclosed** to the resident or his or her representative the **extent of any relationship** which exists within arbitrator or arbitration services company, including*
- ***how often** the facility has contracted with the arbitrator or arbitration service, and*
- ***when** the arbitrator or arbitration service has **ruled for or against the facility**."*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements Overview

- Administration – Arbitration Agreements
- 483.70 (continued)
- Mandatory Submission of Staffing in a Unform Format
- The facilities failure to submit PBJ data will be reflected on their cast for report and result in a deficiency citation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

LTC Regulatory Group

- Starting on September 16, 2019, the requirements for F847 and F848 were added under Administration, §483.70. Let us briefly go through the requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

LTC Regulatory Group

- §483.70 Administration
  - F847 - Binding Arbitration Agreement.
  - F848 - Arbitrator/Venue Selection and Retention of Agreements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
F847 Binding Arbitration Agreements

- §483.70 (n)
  - *The facility must not require any resident or his or her representative to sign an agreement for binding arbitration as a **condition of admission** or as a requirement to continue to receive care.*
  - *(2) (i)The facility must ensure that the agreement is explained in a form and manner that he or she understands and the resident or his or her **representative acknowledges** that he or she understands the agreement;*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

F847 Binding Arbitration Agreements

- Under F847, there are **5 key components** that the facility must comply with if they choose to offer the resident or his or her representative to enter into an agreement for binding arbitration.
  1. The facility **cannot require** the resident or his or her representative to **sign the agreement** as a condition of admission or as a requirement to continue receiving care in the facility.
  2. The facility must **explain the agreement** in a form and manner that the resident or his or her representative can understand. Also, the resident or his or her representative acknowledges that they understand the agreement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
F847 Binding Arbitration Agreements

- §483.70 (n)
  - *(3) must **explicitly grant** the right to **rescind** the agreement within **30 calendar days** of signing it.*
  - *(4) must **explicitly state** that neither the resident nor his or her representative is required to sign an agreement as a condition of admission to, or as a requirement to continue to receive care at, the facility.*
  - *(5) may **not contain** any **language** that **prohibits** or **discourages** the resident or anyone else from **communicating with federal, state,** or **local officials.***

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
F847 Binding Arbitration Agreements

3. Third, the agreement must clearly state that the resident or his or her representative has the **right to rescind** the agreement within 30 days after signing it.
4. Fourth, the agreement must clearly state that the resident or his or her representative is **not required to sign** the agreement as a **condition of admission** or as a **requirement to continue** receiving care in the facility.

- The agreement may not contain any language to prohibit or discourage anyone including the resident or his or her representative to communicate with federal, state or local officials including State Long-Term Care Ombudsman.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
F847 Binding Arbitration Agreements

- §483.70(n)
  - *(2) The facility must ensure that:*
    - *(iii) The agreement provides for the selection of a **neutral arbitrator agreed upon** by both parties; and (iv) The agreement provides for the selection of a venue that is convenient to both parties.*
  - *(6) When the facility and a resident **resolve** a **dispute** through arbitration, a **copy** of the **signed agreement** for binding arbitration and the arbitrator's final decision must be **retained by the facility for 5 years** after the resolution of that dispute on and be available for inspection upon request by CMS or its designee.*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

F847 Binding Arbitration Agreements

- Under F848 Arbitrator/Venue Selection and Retention of Agreements, there are 2 key components:
  1. The agreement must provide for the selection of a neutral arbitrator agreed upon by the facility and the resident or his or her representative and the selection of a venue that is convenient to both parties.
  2. The facility must retain a copy of the signed agreement for binding arbitration and the arbitrator's final decision for 5 years after the facility and the resident or his or her representative resolved a dispute through arbitration.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

Intent of §483.7(n) Requirements

- To ensure that long-term care facilities give residents or their representatives a choice in whether to enter into a binding arbitration agreement.
- To provide a neutral and fair arbitration process.
- Ensure facilities retain a copy of the signed agreement for binding arbitration and the arbitrator's final decision.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

Intent of §483.7(n) Requirements

- Intent.
  - It is the resident or his or her representatives right to make informed decisions and choices about important aspects of resident's health, safety and welfare.
  - The requirements of F847 and F848 are to assure the use of a binding arbitration agreement is voluntary and must be clearly communicated to the residents or their representatives as optional and not required as a condition of admission or to continue to receive care at the facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Definitions

- Arbitration
  - A private process where disputing parties agree that one or several individuals can make a decision about the dispute after receiving evidence and hearing arguments.
- Binding Arbitration Agreement
  - A binding agreement by the parties to submit to arbitration all or certain disputes which have arisen or may arise between them in respect of a defined legal relationship, whether contractual or not. The decision is final, can be enforced by a court, and can only be appealed on very narrow grounds.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Definitions

- Pre-dispute binding arbitration agreement (pre-dispute arbitration agreement or pre-dispute agreement).
  - A binding agreement to resolve a future unknown dispute with an arbitrator prior to any issue or dispute arising.
- Post-dispute binding arbitration agreement (post-dispute arbitration agreement or post-dispute agreement).
  - A binding agreement is signed after the circumstances of the dispute have occurred to resolve the dispute with an arbitrator.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Definitions

- Convenient Venue
  - Convenient Venue is a location, where an arbitration proceedings is held, which should be agreed upon and suitable to both parties.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Definitions

- Arbitrator
  - Arbitrator is a third party who resolves a dispute between others by arbitration and pursuant to an arbitration agreement. Arbitrators are decision makers, with procedures set by the arbitration agreement and state law, except they may not be required to follow federal, or state rules of evidence and their decisions may not be reviewable by a court absent extraordinary circumstances.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Definitions

- Neutral Arbitrator
  - Neutral Arbitrator must be an **impartial** or **unbiased third-party decision marker,** contracted with, and agreed to by both parties to resolve their dispute.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: Arbitration Overview

- Parties subject to arbitration give up their right to have some or all claims heard in court.
- Use of a binding arbitration agreement must be voluntary and must be clearly communicated.
- The quality of care received by the resident is not impacted by a decision to enter or not to enter into an arbitration agreement.
- The agreement must be explained so that the resident or his or her representative understands the terms of the agreement and understands that they are giving up their right to litigation in a court proceeding.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: Arbitration Overview

- It is also important that facilities clarify when a signature is used to acknowledge understanding, when it indicates consent to enter into an agreement, or is used for both.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: Arbitration Overview

- Over the years, long-term care facilities and residents have used arbitration to resolve many disputes.
- Parties subject to arbitration give up their right to have some or all claims heard in court.
- Concerns have been raised about the fairness and transparency related to these agreements. It is important that the arbitration process is TRANSPARENT.
- Therefore, the use of a binding arbitration agreement must be voluntary and must be clearly communicated to the residents or their representatives as optional and not a requirement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: Arbitration Overview

- It is also important that facilities clarify when a signature is used to
  - acknowledge understanding,
  - when it indicates consent to enter into an agreement,
  - or is used for both.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

Guidance: Requirements for Arbitration Agreements – Transparency in the Arbitration Process

- Surveyors
  - Should **determine how the facility ensures residents** or their representatives **understood** and **acknowledged** the terms of the binding arbitration **agreement.**
  - **Must verify through interview** and **record review**, that the resident or their representative **understood what they were signing.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

Guidance: Requirements for Arbitration Agreements – Transparency in the Arbitration Process

- Surveyors
- Determine how the facility ensures residents or their representatives are made aware of arbitration agreements which are embedded within another document obtain copies of any documents or agreements that including information about arbitration.
- Obtain copies of any documents or agreements that including information about arbitration.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

Guidance: Requirements for Arbitration Agreements – Transparency in the Arbitration Process

- During investigation, surveyors must verify through interview and record review that the resident or their representative understood what they were signing.
- In situations where the resident may have **cognitive impairment**, surveyors should **refer to the medical record** to identify the resident's **health care decision-making capacity** at the time the agreement was offered, explained, and entered.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

Guidance: Requirements for Arbitration Agreements – Transparency in the Arbitration Process

- Surveyors should also obtain copies of any documents or agreements that including information about arbitration.
- For example, if a facility's admission agreement has a paragraph referencing arbitration, but also has a separate arbitration agreement, the survey will need to examine both documents to ensure compliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: F848

- Facilities should make reasonable efforts to ensure that the **arbitration agreement provides for the selection of an arbitrator who is impartial, unbiased,** and **without the appearance of a conflict of interest.**
- The binding arbitration agreement must allow for the selection of a **venue** that is suitable in meeting the needs of both the resident or his or her representative, and the facility.
- The venue must be **agreed upon by both parties.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: F848

- When a dispute is resolved through arbitration, facilities are expected to retain copies of the following for 5 years:
  - *These records must be made available for review to surveyors upon request.*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: F848

- In addition, Facilities may put forward **suggestions for the use of specific arbitrators** for residents (or their representatives) to select.
- Where the parties are **unable to reach an agreement on a neutral arbitrator,** the parties should consult the **Federal Arbitration Act, 9 U.S.C. §5, and/or applicable State Law.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Guidance: F848

- The binding arbitration agreement must allow for the selection of a venue that is suitable in meeting the needs of both the resident or his or her representative, and the facility. Convenience for the resident may be determined by his or her needs in terms of ability to get to the venue. The venue must be agreed upon by both parties.
- When a dispute is resolved through arbitration, facilities are expected to retain copies of the following for 5 years. Specifically, the signed binding arbitration agreements and final decisions final decisions. These records must be made available for review to surveyors upon request.
- Note: It is important for surveyors to focus on the record retention requirement, not the content of arbitration final decisions.

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Interviews

- Surveyors should verify with the facility whether arbitration agreements are used to resolve disputes.
- If so, determine compliance with F847 and F848 through interview of sampled residents, resident representatives, resident council/family council (if one exists), Long-Term Care Ombudsman, facility staff; and record review, which includes reviewing the agreement and other relevant documentation.

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Record Review

- Examples of what Surveyors look for when reviewing resident records under F847.
  - Review the binding arbitration agreement, any other pertinent information relevant to the selection of the arbitrator and venue as well as the arbitrator's final decision after resolution of a dispute (if applicable).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Record Review

- F847 Binding Arbitration Agreements
  - The binding arbitration agreement:
    - Clearly states that the resident or his or her representative is not required to enter into the agreement as a condition of admission to the facility, or as a requirement to continue to receive care.
    - Does not include language, which prohibits or discourages the resident or representative from communicating with federal, state, or local officials.
    - Was explained in a form, manner and language that the resident or his or her representative understands.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Record Review

- F848 Arbitrator/Venue Selection and Retention of Agreements
  - Is there evidence that the resident or his or her representative were provided with the opportunity to select a neutral arbitrator?
  - Is there evidence that the resident or his or her representative were provided with the opportunity to select a convenient venue?
  - Is there evidence the facility retained a copy of the signed agreement for binding arbitration and the arbitrator's final decision, after the resolution of a dispute through arbitration for five (5) years?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
F847 Key Elements of Non-Compliance

- The facility failed to:
  - **Explain** the terms of the agreement to the resident or his/her representative in a form and manner that he/she understands.
  - **Inform** the resident or his/her representative they are not required to enter into a binding arbitration agreement, or they have the right to rescind or termination the agreement within 30 calendar days.
  - **Prohibit or Discourage** the resident or his/her representative from communicating with federal, state, or local officials.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
F847 Key Elements of Non-Compliance

- The agreement itself failed to:
  - Contain language which clearly informs the resident or his/her representative they are not required to sign the agreement as a condition of admission to or as a requirement to continue to receive care at the facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements

F848 Key Elements of Non-Compliance

- The facility failed to:
  - Ensure that the agreement provides for the selection of a venue that is convenient, for the selection of a neutral arbitrator.
- For disputes resolved by arbitration, the facility failed to:
  - Retain a copy of the signed agreement for binding arbitration and the arbitrator's final decision (for disputes resolved by arbitration) after the facility and a resident or their representative resolve a dispute through arbitration for five (5) years.
  - Refuse to make the signed agreement or final decision available for inspections upon request by CMS or its designee.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Security Level

- When determining severity, surveyors may use the reasonable person concept.
- Severity Level 1 does not apply for this regulatory requirement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.70 Administration: Binding Arbitration Agreements Security Level

- When citing **immediate jeopardy**, the surveyor's investigation would have to show that noncompliance resulted in the:
  - likelihood for serious psychosocial injury or harm, or
  - caused actual serious psychosocial injury or harm,

  and
  - required immediate action to prevent further serious psychosocial injury or harm from occurring or recurring.

  - (Refer to the Psychosocial Severity Outcome Guide).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
Plan of Correction

- F847 Binding Arbitration Agreements
  - Based on CMS 2567, surveyors identified **systemic noncompliance**, indicating a **complete disregard** or **unawareness of the requirements**, such as the standard use of arbitration **agreements containing language which violates the requirements** at **F847,** and agreement that compliance with the requirement of F847.
  - And the facility has **made no attempt to explain arbitration agreements to residents**.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
Plan of Correction

- F847 Binding Arbitration Agreements
  - When reviewing the Plan of Correction (POC), surveyors must review carefully to ensure:
    - the new/revised arbitration agreement in use complies with the requirement of F847 and
    - residents/ representatives are informed and
    - residents/ representatives are offered a new agreement that compliance with the requirement of F847.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
Plan of Correction

- F848 Arbitrator/Venue Selection and Retention of Agreements
  - Based on CMS 2567, surveyors identified systemic noncompliance with F848, indicating a complete disregard or unawareness of the requirements, such as:
    - Routinely making no attempt to work with the resident or representative in selecting a neutral arbitrator or convenient venue.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.70 Administration: Binding Arbitration Agreements
Plan of Correction

- F848 Arbitrator/Venue Selection and Retention of Agreements
  - When reviewing the Plan of Correction (POC), surveyors must review carefully to ensure that all arbitration agreements:
    - Allow the selection of a
      - neutral arbitrator,
      - convenient venue,
      - defined process for 5-year record retention.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.15 Admission, Transfer, and Discharge

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge

- No new changes related to Phase 3 regulatory requirements.
- Changes made to:
  - F622 - Transfer and Discharge Requirements;
  - F623 - Notice Requirements before Transfer and Discharge;
  - F626 - Permitting Residents to Return to the Facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge

- All of the new regulations and guidance related to Admission, Transfer, and Discharge Rights occurred with Phase 2.
- There were no Phase 3 requirements for this section however, revisions to specific tags in response to feedback and questions from nursing home stakeholders.
- However, changes made to guidance below.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Guidance clarified for situations involving:
  - Discharge from short-term rehabilitation.
  - Surveyors investigate if the Discharge:
    - Is **not based only** on payment source, and
    - Whether discharge is **facility-** or **resident-initiated.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- For F622 Transfer and Discharge Requirements
  - CMS added guidance to clarify specific situations involving transfers and discharges.
    1. CMS added guidance to address the situation where a resident is admitted for short-term, skilled rehabilitation under Medicare, but, following completion of the rehabilitation, the resident may communicate that he or she is not ready to leave the facility. In this situation, if the facility proceeds with discharge, it is considered a facility-initiated discharge and the requirements at Section 483.15(c)(1) and (c)(2)(i)-(ii) apply to ensure the discharge does not violate federal regulations.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Surveyors may need to investigate these situations further to ensure that discrimination based on payment source has not occurred. The guidance also clarifies that in cases where the resident does not appear to object to the discharge, or has not appealed it, the discharge could still be a facility-initiated discharge and must be thoroughly investigated to determine if the discharge is resident- or facility-initiated.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Guidance clarified for situations involving:
  - Medicare ends/resident still needs long-term care. Resident is offered options to remain:
    - Pay privately;
    - Assist resident to apply for Medicaid.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Additionally, a facility has certain responsibilities when there is a situation where Medicare coverage has ended but the resident continues to need long- term care services. The facility should offer the resident the ability to remain, which may include:
  - The option to pay privately for a bed , or if private payment for the bed is not an option for the resident, the facility should provide the resident with necessary assistance to apply for Medicaid.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Assist resident to apply for Medicaid and explain:
  - If denied, resident is responsible to pay for all days after Medicare payment ended; and
  - If eligible, but no Medicaid beds, or facility only participates in Medicare, resident would be discharged to facility with available Medicaid beds if the resident wants to have the stay paid by Medicaid.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Note that:
  - Residents cannot be discharged for nonpayment while Medicaid is pending, or if found eligible.
  - Surveyors should know facility certification status, and/or if there is a distinct part.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- If assisting the resident with applying for Medicaid, facilities should explain that if the resident is denied for Medicaid, the resident would be responsible for payment for all days after Medicare payment ended. If the resident is found eligible, and no Medicaid bed is available or the facility only participates in Medicare, the resident would be discharged to another facility with available Medicaid beds if the resident wants to have the stay paid by Medicaid.
- The resident cannot be discharged for nonpayment while a determination on the resident's Medicaid eligibility is pending, or after he or she has been found eligible for Medicaid.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- The guidance instructs surveyors that they should be aware of a facility's Medicare and Medicaid certification status and/or the presence of a distinct part as this can affect whether a resident's discharge for non-payment is justified and is a relevant part of the investigation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- Emergent transfers to **acute care** and permitting return to nursing home. Things to know:
  - When a resident is transferred to acute care, they are generally **expected to return**.
  - Initiation of **discharge** while resident in hospital must be based on resident's **current condition** when resident seeks return to facility.
  - Discharge criteria at §483.15(c)(i) **must be met**.
  - Document danger that permitting resident to return would pose if facility does not permit return.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- CMS also clarified things surveyors should know when a resident is transferred to acute care and permitting them to return to the nursing home.
- When a resident is emergently transferred to acute care, these scenarios are considered facility-initiated transfers, not discharges, because the resident's return is generally expected.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- When facility initiates a discharge while the resident is in the hospital following an emergency transfer, the facility must have evidence that the resident's status at the time the resident seeks to return to the facility (not at the time the resident was transferred for acute care) meets one of the criteria at §483.15(c)(i). The resident also has the right to return to the facility pending an appeal of any facility-initiated discharge unless the return would endanger the health or safety of the resident or other individuals in the facility. In this situation, the facility must document the danger that the failure to transfer or discharge would pose.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes for F622 – Transfer & Discharge Requirements

- Residents who are sent to the acute care setting for routine treatment/planned procedures must also be allowed to return to the facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- For F622, CMS added deficiency categorization examples to show how a discharge which violates Federal requirements can cause actual and potential harm to a resident. The examples illustrate both psychosocial and physical harm.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.15 Admission, Transfer, and Discharge
Key Changes for F622 – Transfer & Discharge Requirements

- New deficiency categorization examples added:
  - Examples show how discharges which violate Federal regulations can cause actual and potential harm.
  - Examples illustrate psychosocial and physical harm.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F623 – Notice of Requirements Before Transfer/Discharge

- New guidance clarifies:
  - The transfer or discharge notice should contain the specific transfer or discharge location, such as name of new provider or residential address.
  - Changes to the notice could necessitate a new notice with new appeal rights and may require further investigation to ensure transfer or discharge complies with federal requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F623 – Notice of Requirements Before Transfer/Discharge

- F623 Notice of Requirements Before Transfer/Discharge c
  - Contains guidance related to the requirement to provide a resident with a notice of transfer or discharge in advance of the transfer or discharge.
  - In the section on the contents of the notice, we added that the facility must provide, in the notice, the specific location to which the resident is being transferred or discharged such as the name of the new provider or description and/or address if the location is a residence.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F623 – Notice of Requirements Before Transfer/Discharge

- CMS also added language to the section on changes to the notice to clarify that surveyors should be aware that if a change in destination indicates that the original basis for discharge has changed, a new notice is required, and additional appeal rights may exist for the resident. This situation may require further investigation to determine whether the facility is in compliance with the Transfer and Discharge requirements at 42 CFR 483.15(c).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F623 – Notice of Requirements Before Transfer/Discharge

- For example, a facility may determine it cannot meet a resident's needs and arranges for discharge to another nursing home which can meet the resident's needs. Before the discharge occurs, the receiving facility declines to take the resident and the discharging facility changes the destination to a setting that does not appear to meet the resident's ongoing medical needs. This could indicate that the basis for discharge has changed and would require further investigation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F626 – Permitting Residents to Return to Facility

- Clarified that requirement to permit residents to return after hospitalization or therapeutic leave applies to all residents regardless of payment source.
- Added language to investigative procedure to help surveyors investigate situations where a facility does not permit return due to:
  - Lack of an available bed.
  - Inability to meet resident's needs.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F626 – Permitting Residents to Return to Facility

- CMS made several revisions to F626, Permitting Residents to Return to the Facility. First, we clarified that policies on bed-hold and permitting residents to return after hospitalization or therapeutic leave apply to all residents, regardless of payment source.
- CMS also added language in the summary of the investigative procedure section of F626 to help surveyors investigate situations where a facility does not permit a resident to return due to lack of an available bed or because the facility says it cannot meet the resident's needs.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F626 – Permitting Residents to Return to Facility

- A deficiency categorization example was added to show actual harm from a facility not permitting a resident to return after a hospitalization.
  - The resident had lived in the nursing home for several months.
  - The resident was transferred to a behavioral health hospital.
  - The nursing home failed to allow the resident to return.
  - The hospital transferred the resident to a nursing home farther away resulting in increased anxiety and depression for the resident.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

Key Changes to F626 – Permitting Residents to Return to Facility

- CMS also added a deficiency categorization example at level 3 of F626 to show how actual harm can occur to a resident when a facility does not permit the resident to return. In the example, a resident is transferred to a behavioral health hospital.
- The nursing home facility failed to allow the resident to return to the facility where the resident had lived for several months. When the facility refused to allow the resident to return after the hospitalization, the hospital transferred the resident to a different nursing home 40 minutes away, where he did not know anyone, and where he developed increased anxiety and depression.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.15 Admission, Transfer, and Discharge

F622, F623, F626 – Against Medical Advice Discharges (AMA)

- CMS added language to F622, F623 and F626 to address against medical advice (AMA) discharges.
- These situations may be facility-initiated discharges and must meet the requirements at 483.15(c).
- Surveyors should thoroughly investigate these situations to ensure compliance.
- Is there evidence that a resident or resident representative was forced, pressured or intimidated into leaving the facility?

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.40 Behavioral Health Services

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F740	Behavioral Health Services	Removed reference to Appendix P and added reference to **Psychosocial Outcome** Severity Guide; added language related to mental health and substance use disorders throughout guidance.	Significant
F741	Sufficient/Competent Staff-Behavior Health Needs	Removed reference to Appendix P and added reference to Psychosocial Outcome Severity Guide; Minor change to correct reference to F679; Added language related to history of trauma and/or post-traumatic stress disorder throughout guidance; Added language related to mental health and substance use disorders throughout guidance.	Significant

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F742	Treatment/Services for Mental/Psychosocial concerns	Removed reference to Appendix P and added reference to Psychosocial Outcome Severity Guide.	Technical
F743	No Pattern of Behavioral Difficulties Unless Unavoidable	Removed reference to Appendix P and added reference to Psychosocial Outcome Severity Guide.	Technical
F744	Treatment/Service for Dementia	Removed reference to Appendix P and added reference to Psychosocial Outcome Severity Guide.	Technical

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services

- All of the tags within the Behavioral Health Services regulatory section were revised, except F745. Changes to tags F742, F743, and F744 were minor and involved removal of reference to Appendix P and the addition of reference to the Psychosocial Outcome Severity Guide.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F740 Behavioral Health Services
  - Additions included:
    - Reference to Preadmission Screening and Resident Review (PASARR) requirements.
    - Language pertaining to the use of behavioral contracts, including examples of issues that they may address.
    - Information on schizophrenia and bipolar disorder.
    - A new severity level 4 example under the Deficiency Categorization section.
    - Behavioral health care and services resources.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F740 Behavioral Health Services
  - For F740, we added a reference to PASARR requirements specific to residents diagnosed with mental disorders.
  - Additionally, we discussed the use of behavioral contracts. This included a list of issues that may be addressed in this type of agreement. However, a behavioral contract cannot conflict with resident rights or other requirements of participation.
  - CMS also added information on schizophrenia and bipolar disorder, in addition to providing clarification in the paragraphs pertaining to depression and anxiety disorders.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F740 Behavioral Health Services
  - A new severity level 4 example was added in the deficiency categorization section, pertaining to the mental health needs of a resident diagnosed with a substance use disorder.
  - CMS also added resources related to behavioral health care and services.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs
  - Intent: Sufficient staff who possess competencies/skills to meet behavioral health needs of residents, … including those with a history of trauma and/or post- traumatic stress disorder (PTSD).
  - Trauma results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - PTSD occurs in some individuals who have encountered a shocking, scary, or dangerous situation. Symptoms usually begin early, within three months of the traumatic incident, but sometimes they begin years afterward. Symptoms must last more than a month and be severe enough to interfere with relationships or work to be considered PTSD.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - CMS added references to residents that have a history of trauma and/or post-traumatic stress disorder.
  - This was in addition to residents living with mental and psychosocial disorders. This also included the addition of definitions for trauma and post-traumatic stress disorder.
  - Trauma results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - Post-traumatic stress disorder occurs in some individuals who have encountered a shocking, scary, or dangerous situation. Symptoms usually begin early, within three months of the traumatic incident, but sometimes they begin years afterward. Symptoms must last more than a month and be severe enough to interfere with relationships or work to be considered PTSD.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - Additions included:
    - Substance Use Disorder is defined as recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.
    - Information pertaining to the use of the facility assessment for behavioral health care needs.
    - Additional examples of non-pharmacological interventions.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - Additions included:
    - A new severity level 2 example under the Deficiency Categorization section.
  - CMS also added references to residents that have a diagnosed mental health and/or substance use disorder.
  - This included the addition of the definition of substance use disorder.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - Substance Use Disorder (or SUD) is defined as recurrent use of alcohol and/or drugs that causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.
  - Guidance was also added related to how the behavioral health care needs of those with a SUD or other serious mental disorder should be part of the facility assessment under §483.70(e) (F838) and the facility should determine if they have the capacity, services, and staff skills to meet the requirements as discussed in this tag.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.40 Behavioral Health Services
Key Changes to Behavioral Health Services

- F741 Sufficient/Competent Staff-Behavioral Health Needs (continued)
  - Additionally, examples of non-pharmacological interventions specific to residents diagnosed with mental health and/or substance use disorders were added.
  - In addition, a new severity level 2 example was added in the deficiency categorization section, pertaining to the care planned interventions of a resident diagnosed with a substance use disorder who returned from a leave of absence.
  - CMS also made a technical correction to F741 to update a reference to F679.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

§483.85 Compliance and Ethics Program

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Overview

- New Compliance and Ethics Program requirements in F895
- Intent and definitions.
- Requirements for all facilities and additional requirements for operating organizations with five or more facilities.
- Questions surveyors should consider when investigating F895.
- Potential tags for additional consideration.
- Compliance and Ethics training requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Overview

- CMS will review the requirements of new F-Tag F895 for the Compliance and Ethics Program, will also review the intent of these requirements, pertinent definitions, requirements that apply to all facilities as well as additional requirements that apply to operating organizations with 5 or more facilities, investigative procedures for surveyors and training requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

- To ensure that facilities have in operation an effective compliance and ethics program that uses internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements to deter criminal, civil and administrative violations and promote quality of care for nursing home resident.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

- The intent of the new compliance and ethics program requirements at F895 is to ensure the facility has an effective system to deter any criminal, civil and administrative violations, which ultimately promotes the quality of care for nursing home residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

- On March 16, 2000, the Department of Health and Human Services, Office of the Inspector General also know as OIG, released Compliance Program Guidance for Nursing Facilities to promote “a higher level of ethical and lawful conduct throughout the entire health care industry”. The OIG previously issued guidance for other segments of the health care industry based on the belief that “a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations, and program requirements.”

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

- This guidance also provided the basis for the Patient Protection and Affordable Care Act which amended a section of the Social Security requiring Medicare skilled nursing facilities and Medicaid nursing facilities to have a compliance and ethics program. The OIG guidance recommended seven elements which should be included in an effective, comprehensive compliance and ethics program:

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

1. Implementing written policies, procedures and standards of conduct.
2. Designation of a compliance officer and compliance committee.
3. Conducting effective training and education.
4. Developing effective lines of communication.
5. Enforcing standards through well-publicized disciplinary guidelines.
6. Conducting internal monitoring and auditing.
7. Responding promptly to detected violations and corrective action.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

- There are a number of common risk areas which are mostly associated with the delivery of health care to nursing facility residents. Some of them include:
  - sufficient staffing,
  - comprehensive care plans,
  - medication management,
  - infection prevention,
  - appropriate use of psychotropic medications and
  - resident abuse, neglect and safety.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Intent

- Additional risk areas include resident rights, fraud prevention, billing and cost reporting, employee screening, resident assessment accuracy, creation and retention of records, falsification and modification of documentation, conflicts of interest, kickbacks, inducements and self-referrals.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Regulatory Definitions

- High-Level Personnel
  - An individual(s) who has substantial control over the operating organization or who has a substantial role in the making of policy within the operating organization.
- Operating Organization
  - The individual(s) or entity that operates a facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Regulatory Definitions

- In the requirements, there are two specific regulatory definitions we want to highlight. The first is high level personnel which is the person or people who have substantial control over the organization or who has a substantial role in making policies in the operating organization.
- The second definition clarifies that an operating organization is one or more individuals or entity that operates a facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- The operating organization of each facility must have a compliance and ethics program that has been reasonably designed, implemented, maintained and enforced, so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Social Security Act and in promoting quality of care.
- It is important for the facility to consider their facility assessment developed according to §483.70(e) in identifying risk areas, developing and maintaining their compliance and ethics program, and determining resources needed for the program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c) Required components for all facilities.
- The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act. and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- The operating organization must have written standards, policies and procedures for its compliance and ethics program, which include at a minimum:
  - Designation of an appropriate compliance and ethics program contact to whom an individual can report suspected violations;
  - An alternate method of reporting suspected violations anonymously without fear of retribution; and
  - Disciplinary standards that describe the consequences for committing violations for the entire staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.
- §483.85(c)(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- The operating organization must assign specific individuals within the high-level personnel of the organization with the overall responsibility of overseeing adherence to the compliance and ethics program's standards, policies, and procedures.
- High-level personnel means individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization. The individuals considered ''high-level personnel'' will differ according to each operating organization's structure.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- Some examples include, a director; executive officers including the chief executive officer; members of the board of directors; an individual in charge of a major business or functional unit of the operating organization; or an individual with a substantial ownership interest in the operating organization.
- The program must also include provisions ensuring that the specific individual designated with oversight responsibility has sufficient resources and authority to assure compliance with program standards, policies, and procedures. The resources devoted should include both human and financial resources.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at §483.95(f) or orientation programs or disseminating information that explains in a practical manner what is required under the program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- Organizations must exercise the care that a reasonable person would use under the same circumstances when delegating substantial discretionary authority to individuals, to ensure that the delegation is not made to an individual who the operating organization knew, or should have known, through the exercise of due diligence, had engaged in or had the predisposition to engage in unethical acts, or potential criminal, civil and/or administrative violations of the Act.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- The facility is also required to effectively communicate to the entire staff, the standards, policies and procedures of the compliance and ethics program. Requirements include, mandatory participation in training, orientation programs, and/or dissemination of information that explains what is required under the program, in a practical manner.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- Under 483.85(c)(6), the facility must take reasonable steps to achieve compliance with the program's standards, policies and procedures. These steps include:
  - Utilizing monitoring and auditing systems to detect criminal, civil, and administrative violations under the Social Security Act, by any of the facility's staff.
  - Publicizing a reporting system whereby any of the organization's entire staff could report violations anonymously within the operating organization without fear of retaliation, and
  - Having a process for ensuring the integrity of any reported data.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- The compliance and ethics program must establish appropriate disciplinary mechanisms and effectively communicate those mechanisms, so that the operating organization's entire staff is clearly aware of the consequences of program violations.
- The operating organization is required to consistently enforce its standards, policies, and procedures through appropriate disciplinary mechanisms which may include, discipline of individuals who fail to detect and report a violation to the appropriate party identified in the organization's compliance and ethics program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(c)(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- After an operating organization detects a violation, it must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations. This includes any necessary modification to the organization's program.
- The program should clearly identify the reasonable steps to take when a violation is detected. Such steps may include a corrective action plan, the return of overpayments, a report to the government and/or or a referral to criminal and/or civil law enforcement authorities. The steps will differ depending upon the size of the operating organization, the position of the individual reporting the violation, and the type of violation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- For example, an operating organization's program may state that a staff member should immediately notify their immediate superior when he or she detects a violation. However, if it is the immediate superior or the operating organization's management whom the staff member believes is committing the violation, the staff member should have an alternative process to report the violation, such as, an executive officer of the organization, the Office of the State Long-Term Care Ombudsman or other appropriate agency or law enforcement authority.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- Facilities should integrate the information and data from their compliance and ethics programs into their Quality Assurance and Performance Improvement, also known as QAPI program. The QAPI committee should work with the compliance officer to determine if there are trends or patterns of systemic problems.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- §483.85(e) Annual review.
  - The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program Requirements for All Facilities

- The operating organization for each facility must review its compliance and ethics annually.
- Additionally, as an operating organization becomes aware of changes in laws or requirements, it should modify its program to ensure it is current with requirements.
- The operating organization's performance in prior years should also be used to improve its program. As an operating organization revises its program, it should ensure that those changes are communicated to its entire staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.85 Compliance and Ethics Program

Additional Requirements for Operating Organizations with Five or More Facilities

- §483.85(d) Additional required components for operating organizations with five or more facilities. In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:
  - §483.85(d)(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in §483.95(f).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.85 Compliance and Ethics Program

Additional Requirements for Operating Organizations with Five or More Facilities

- There are additional requirements for operating organizations with five or more facilities.
- These organizations must have a more formal compliance and ethics program that includes written policies which define the standards and procedures their employees must follow.
- They must develop a compliance and ethics program that is appropriate for the complexity of their organization and the facilities they operate.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.85 Compliance and Ethics Program

Additional Requirements for Operating Organizations with Five or More Facilities

- Additionally, operating organizations with five or more facilities must have a mandatory annual training program. The annual training should be delivered in a practical manner based on its resources, the complexity of the operating organization and its facilities and in accordance with compliance and ethics training requirements found at F946.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.85 Compliance and Ethics Program

Additional Requirements for Operating Organizations with Five or More Facilities

- §483.85(d)(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.
- §483.85(d)(3) Designated compliance liaisons located at each of the operating organization's facilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.85 Compliance and Ethics Program

Additional Requirements for Operating Organizations with Five or More Facilities

- Operating rating organizations with 5 or more facilities must designate a compliance officer for whom the compliance and ethics program is a major responsibility.
- The operating organization should ensure that the assigned compliance officer has sufficient time and other resources to fulfill all of his or her responsibilities under the operating organization's compliance and ethics program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.85 Compliance and Ethics Program

Additional Requirements for Operating Organizations with Five or More Facilities

- The compliance officer should be able to communicate with the governing body without being subject to any coercion or intimidation. This ensures that the compliance officer is not unduly influenced by other managers or executive officers, such as the general counsel, chief financial officer or chief operating officer.
- Additionally, the designated compliance liaison must be located at each of the operating organization's facilities. At a minimum, the facility-based liaison should be responsible for assisting the compliance officer with his or her duties under the operating organization's program at their individual facilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Questions Surveyors Should Consider

- When investigating concerns related to a criminal, civil and administrative violation in the facility, surveyors should review the facility's written standards, policies and procedures for the compliance and ethics program and interview high-level personnel, who are designated to oversee the program and staff.
- The guidance also contains probes in F895 to consider during investigation and when making compliance determinations. Examples include:

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Questions Surveyors Should Consider

- When reports or reasonable suspicions of violations are identified, did the organization take prompt action to respond to the violations and prevent further occurrences?
- Does the operating organization review the program annually and as needed, and in response to organization, facility and/or regulatory changes?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Questions Surveyors Should Consider

- When investigating concerns related to a criminal, civil and administrative violation in the facility, surveyors should review the facility's written standards, policies and procedures for the compliance and ethics program and interview high-level personnel, who are designated to oversee the program and staff. The guidance contains probes in F895 to consider during investigation and when making compliance determinations. Some of the probes include:

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Questions Surveyors Should Consider

- Does the operating organization have written standards, policies and procedures for the compliance and ethics program that are reasonably capable of reducing the possibility of criminal, civil and administrative violations under the Act?
- Interview high-level personnel designated to oversee the organization's compliance and ethics program about their involvement in the program to determine:
  - how the facility uses monitoring and auditing systems to detect criminal, civil, and administrative violations by staff;
  - if they are aware of the potential violation under investigation and what was their response.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Questions Surveyors Should Consider

- Ask staff if:
  - they are aware of the facility's compliance and ethics program;
  - there is a method for staff to anonymously report suspected violations;
  - they are confident in reporting compliance matters without fear of retaliation.
- If the operating organization has five or more facilities, have a compliance officer and a facility-based compliance liaison been designated?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Potential Tags for Additional Consideration

- If a negative or potentially negative resident outcome is determined to be related to the facility's failure to meet compliance and ethics requirements, it should also be investigated under the appropriate quality of care or other relevant requirement.
- For concerns related to systems of care and management practices, written policies and procedures for feedback, data collection systems, monitoring, analyzing and acting on available data to make improvements, see Quality Assurance and Performance Improvement (QAPI) requirements in §483.75.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
Potential Tags for Additional Consideration

- As part of this training, we want to emphasize that surveyors should always investigate the appropriate quality of care requirements when a determination is made related to the facility's failure to meet the requirements of F895.
- Regarding concerns that are related to the facility's systems of care and management practices, written policies and procedures for feedback, data collection systems, monitoring, analyzing and acting on available data, surveyors should also consider the requirements in F867 Quality Assurance and Performance Improvement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.85 Compliance and Ethics Program
483.95 Training Requirements

- F946 Compliance and Ethics Training
  - §483.95(f) Compliance and ethics.
    - The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85—
- §483.95(f)(1) An effective way to communicate the program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.
- §483.95(f)(2) Annual training if the operating organization operates five or more facilities.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.60 Food and Nutrition Services

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.60 Food and Nutrition Services

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F812	Food Procurement, Store/ Prepare/Serve - Sanitary	Guidance reorganized for clarification; added language related to culture change dining practices.	Significant

- Revisions were made to **F812** to address concerns related to **culture change** in long-term care settings. These changes were specifically related to **dining practices**.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.60 Food and Nutrition Services
Key Changes to Food and Nutrition Services – F812

- F812 Food Procurement, Store/Prepare/Serve – Sanitary
  - Additions included:
    - Separation of food distribution and food service.
    - Clarification of the definition for Food Distribution.
    - Definition for Food Service.
    - Details on staff hair restraint use.
    - Details on staff glove use.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.60 Food and Nutrition Services
Key Changes to Food and Nutrition Services – F812

- Previously, food distribution and food service operations were grouped together under F812. With these revisions, we separated food distribution and food service.
- In doing so, CMS further clarifies food distribution by revising the definition and adding a new definition for food service.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

September 13, 2022

483.12 Freedom From Abuse, Neglect and Exploitation

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F600	Abuse/Neglect	Removed language from sexual abuse, included additional guidance related to neglect	Significant
F602	Misapprop/Exploit	Minor changes to update references to Appendix P	Technical
F603	Involuntary Seclusion	Minor changes to update references to Appendix P	Technical
F604	Physical Restraints	Clarification of when a bed rail meets the definition of a physical restraint	Significant
F605	Chemical Restraints	Minor changes to update references to Appendix P	Technical
F606	Not Employ Staff w/Adverse Action	Revised intent to match the regulation text	Technical

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F607	Abuse Policies	Added guidance for coordination with QAPI and provisions the former F608	Significant
F608	Reporting of Suspected Crimes	Deleted – Guidance is at F607/F609	Significant
F609	Reporting Alleged Violations	Revised definitions and guidance related to the timing of reports, added language related to what facilities must report, added provisions from the former F608	Significant

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- All resident-to-resident altercations do not result in abuse. Surveyors must investigate.
- Removed the language: "Residents without the capacity to consent to sexual activity may not engage in sexual activity."
- Added language: "The facility must take steps to ensure that the resident is protected from abuse. These steps should include evaluating whether the resident has the capacity to consent to sexual activity."

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- CMS has made a number of changes for citations related to abuse and neglect. For guidance related to resident-to-resident abuse, CMS emphasized that not every resident-to-resident altercation results in abuse. Residents do have social interactions with one another and will not always agree. Surveyors must investigate whether the incident meets the definition of “abuse”.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- Under sexual abuse, we removed the sentence: “Residents without the capacity to consent to sexual activity may not engage in sexual activity.” This sentence could unintentionally give the impression that all residents without the capacity to consent are not allowed to have any physical intimacy; therefore, we deleted this sentence. CMS wants to make clear, however, that sexual contact is not consensual if the victim is sedated, is temporarily unconscious, or is in coma. Also, the facility must take steps to ensure that the resident is protected from abuse.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- These steps should include evaluating whether the resident has the capacity to consent to sexual activity.
- This should exactly match the language that is in our guidance – if not, could be problematic for Allina.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- Past Non-Compliance
  - Investigate each instance thoroughly to determine if the facility took all appropriate actions.
  - Determine the date on which the facility had returned to substantial compliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- In addition, we provided more information under the section for past noncompliance. CMS reminds surveyors that prior to citing a deficiency as past- noncompliance, surveyors should investigate each instance thoroughly to determine if the facility took all the appropriate actions to correct the non-compliance and determine the date on which the facility had returned to substantial compliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- Appropriate steps to remediate the non-compliance and protect residents from additional abuse immediately.
  - Taking steps to prevent further potential abuse;
  - Reporting the alleged violation and investigation within required timeframes;
  - Conducting a thorough investigation of the alleged violation;
  - Taking appropriate corrective action; and
  - Revising the resident's care plan if the resident's needs change.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Abuse

- When facility is cited for abuse, the facility must take all appropriate steps to rectify the non-compliance and protect residents from additional abuse immediately. Failure to take the above steps could result in findings of current non-compliance and increased enforcement action.
- In addition, the resident's care plan must be revised if the resident's needs change as a result of the incident of abuse.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Neglect

- Indifference or disregard for resident care, comfort or safety, resulting in, or may result in, physical harm, pain, mental anguish or emotional distress.
- Non-compliance at Quality of Care does not always result in Neglect at F600.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Neglect

- In addition, under Tag F600 at neglect, CMS added some language related to when neglect occurs. It is important to remember that not every deficiency at Resident's Rights, Quality of Care, or Quality of Life will result in a finding of neglect. Neglect includes cases where the facility's indifference or disregard for resident care, comfort or safety resulted in, or could have resulted in, physical harm, pain, mental anguish or emotional distress. In other words, the collective effect of different individual failures in the delivery of care and services by staff leads to an environment that promotes neglect.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Neglect

- Neglect occurs when the facility is aware of, or should have been aware of, goods or services that a resident requires but the facility fails to provide them to the resident, resulting in, or may result in, physical harm, pain, mental anguish, or emotional distress.
- The guidance provides an example where there was noncompliance under Quality of Care, but not Neglect at F600, to help illustrate this point to surveyors. In one of the examples, a scenario was provided where a survey team identifies that a facility had failed to perform a skin assessment for a resident, resulting in failure to implement interventions to prevent the development of an avoidable Stage 2 pressure ulcer for a resident.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Neglect

- Upon further investigation, the survey team finds that the facility identified the pressure ulcer and treated it with no further worsening. While the survey team would identify noncompliance at F686, the facility would not generally be cited at F600 as well. A citation at neglect would require additional evidence that identifies that the facility knew, or should have known, to provide necessary staff, supplies, services, policies, training, or staff supervision and oversight to meet the resident's needs, but continued to fail to take action, necessary to avoid harm to the resident.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Deficient Practice Statement

- Abuse Template
  - Based on [observations/interviews/record review], the facility failed to protect the resident's(s') right to be free from [Type(s) of abuse: mental abuse/verbal abuse/physical abuse/sexual abuse/deprivation of goods and services] by [Perpetrator type: staff/a resident/a visitor]….
- Neglect Template
  - Based on [observations/interviews/record review], the facility failed to protect the resident's(s') right to be free from neglect….

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F600-Neglect

- For tags related to abuse and neglect, the guidance includes a template for the Deficient Practice Statement for Tag F600, as shown on this slide. Surveyors should follow this, as it will assist CMS in identifying the different types of abuse and neglect cases, and the type of perpetrator involved.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes to F604

- Physical Restraints
  - When is a bed rail a restraint?
    - It keeps a resident from voluntarily getting out of bed in a safe manner due to his/her physical or cognitive inability to lower the bed rail independently.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes to F607

- Facilities must develop and implement policies and procedures that include coordination with QAPI.
  - How are cases communicated to the QAA Committee?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes to F607

- Under Tag F607, we included guidance to implement a Phase 3 requirement — nursing homes are now required to include QAPI coordination in their policies and procedures for prohibiting abuse and neglect. CMS would expect that the facility's policies and procedures would direct staff in how information is shared with the Quality Assessment and Assurance, or QAA Committee—this is important so that the QAA Committee could oversee facility processes and determine whether more systemic actions are necessary.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes to F607/F609

- Deleted – F608
- F607 Abuse Policies
  - Citations related to the failure to develop and implement written policies and procedures related to posting a conspicuous notice of employee rights and prohibiting and preventing retaliation.
- F609 Reporting Alleged Violations
  - Citations related to the facility's failure to ensure the reporting of suspected crimes and notifying covered individuals of their reporting responsibilities.
- The respective Investigative Protocols have also been moved.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes to F607/F609

- In addition, changes were made regarding which tags to cite when a facility is not in compliance with requirements related to reporting a suspicion of a crime. F608 should no longer be used for citing deficiencies and has been deleted. Instead, the requirements under 1150B will be split into two tags:
  - Tag F607 will be used for citations related to the failure to develop and implement written policies and procedures related to posting of conspicuous notice of employee rights and prohibiting and preventing retaliation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes to F607/F609

- Tag F609 will be used for citations related to the facility's failure to ensure the reporting of suspected crimes and notifying covered individuals of their reporting responsibilities.
- With this change, CMS also moved the Investigative Protocol from F608 to tags F607 and F609. For example, if there is an allegation of retaliation by the facility against a covered individual, the Investigative Protocol under Tag F607 should be used.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609 Reporting of Suspected Crimes

- Deficient practice statement: Based on [observations/interviews/record review], the facility failed to develop and/or implement policies and procedures for ensuring the reporting of a reasonable suspicion of a crime in accordance with section 1150B of the Act.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Key Changes for F609 Reporting of Suspected Crimes

- CMS recognizes that the failure to ensure the reporting of suspected crimes is now under the same tag for the reporting of alleged violations. In order to assist in reporting, our guidance instructs surveyors to include standardized language in the Deficient Practice Statement, if F609 is cited related to failure to ensure the reporting of crimes. This standardized language is displayed on the slide.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Key Changes for F609 Reporting of Suspected Crimes

- Examples of actions that policies and procedures should address:
  - Orienting new staff and assuring that covered individuals are annually notified;
  - Identifying barriers and implementing interventions to remove barriers and promote a culture of transparency and reporting;
  - Working with law enforcement annually to determine which crimes are reported;
  - Assuring that covered individuals can identify what is reportable and providing in-service training; and
  - Providing periodic drills.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609 Reporting of Suspected Crimes

- Examples of actions that policies and procedures (continued):
  - Surveyors should investigate and document the failure to develop and/or implement policies and procedures for reporting suspected crimes.
  - If the covered individual refuses to report, or the surveyor cannot verify that the report was done, the surveyor must consult with his/her supervisor immediately.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Key Changes for F609 Reporting of Suspected Crimes

- Under Tag F609, to ensure the reporting of suspected crimes, CMS provides guidance to surveyors about what the facility's policies and procedures should address. Examples described in the guidance include, but are not limited to, the following:
  - Orienting new staff to the reporting requirements and assuring that covered individuals are annually notified of their responsibilities in a language they understand.
  - Identifying barriers on reporting such as fear of retaliation or causing trouble for someone and implementing interventions to remove barriers and promote a culture of transparency and reporting.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Key Changes for F609 Reporting of Suspected Crimes

- Working with law enforcement annually to determine which crimes are reported.
- Assuring that covered individuals can identify what is reportable as a reasonable suspicion of a crime and providing in-service training.
- Providing periodic drills across all levels of staff and all shifts to assure that covered individuals understand the reporting requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Key Changes for F609 Reporting of Suspected Crimes

- Even in the presence of a policy and procedure, failure to report a reasonable suspicion of a crime is indicative of failure to implement the facility's policies and procedures.Surveyors should investigate and document the failure to develop and/or implement policies and procedures for reporting suspected crimes. For example, this may include how the facility may have not provided notification to its employees or how covered individuals are fearful of reporting or do not want to get others in trouble.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Key Changes for F609 Reporting of Suspected Crimes

- Also, the guidance was revised to instruct surveyors of situations where covered individuals in the facility had not reported a suspected crime to law enforcement. If the covered individual refuses to report, or the surveyor cannot verify that the report was done, the surveyor must consult with his/her supervisor immediately, and the State Agency must report the potential criminal incident to law enforcement immediately.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
F609 Reporting of Alleged Violations

- Clarified guidance for alleged violations which must be reported:
  - Staff to resident abuse.
  - Resident to resident altercations.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
F609 Reporting of Alleged Violations

- Over the years, CMS has received questions from surveyors and providers regarding the reporting requirements, especially in the areas of resident-to-resident altercations, neglect, and misappropriation of resident property and exploitation. Although there weren't any changes to the regulations related to the reporting of alleged violations of abuse, neglect, and exploitation, CMS added additional guidance to tag F609, including examples of each type of alleged violation. Please note that some States may require additional types of incidents to be reported; however, surveyors would not review these incidents under F609 and would review these under their State licensure authority.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
F609 Reporting of Alleged Violations

- What types of alleged violations related to abuse must be reported.
  - All allegations of staff to resident abuse must be reported.
  - Staff may receive allegations from any source, including other staff, residents, and family members.
  - Also, each occurrence must be reported.
  - If staff are aware of or witnessed any abuse that occurs, it must be reported.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
F609 Reporting of Alleged Violations

- With respect to reporting resident to resident altercations, facilities are not required to report all altercations to the State under Federal regulations.
- CMS knows that arguments and altercations occur among residents, as they do in any social setting. In the Interpretive Guidance, CMS carved out examples of what must be reported, and would require additional investigation by the facility to determine whether resident to resident abuse occurred.
- CMS also described cases that facilities do not need to report.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Mental/Verbal Conflict

- Required to Report
  - Bullying.
  - Threats of Violence.
- Not Required to Report
  - Non-targeted outbursts.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Mental/Verbal Conflict

- CMS also separated resident altercations into the following categories –
  - Mental/Verbal Conflict,
  - Sexual Contact, and
  - Physical Altercations.
  - Under the category of Mental/Verbal Conflict, we would expect, for example, that bullying, or threats of violence are examples of altercations that must be reported to the State. CMS would not expect the facility to report non-targeted outbursts.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Mental/Verbal Conflict

- CMS also separated **resident altercations** into the following categories:
  - Mental/Verbal Conflict.
  - Sexual Contact.
  - Physical Altercations.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Resident-to-Resident Altercations – Sexual Contact

- Not Required to Report
  - Sexual contact (consensual) between residents who have the capacity to consent.
  - Affectionate contact such as hand holding or hugging or kissing a resident who indicates that he/she consents to the action through verbal or non- verbal cues.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Sexual Contact

- CMS guidance on what types of sexual contact to report. Facilities are not required to report all sexual contact between residents.
- For example,
  - Consensual sexual contact between residents who have the capacity to consent to sexual activity would not have to be reported.
  - Affectionate contact such as hand holding or hugging or kissing a resident who indicates that they consent to the action through verbal or non-verbal cues would not need to be reported.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Resident-to-Resident Altercations – Sexual Contact

- Sexual activity between residents in a relationship, such as married couples or partners, unless one of the residents indicates that the activity is unwanted through verbal or non-verbal cues, would not need to be reported.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Sexual Contact

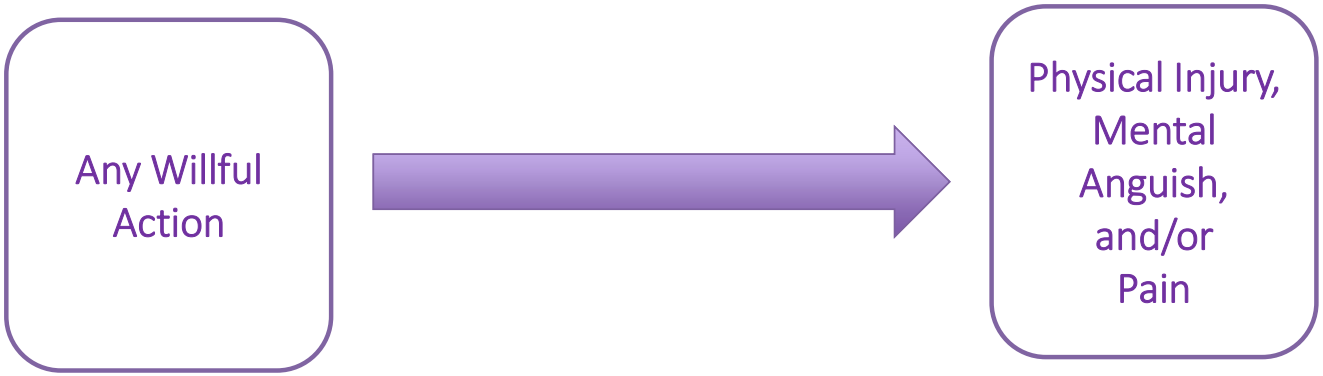
- Required to Report
  - Touching a resident's sexual organs and the resident being touched indicates the touching is unwanted through verbal or non-verbal cues.
  - Sexual activity or fondling where one of the resident's capacity to consent to sexual activity is unknown.
  - Instances where the alleged victim is transferred to a hospital for examination and/or treatment of injuries resulting from possible sexual abuse.
  - Other unwanted actions for the purpose of sexual arousal or sexual gratification.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Resident-to-Resident Altercations – Physical



Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Physical

- Resident Physical Altercations.
  - CMS outlined, that any resident-to-resident altercation where a willful action results in physical injury, mental anguish, or pain must be reported.
  - Willful actions include, but are not limited to,
    - hitting, slapping, punching, and choking.
  - CMS included examples of willful actions and the results of those actions, such as physical injuries, mental anguish, and pain.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Altercations – Physical

- Resident Physical Altercations.
- Physical altercations that don't result in physical injury, mental anguish, and pain do occur.
- While these types of cases do not have to be reported, physical altercations can increase the risk for abuse to occur in the facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation Resident-Resident Physical Altercations Not Reported

- The facility must meet requirements related to:
  - Appropriate Assessment.
  - Care Planning by the interdisciplinary team.
  - Implement Care Planning interventions, as necessary.
  - Provide Care and services according to acceptable standards of practice to prevent harm as a result of resident-to-resident altercations.
  - Development and implementation of Policies and Procedures to prevent abuse.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Resident-to-Resident Physical Altercations Not Reported

- The development and implementation of policies and procedures to prevent abuse of residents.
- Through these actions, the facility can determine areas of needed improvement n care/service provision, staff training or staff placement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609

- Clarified guidance for alleged violations.
  - Injuries of unknown source.
- CMS has received questions from surveyors about which injuries must be reported, such as bruises and skin tears.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Injuries of Unknown Source

- An injury should be classified as an "injury of unknown source" when ALL of the following criteria are met:
  - The source of the injury was not observed by any person; and
  - The source of the injury could not be explained by the resident; and
  - The injury is suspicious because of:
    - The extent of the injury, or
    - The location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma), or
    - The number of injuries observed at one particular point in time, or
    - The incidence of injuries over time.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Injuries of Unknown Source

- To illustrate this better, we provided examples of what facilities are required to report and not required to report. Some examples of injuries that must be reported include unobserved or unexplained:
  - Skin tears in sites other than the arms or legs.
  - Symmetrical skin tears on both arms.
  - Patterned bruises that suggest hand marks or finger marks, or bruising pattern caused by an object.
  - Bilateral bruising of the inner thighs, and “wrap around” bruises that encircle the legs, arms or torso.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Injuries of Unknown Source

  - Facial injuries, including facial fractures, black eye(s), bruising, or bleeding or swelling of the mouth or cheeks with or without broken or missing teeth.
- In the guidance, we have also identified injuries that would not require a report, such as bruising in an area where the resident has had recent medical tests as long as there is no other indication that abuse, or neglect occurred.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609

- Clarified guidance for alleged violations.
  - Neglect

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609

- CMS' interpretive guidance provides information to surveyors about reporting alleged violations of neglect. In developing the guidance for reporting neglect, we had reviewed examples from CMS-2567s. Through our review, we had identified situations where facility failures continued but were not reported to supervisory staff or administration, resulting in the State survey agency not being notified. In other cases, staff report failures but there is a lack of action. In these situations, neglect can occur. For example, CMS expects that a facility would report if there are repeated lapses in care that result in the development of an avoidable Stage 3 or 4 pressure ulcer. It is important that facility staff report such instances, as it could prevent further harm to residents in the facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation
Misappropriation of Resident Property/Exploitation

- CMS' interpretive guidance provides examples of alleged violations of misappropriation of resident property and exploitation that must be reported.
- Examples of what must be reported:
  - Theft of personal property, such as jewelry.
  - Unauthorized or coerced purchases on a resident's credit card.
  - Missing prescription medications.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Misappropriation of Resident Property/Exploitation

- Examples of items that aren't required to be reported include the theft of minor items with little to no monetary or sentimental value.
- CMS has spent most of their time so far talking about what types of alleged violations that facilities must report.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609

- Clarified what information to include in the initial and investigation reports.
  - This information is located as Exhibits in the SOM.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Key Changes for F609

- CMS is now going to move forward and discuss examples of information that is included in facility reports. There are two reports that facilities must submit for each alleged violation- an initial report and an investigation report. Samples of these reports are found as exhibits in the SOM.
- To recap, if the alleged violation involves abuse or serious bodily injury, it must be reported immediately, but no later than 2 hours. If the alleged violation involves neglect, misappropriation of resident property, or exploitation and involves no serious bodily injury, it must be reported no later than 24 hours.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Initial Reporting – Examples of Information

- In the initial report, facilities must provide sufficient information to describe the alleged violation and indicate how residents are being protected. It is important that this information is as complete as possible so that the SA can initiate actions necessary to oversee the protection of residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.12 Freedom From Abuse, Neglect, and Exploitation
Initial Reporting – Examples of Information

- Examples of information that should be reported which include, but are not limited to the following:
  - Basic facility information.
  - Allegation type.
  - When the facility became aware of the incident.
  - Information about the alleged victim and perpetrator.
  - Witnesses.
  - Details about the allegation, including outcomes to the alleged victim.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Initial Reporting – Examples of Information

- Notifications that were made to law enforcement or other agencies.
- Steps taken immediately to ensure resident(s) are protected.
- Who is submitting the report.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation Investigation Reporting – Examples of Information

- Similarly, for the investigation report, facilities must provide sufficient information to describe the results of the investigation, and indicate any corrective actions taken, if the allegation was verified. The report should include any updates to information provided in the initial report and provide the following additional information:
  - Any additional outcomes to the resident.
  - Whether the allegation was reported to the resident representative.
  - Whether the allegation was reported to another agency.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation Investigation Reporting – Examples of Information

- Steps taken to investigate the allegation. This may include a summary of interviews with the alleged victim, witnesses, the alleged perpetrator, other residents who have had contact with the alleged perpetrator, staff responsible for oversight of the location where the alleged victim residents, and staff responsible for oversight of the alleged perpetrator.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation Investigation Reporting – Examples of Information

- Information from the resident's record.
- Summary of other documents obtained, such as a police report, discharge summaries.
- Conclusion.
- Corrective action taken.
- Who investigated the incident.
- Who is submitting the report.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation Investigation Reporting – Examples of Information

- The facility must submit reports that are accurate, to the best of its knowledge at the time of submission of the report. It is important that facilities not make reports that are misleading, such as reports that deliberately omit facts, or reports that are designed to make the incident appear less serious than it was, or reports that misrepresent the facility's response. Deliberate misrepresentations or omissions could result in a deficiency at F609 or may give rise to other deficiencies. CMS understands that facilities may not have all of the information required at the time they submit the report, for example, results of a resident's medical exam or laboratory tests may still be pending at the time of initial reporting.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation Investigation Reporting – Examples of Information

- However, facilities must submit the information they have available at the time of reporting.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Revisions to the Critical Element Pathways for Abuse & Neglect

- Critical Element Pathway for Abuse – Form CMS-20059
- Critical Element Pathway for Neglect – Form CMS-20130

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.12 Freedom From Abuse, Neglect, and Exploitation

Revisions to the Critical Element Pathways for Abuse & Neglect

- To reflect the changes to the Interpretive Guidance, CMS has also made changes to the Critical Element Pathways for both abuse and neglect. Please refer to CMS-20059 for the CE pathway for Abuse and CMS-20130 for Neglect.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

§483.80 Infection Control

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F-Tags

- Regulatory Group: Infection Control
  - F880: Infection Prevention and Control
  - F881: Antibiotic Stewardship Program
  - F882: Infection Preventionist Qualifications/Role
  - F883: Influenza and Pneumococcal Immunizations
- Regulatory Group: Quality Assurance and Performance Improvement
  - F868: QAA Committee

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- Facilities must be able to demonstrate its measures to minimize the risk of Legionella and other opportunistic waterborne pathogen outbreaks in building water systems.
- An example of such is a documented water management program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- F-Tag 880 has added information related to water management.
- Facilities must be able to demonstrate its measures to minimize the risk of Legionella and other opportunistic waterborne pathogen outbreaks in building water systems.
- An example of such is a documented water management program.

Harmony Healthcare INTERNATIONAL

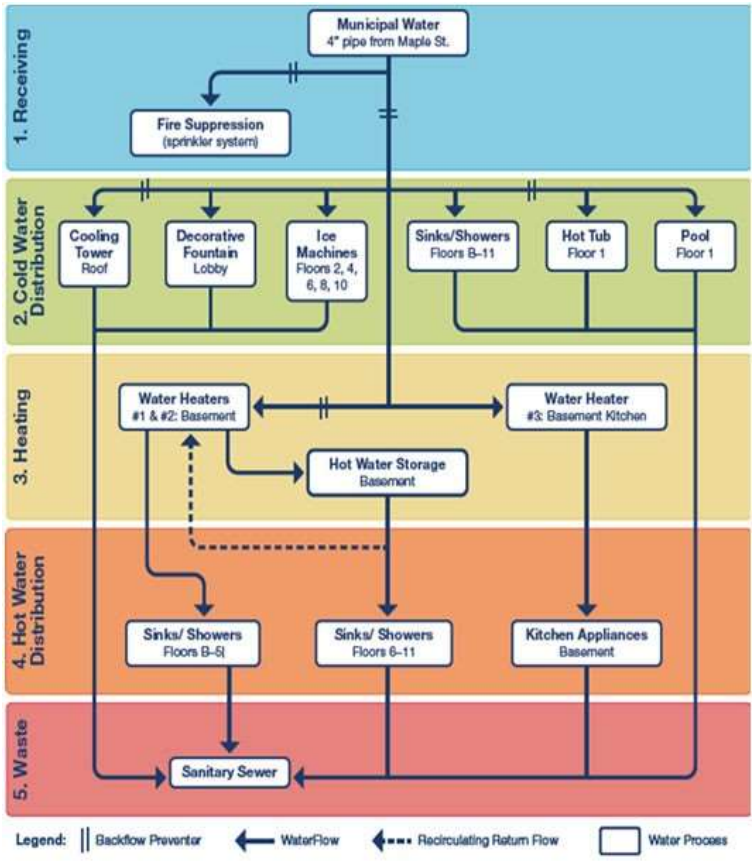
Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- A facility must use nationally accepted standards (e.g., ASHRAE, CDC, EPA) to minimize the risk of waterborne pathogens.
- A facility must use nationally accepted standards (for example, ASHRAE formerly the American Society of Heating, Refrigerating, and Air Conditioning Engineers, the Centers for Disease Control and Prevention or CDC, and/or the U.S. Environmental Protection Agency or EPA) to minimize the risk of waterborne pathogens.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- An assessment of the building water system to identify where opportunistic waterborne pathogens could grow and spread.



Harmony Healthcare INTERNATIONAL

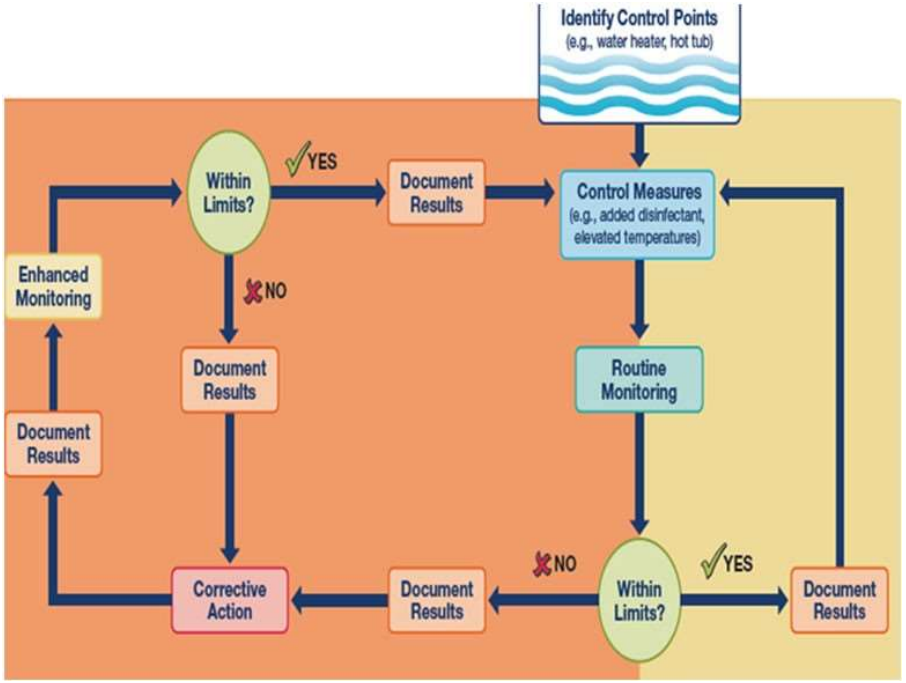
Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- Current standards recommend the following and surveyors should determine through interview (or record review as necessary) whether the facility has:
  - Assessed the building water system to identify where opportunistic waterborne pathogens could grow and spread. For example, facilities may have a description of the building water systems using text and flow diagrams.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- Measures to prevent the growth of opportunistic waterborne pathogens (also known as control measures) and how the facility will monitor them; and
- Established ways to intervene when control limits are not met.



Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- Whether the facility has measures in place to prevent the growth of opportunistic waterborne pathogens (also known as control measures) and how the facility will monitor them. For example, control measures can include visible inspections, use of disinfectant, and/or temperature control that may require mixing valves to prevent scalding. Monitoring may include testing protocols for control measures, acceptable ranges of control measures, and documenting results of testing.
- Additionally, the facility should have established ways to intervene when their control limits are not met.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- Interview and record review:
  - Were there any diagnosed cases of legionellosis in residents since the last recertification survey?
- If there was a case of legionellosis identified:
  - Did the facility implement adequate prevention and control measures prior to and once the issue was identified?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F880 – Water Management

- Through interview with the infection preventionist and record review, surveyors should determine whether the facility has:
  - Had a resident with legionellosis since the last recertification survey. Surveyors should determine what actions the facility took in response to the identified case in the facility.
- The State Survey Agency should work with local/state public health authorities, if possible, to determine if the water management was inadequate to prevent the growth of Legionella or other opportunistic waterborne pathogens and whether the facility implemented adequate prevention and control measures once the issue was identified.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F881 – Feedback to Practitioners

- Revised the requirement to provide feedback to prescribing practitioners.
- Updates with the Antibiotic Stewardship Program (or ASP) at Tag F881 starting with the language around feedback to prescribing practitioners.
- Requirements revised to provide feedback to prescribing practitioners regarding antibiotic resistance data, their antibiotic use and their compliance with facility antibiotic use protocols.
- While providing feedback to prescribing practitioners is recommended to improve prescribing practices and resident outcomes, it is no longer required as an element for compliance with F881.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F881 – ASP Sampling and Tag Clarification

- If there are concerns with the antibiotic stewardship program (ASP):
  - Assess whether resident(s) are being prescribed antibiotic(s) unnecessarily and whether there were any negative outcomes such as an adverse drug event.
    - MUST include at least one resident on an antibiotic in the sample.
  - If a resident has been prescribed antibiotics unnecessarily, cite F757.
  - If the facility does not have or is not implementing the ASP, cite F881.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F881 – ASP Sampling and Tag Clarification

- If there are concerns with the ASP, surveyors must include at least one resident on an antibiotic in the resident sample to assess whether the resident(s) is being prescribed an antibiotic(s) unnecessarily and whether there were any negative outcomes such as an adverse drug event.
- Instances of prescribing antibiotics unnecessarily should be cited at §483.45(d), which is F-Tag 757. These findings may support citing F881 as well, in which case the surveyor must also show that the facility is not implementing part or all of the ASP.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 Infection Preventionist (IP)

- The Infection Preventionist (IP) is responsible for assessing, developing, implementing, monitoring, and managing the IPCP.
- Regulatory language states that the IP is responsible for the infection prevention and control program, or IPCP.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 Infection Preventionist (IP)

- This includes assessing, developing, implementing, monitoring, and managing the IPCP. This does not mean that the IP cannot or should not collaborate with other staff.
- For example, under F881, CMS states that development of the antibiotic stewardship program should include leadership support and participation of the medical director, consulting pharmacist, and nursing and administrative leadership. While a well running IPCP is a team effort, the IP is responsible for making sure the program meets regulatory requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 Infection Preventionist (IP)

- Surveyors should determine that the facility designated one or more individual(s) as the infection preventionist, who are responsible for the facility's IPCP.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist Professional (IP) Training

- Professionally trained in:
  - Nursing
  - Medical Technology
  - Microbiology
  - Epidemiology
  - Other Related Field

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist Professional (IP) Training

- Requirements of the Position
  - The regulation states that the IP must be professionally-trained in nursing, medical technology, microbiology, epidemiology, or other related field. The facility must provide documentation of the IP's primary professional training.
  - A professionally-trained nurse must have earned a certificate/diploma or degree in nursing.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist Professional (IP) Training

- Requirements of the Position
  - If the facility employs a medical technologist as the IP, then the facility must provide evidence of an associate's degree (or higher) in medical technology or clinical laboratory science.
  - If the facility employs a microbiologist or epidemiologist as the IP, then the facility must provide evidence of a bachelor's degree (or higher) in microbiology or epidemiology since this is the entry-level degree for these fields.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist Professional (IP) Training

- Requirements of the Position
  - Examples of other related fields of training that are appropriate for the role of an IP include physicians, pharmacists, and physician's assistants, and the facility must show the IP's completion of this training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist (IP) Hours

- The IP must work at least part-time at the facility.
- In Section 483.80(b)(3), the language states that the IP must work at least part-time at the facility. There is not a specified number of hours the IP must work. The reason for this is the hours per week can vary greatly based on the facility and its resident population. Therefore, the amount of time required to fulfill the role should be determined by the facility assessment, conducted according to section §483.70(e), to determine the staff hours it needs for its IPCP.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist (IP) Hours

- As part of this, a nursing home should consider resident census as well as resident characteristics and the complexity of the healthcare services it offers in determining the amount of IP hours needed The IP must have the time necessary to properly assess, develop, implement, monitor, and manage the IPCP for the facility; address training requirements, and participate on the QAA committee.
- The surveyor should perform interviews to determine if the IP has adequate time to perform the role.
- The second part of the requirement states that the IP must work “at the facility.”

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist (IP) Hours

- This does mean that the IP must physically work onsite at the facility, and not at a separate location such as a corporate office. If you think about it, it is hard to manage an IPCP to include infection control practices such as hand hygiene, environmental cleaning and disinfection, and implementation of transmission-based precautions if you are not on-site. Therefore, surveyors should interview the IP and other facility staff to determine where work is performed.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
F882 – Infection Preventionist (IP) Specialized Training

- The IP must have completed specialized training in infection prevention and control.
- The specialized training in infection prevention and control must be beyond the initial professional training or education previously mentioned. Infection prevention and control training must be sufficient to perform the role of the IP, and the facility must provide evidence of completion of the specialized training to the surveyor. For example, this may include a certificate of training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
IP Participation on the QAA Committee

- §483.80 (c) IP participation on quality assessment and assurance committee.
  - The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.
  - Cite at F868.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
IP Participation on the QAA Committee

- IP must be a participant on the facility's QAA committee and report on the IPCP and on incidents, for example, healthcare-associated infections, identified under the program. Reporting may include, but is not limited to, facility process and outcome surveillance, occupational communicable diseases (for example, influenza), and
- The antibiotic stewardship program related to antibiotic use and resistance data. In order to be considered an active participant, the IP should attend each QAA meeting. If the IP cannot attend, another staff member should report on his/her behalf.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
IP Participation on the QAA Committee

- The IP's participation on the QAA committee is reviewed for each recertification survey under the QAA and QAPI Plan pathway. If the surveyor finds a deficiency, then the surveyor would cite at tag F868. Since IP participation was mentioned under the regulatory language at both section 483.80(c) and section 483.75(g), CMS chose F868 as the logical place to include reviewing and citing for this requirement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
Immunization Update

- Removed the outdated language related to the Advisory Committee on Immunization Practices (ACIP) recommendations for the 13-valent pneumococcal conjugate vaccine (PCV13) in those ≥65 years.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
Immunization Update

- Revised Language under F-Tag F883
  - On November 22, 2019, the Advisory Committee on Immunization Practices or ACIP released updated recommendations on the use of 13-valent pneumococcal conjugate vaccine (or PCV13) among adults aged greater than or equal to 65 years. ACIP states that PCV13 vaccination is no longer routinely recommended for all adults aged greater than or equal to 65 years. Instead, shared clinical decision-making for PCV13 use is recommended for these individuals who do not have an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant and who have not previously received PCV13.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.80 Infection Control
Immunization Update

- Revised Language under F-Tag F883
  - Facilities must follow the ACIP recommendations for vaccines.
  - Surveyors should review residents' medical records for pneumococcal immunization status per ACIP recommendations and remain vigilant on ACIP updates to recommendations.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

§483.45 Pharmacy Services

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services

- For the Pharmacy Services regulatory section, CMS has made small but significant changes to guidance at F755 Pharmacy Services, F757 Unnecessary Medications and F758 Unnecessary Psychotropic Medications and PRN Use.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services

- There were no new Phase 3 regulations for these tags but changes to guidance were made for clarification and in response to questions from nursing home stakeholders. Language was changed regarding disposal of used fentanyl patches and antibiotic stewardship requirements. For F758 guidance, new language has been added regarding other classes of medications not specifically listed in the psychotropic medication regulation. CMS also added language related to potential misdiagnosing of residents with a condition for which antipsychotics are an approved use such as schizophrenia. The new diagnosis then excludes the resident from the long-stay anti-psychotic quality measure.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Changes to Pharmacy Services F755

- Revised guidance on disposal of used Fentanyl patches.
  - The Food and Drug Administration instructions to fold used patch and flush down toilet are not always appropriate for nursing homes.
  - The Environmental Protection Agency does not currently ban flushing of pharmaceuticals (unless considered hazardous—Fentanyl patches are not classified as hazardous), but state and local laws may restrict flushing of pharmaceuticals.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Changes to Pharmacy Services F755

- Nursing homes may use drug disposal systems if they can show the system minimizes accidental exposure and diversion.
- Disposal of fentanyl patches in common areas or resident room trash cans or sharps containers would not be compliant as these methods do not prevent accidental exposure or diversion.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Changes to Pharmacy Services F755

- CMS revised the guidance on disposal of used Fentanyl patches. CMS explained how the Food and Drug Administration instructions to fold the used patch and flush down the toilet are not always appropriate for nursing homes. CMS also explains that the Environmental Protection Agency does not currently ban flushing of pharmaceuticals unless they are considered hazardous—Fentanyl patches are not classified as hazardous. However, state and local laws may restrict flushing of pharmaceuticals. The guidance states that nursing homes may use drug disposal systems for fentanyl patches if they can show that the system minimizes accidental exposure and diversion.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Changes to Pharmacy Services F755

- The guidance states that disposal of fentanyl patches in common areas or resident room trash cans or sharps containers would not be compliant as these methods do not prevent accidental exposure or diversion.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to Pharmacy Services F757 and F758

- Key Elements of Non-compliance for F757 and F758 – new guidance directs surveyors to consider F881 if unnecessary antibiotic use also indicates that a facility is not implementing part or all of the antibiotic stewardship program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to Pharmacy Services F757 and F758

- In the Key Elements of Non-compliance section of the guidance for F757and F758, a “Note” has been added. The note directs the survey team to consider whether a facility is compliant with F881, the tag for the Antibiotic Stewardship Program, if the team has found evidence of unnecessary antibiotic use. The unnecessary antibiotic use could indicate that a facility is not implementing part or all of an antibiotic stewardship program, which entails using protocols that utilize an infection assessment tool, monitoring of antibiotic use, or feedback and education to prescribing providers.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to F758

- F758 Unnecessary Psychotropic/PRN Use
  - In November 2017, the regulations and guidance expanded the category of antipsychotic medications to psychotropic medications (antipsychotics, anti-depressants, anti-anxiety drugs, hypnotics) to address the concern that use of other psychotropic medications may increase as nursing homes attempt to decrease antipsychotic use.
  - Guidance also describes other medications which affect brain activity – may be clinically indicated but can also have adverse consequences.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to F758

- F758 Unnecessary Psychotropic/PRN Use
  - The use of these “other medications” is subject to the psychotropic medication requirements if documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication.
  - For example, a seizure medication is being given to a resident with no history of seizures, but the medical record shows the medication is given to treat agitation. The use of the seizure medication should be consistent with the psychotropic medication requirements under §483.45(e).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to F758

- F758 Unnecessary Psychotropic/PRN Use
  - The Phase 2 regulations and guidance released in November of 2017 expanded the category of antipsychotic medications to the new category of psychotropic medications. The regulation defines a psychotropic medication as any drug that affects brain activities associated with mental processes and behavior. This new category includes medications in the categories of anti-psychotics, anti-depressants, anti-anxiety medications, and hypnotics.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to F758

- F758 Unnecessary Psychotropic/PRN Use
  - This change was made out of concern that use of psychotropic medications other than anti-psychotics could increase as nursing homes attempt to decrease use of antipsychotic medications through efforts such as the National Partnership to Improve Dementia Care.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to F758

- F758 Unnecessary Psychotropic/PRN Use
  - The guidance also described other medications which affect brain activity. These medications may be clinically indicated but can also have adverse consequences. New guidance explains that these "other" medications are subject to the psychotropic medication requirements if documented use appears to be a substitution for another psychotropic medication rather than for the approved or original indication.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Key Changes to F758

- F758 Unnecessary Psychotropic/PRN Use
  - An example could be a seizure medication which is being given to a resident with no history of seizures. However, the medical record shows the medication is prescribed and given to treat symptoms of agitation. In this case, the use of the seizure medication should be consistent with the psychotropic medication.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- Language was added to the gradual dose reduction section:
  - *Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence. Compliance with the requirement to perform a GDR may be met if, for example, within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, a facility attempts a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated.*
- Resources for gradual dose reduction information were added.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- CMS also added language related to the gradual dose reduction guidance in F758. CMS added language to further describe gradual dose reductions which states that:
  - *Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence.*
  - Resources were also added to provide information on gradual dose reductions.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- Added language about the potential misdiagnosis of residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which excludes the resident from the long-stay antipsychotic quality measure.
- For this potential misdiagnosis issue, surveyors should consider investigating:
  - §483.21(b)(3)(i), F658, to determine if the practitioner's diagnosing practices meet professional standards.
  - §483.20(g), F641 to determine if the facility completed an assessment which accurately reflects the resident's status.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- CMS added language to address situations CMS has identified where residents are potentially misdiagnosed with a condition for which antipsychotics are an approved use, such as a new diagnosis of schizophrenia. This diagnosis excludes the resident from the long-stay antipsychotic quality measure.
- When investigating a potential misdiagnosis, surveyors should consider section 483.21(b)(3)(i), F658 to determine if the practitioner's diagnosing practices meet professional standards and section 483.20(g), F641 to determine if the facility completed an assessment which accurately reflects the resident's status. Language was also added to the guidance for F658 and F641 to align with the changes in F758.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- Added language to direct surveyors to evaluate if a resident experienced psychosocial harm related to side effects of medications.
- Did side effects such as sedation, lethargy, agitation, mental status changes, or behavior changes:
  - affect a resident's abilities to perform activities of daily living or interact with others,
  - cause the resident to withdraw or decline from usual social patterns,
  - show the resident has decreased engagement in activities, and/or
  - cause diminished ability to think or concentrate.
- Updated the deficiency categorization section.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- CMS added language to the section on investigating concerns and the side effects table which directs surveyors to evaluate if a resident has experienced psychosocial harm related to side effects of medications. Surveyors should look at whether side effects such as sedation, lethargy, agitation, mental status changes, or behavior changes affected:
  - the resident's abilities to perform activities of daily living or to interact with others;
  - cause the resident to withdraw or decline from usual social patterns;
  - show the resident has decreased engagement in activities; and/or
  - cause diminished ability to think or concentrate.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.45 Pharmacy Services
Additional Changes to Pharmacy Services F758

- CMS updated the deficiency categorization section to ensure the examples show the appropriate severity level.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

§483.90 Physical Environment
Phase 3 Regulatory Updates

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.90 Physical Environment
483.90(g) (1)-(2) Resident Call System

- The facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from:
  - *§483.90(g)(1) Each resident's bedside; and*
  - *§483.90(g)(2) Toilet and bathing facilities.*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.90 Physical Environment
483.90(g) (1)-(2) Resident Call System

- The phase 3 requirements added that the communication system relays the call directly to a staff member or to a centralized staff work area from each resident's bedside; and from the toilet and bathing facilities.
- This communication system can be a wireless system to call staff members directly.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.90 Physical Environment
483.90(g) (1)-(2) Resident Call System

- The system must be accessible to residents:
  - While in their bed or
  - Other sleeping accommodations within the resident's room.
- The system must be accessible at each:
  - Toilet, Bath, Shower
    - The system should be accessible to residents lying on the floor.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.90 Physical Environment
483.90(g) (1)-(2) Resident Call System

- The call system must be accessible to residents while in their bed or other sleeping accommodations within the resident's room.
- In addition, the call system must be accessible to the resident at each toilet, bath or shower and should be accessible to a resident lying on the floor.
- Residents and their representatives should be interviewed about whether calls are being answered. For instance, "Do you have access to your call light at all times while in your room, bathroom or shower?"

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.90 Physical Environment
483.90(g) (1)-(2) Resident Call System

- Probing questions could include – Has the call system been in need of repair recently.
- If yes, ask: What did the facility do if the call system was not working?: Were any needed repairs made timely?
- Does the facility have a process to routinely ensure the call system for residents is operational?
- During a loss of power will the resident call system be operational or is an alternate means of communicating with the staff put into place?

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.30 Physician Services

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.30 Physician Services
F712 Physician Visits – Frequency/Timeliness/Alternate NPPS

- Column 1 was divided into two columns and orders added to column three.

Table 1: Authority for Non-Physician Practitioners to Perform Visits, Sign Orders and Sign Medicare Part A Certification/Re-Certifications When Permitted by the State

	Initial Comprehensive Visit	Admission Orders	Other Required Visits & Orders	Other Medically Necessary Visits & Orders	Certification/ Recertification
SNFs: PA, NP & CNS employed by the facility	May not perform	May not provide	May perform alternate visits and sign	May perform and sign	May not sign
SNFs: PA, NP & CNS not a facility employee	May not perform	May not provide	May perform alternate visits and sign	May perform and sign	May sign as permitted under State Laws
NFs: PA, NP & CNS employed by the facility	May not perform	May not provide	May not perform or sign	May perform and sign	Not Applicable
NFs: PA, NP & CNS not a facility employee	May perform	May provide*	May perform and sign	May perform and sign	Not Applicable

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.30 Physician Services
F712 Physician Visits – Frequency/Timeliness/Alternate NPPS

- The Table in F712, depicting the Authority for non-physician practitioners to perform visits, sign orders and sign Medicare Part A Certifications and Re-certifications, has been updated. Column 2, which previously contained the Initial Comprehensive Visit and Admission Orders, has been split into two separate columns. The permissions in these columns have not changed, the columns were just divided for ease of use.
- In Column 4, Other required visits. signing orders has been added to each of the rows, for clarity.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.30 Physician Services
F712 Physician Visits – Frequency/Timeliness/Alternate NPPS

- In Column 6, “as permitted by State Laws” was added, to indicate that a non- physician practitioner may sign the Medicare Part A Certifications and re-certifications in accordance with State Laws.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.30 Physician Services
F712 Physician Visits – Frequency/Timeliness/Alternate NPPS

- Updated the existing example of Level 2 non-compliance.
- "The facility failed to ensure the physician personally conducted an initial comprehensive visit within the first 30 days after admission, for a resident under a Medicare Part A stay."
- In F712, CMS added "personally" to the existing Level 2 example. In the Skilled nursing facility setting the physician is required to personally conduct the initial visit and cannot delegate the task to a non-physician practitioner. In contrast, the physician is permitted to delegate the initial visit to a non-physician practitioner in the Nursing Facility.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

September 13, 2022

Psychosocial Outcome Severity Guide
and
Citations at F600-Abuse

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Psychosocial Outcome Severity Guide & Citations at F600-Abuse Key Changes

- Psychosocial Outcome Severity Guide
  - Appendix PP, Tag F600-Deficiency Categorization.
  - During this training, CMS will be reviewing revisions made to the Psychosocial Outcome Severity Guide. The Guide shows surveyors how to consider the psychosocial outcome to a resident, as a result of a facility's noncompliance. In addition, this training reviews how to apply the principles described in the Psychosocial Outcome Severity Guide to cases of abuse at Tag F600 in Appendix PP.

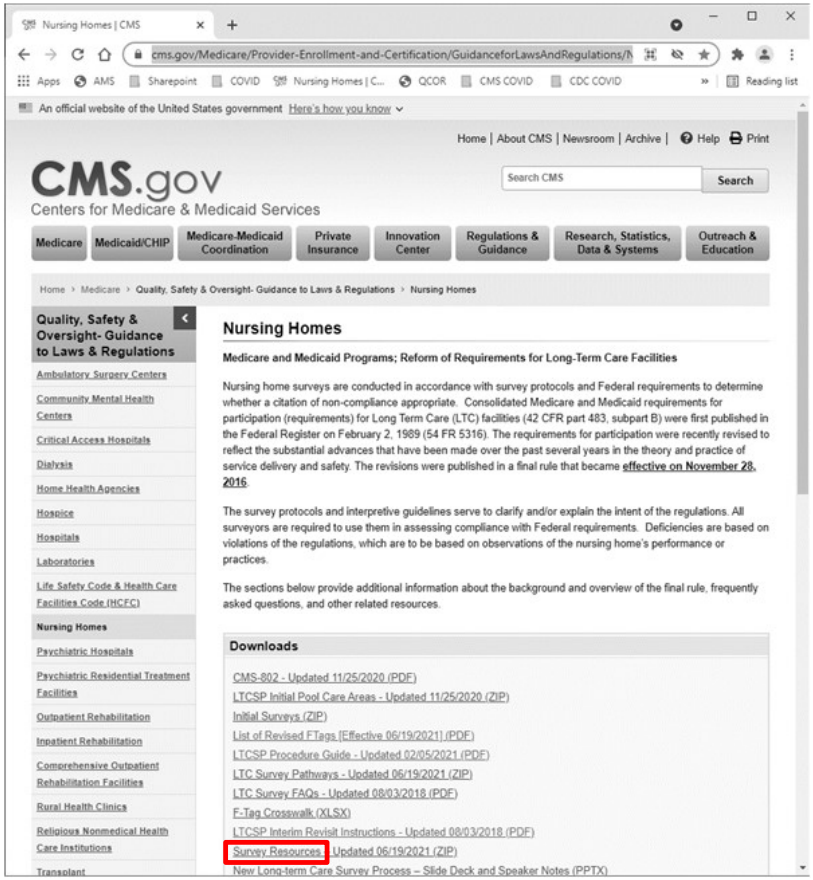
Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Where to Find the Psychosocial Outcome Severity Guide

- File location: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes under Survey Resource.



Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Where to Find the Psychosocial Outcome Severity Guide

- The Guide is not a part of Appendix PP of the State Operations Manual; however, it is found in the Nursing Home Survey Resources folder on CMS' website.

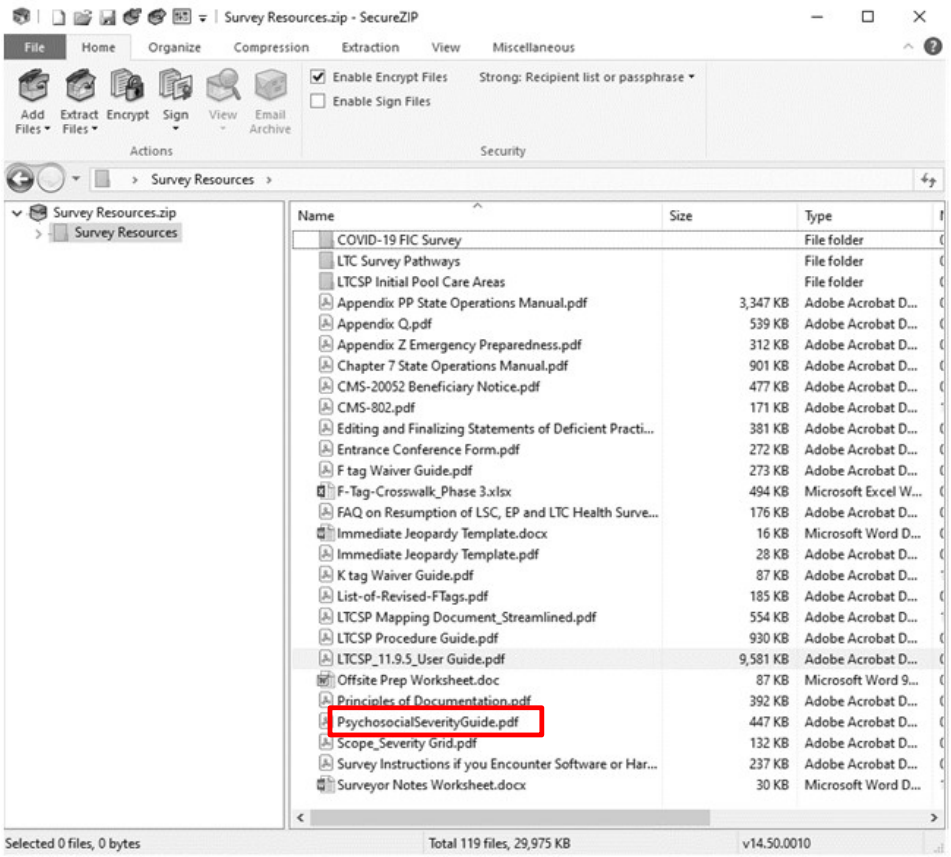
Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Where to Find the Psychosocial Outcome Severity Guide

- Open the folder, the red box indicates where to find the Guide.



February 27, 2023

Harmony Healthcare INTERNATIONAL

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Psychosocial Outcome Severity Guide - Purpose

- The Psychosocial Outcome Severity Guide
  - Guides surveyors determine the severity of psychosocial outcomes resulting from identified noncompliance at a specific F-Tag.
  - Is used in conjunction with the scope and severity grid to determine the severity of outcomes to each resident.
  - Applies to any regulatory grouping (e.g., Quality of Life, Quality of Care) that resulted in, or may result in, a negative psychosocial outcome.
  - Describes how to apply the reasonable person concept, such as when the impact on the resident may not be apparent or documented.

Harmony Healthcare INTERNATIONAL

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Psychosocial Outcome Severity Guide - Purpose

- The Psychosocial Outcome Severity Guide
  - CMS wants to emphasize that surveyors must determine whether noncompliance exists first, before determining the severity level of a deficiency.
  - This guide is not intended to replace the current scope and severity grid.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse New Definitions

- “Fear ” is defined as an unpleasant often strong emotion caused by anticipation or awareness of danger.
- “Psychosocial” refers to the combined influence of psychological factors and the surrounding social environment on physical, emotional, and/or mental wellness.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse New Definitions

- The “reasonable person concept” refers to a tool to assist the survey team’s assessment of the severity level of negative, or potentially negative, psychosocial outcome that a deficiency may have had on a reasonable person in the resident’s position.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Investigating Psychosocial Outcomes

Severity of Psychosocial Outcome		
Interviews	Observation	Record Review

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Investigating Psychosocial Outcomes

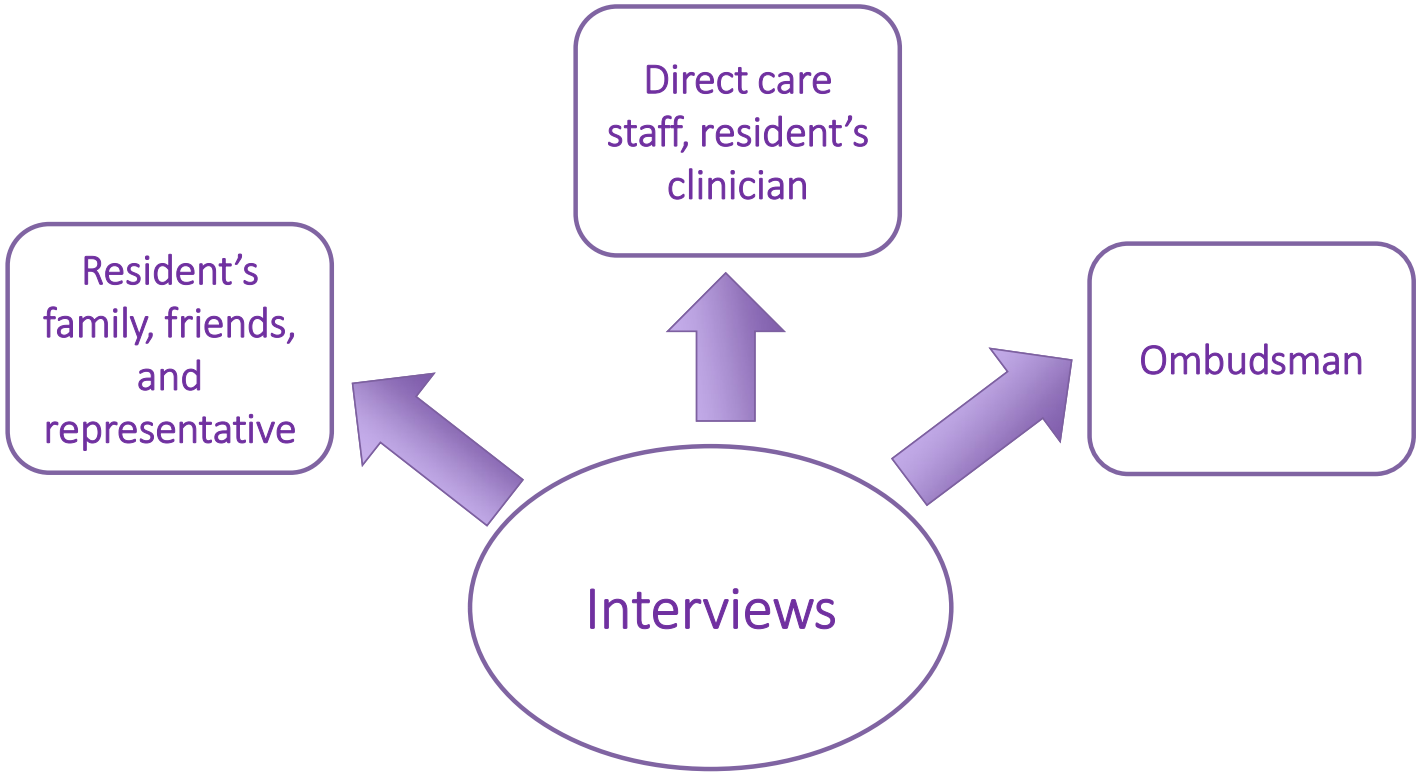
- In the revised Psychosocial Outcome Severity Guide, CMS also provides information to surveyors about how to investigate psychosocial outcomes to the resident. Surveyors should obtain evidence through observation, interview and record review of the impacted resident. The team should interview the resident and collect information regarding the resident's verbal and non-verbal responses. If a psychosocial outcome is identified, compare the resident's behavior and mood before and after the noncompliance, and any identified history of similar incidents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Investigating Psychosocial Outcomes



Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Investigating Psychosocial Outcomes

- When a surveyor cannot conduct an interview with the resident for any reason, or there are no apparent or documented changes to behavior, the surveyor should attempt to interview other individuals who are familiar with the resident's routine or lifestyle, such as the resident's representative or family, direct care staff, resident's clinician, or the ombudsman.
- If no such changes are apparent or documented, the surveyor should consider the response a reasonable person would exhibit in light of the triggering event.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

When Should the Surveyor Use the Reasonable Person Concept?

- There are no apparent or documented changes to the resident's behavior.
- When a resident may not be able to express their feelings, there is no discernable response, or when circumstances may not permit the direct evaluation of the resident's psychosocial outcome.
- When a resident's reaction is markedly different with the level of reaction a reasonable person in the resident's position would have to the deficient practice.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse
When Should the Surveyor Use the Reasonable Person Concept?

- Let's review when the surveyor should use the reasonable person concept. There are three examples described in the Guide:
  - The reasonable person concept may be used when there are no apparent or documented changes to the resident's behavior.
  - It may also be used when a resident may not be able to express their feelings, there is no discernable response, or when circumstances may not permit the direct evaluation of the resident's psychosocial outcome.
  - Lastly, it may be used when a resident's reaction is markedly different with the level of reaction that a reasonable person in the resident's position would have to the deficient practice.

Harmony Healthcare INTERNATIONAL

Psychosocial Outcome Severity Guide & Citations at F600-Abuse
Application of the Reasonable Person Concept

- Considerations regarding the resident's position:
  - The resident may consider the facility to be his/her "home," where there is an expectation that he/she is safe, has privacy, and will be treated with respect and dignity.
  - The resident trusts and relies on facility staff to meet his/her needs.
  - The resident may be frail and vulnerable.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse
Application of the Reasonable Person Concept

- The surveyor should document the resident's actual response and the perspectives of someone familiar with the resident.
- In addition, the surveyor should apply the reasonable person concept, which may reveal that the resident is likely to, or may potentially, suffer a greater psychosocial harm.
- The survey team should document on the CMS-2567 when it applies the reasonable person concept in determining the psychosocial outcome(s) for a deficiency.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse
Application of the Reasonable Person Concept

- The surveyor should document evidence that describes the resident's actual response and the perspectives of someone familiar with the resident. In addition, the surveyor should apply the reasonable person concept, which may reveal that the resident is likely to, or may potentially, suffer a greater psychosocial harm.
- The survey team should document on the CMS-2567 when it applies the reasonable person concept in determining the psychosocial outcome for a deficiency.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Examples of Severity Level 4 – Immediate Jeopardy

- CMS also revised examples of psychosocial outcomes under each severity level. This training will describe only a few of these revisions.
- Under Immediate Jeopardy, psychosocial outcomes under this category include, but are not limited to, the following examples:
  - Anger, agitation, or distress that has caused aggression that can be manifested by self-directed responses.
  - Crying, moaning, screaming, or combative behavior that is above the resident's baseline.
  - Fear/anxiety that may be manifested as panic, immobilization, and/or agitated behavior(s) (e.g., trembling, cowering).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Examples of Severity Level 3 – Actual Harm

- Decline from former social patterns that does not rise to a level of immediate jeopardy.
- Depressed mood that may be manifested by verbal and nonverbal symptoms, such as a change in psychomotor retardation (e.g., slowed speech, thinking, and body movements; increased pauses before answering) unrelated to medical diagnosis.

Harmony Healthcare INTERNATIONAL

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Examples of Severity Level 2 – No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

- Sadness, as reflected in facial expression and/or demeanor, or verbal/vocal disappointment.
- Feelings and/or complaints of discomfort or irritability.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Examples of Severity Level 1: No Actual Harm with Potential for Minimal Harm

- Level 1 is not an option because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. Therefore, the deficiency is at least a Severity Level 2 because it has the potential for more than minimal harm.

Harmony Healthcare INTERNATIONAL

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Psychosocial Outcome and Abuse

- Determining the severity of psychosocial outcomes for abuse can present unique challenges to surveyors.
  - It is important for the surveyor to gather and document any information that identifies any psychosocial outcomes resulting from the noncompliance.
  - For abuse, surveyors should also consider that the psychosocial outcome of abuse may not be apparent at the time of the survey.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Psychosocial Outcome and Abuse

- CMS wanted to take some time to discuss how to apply the Psychosocial Outcomes Severity Guide to citations at F600 for abuse. CMS recognizes that determining the psychosocial outcomes for abuse can present unique challenges to surveyors. Oftentimes, the psychosocial outcome of abuse may not be apparent at the time of the survey, since it may take months or years to manifest itself and can have long- term effects on the resident and his/her relationship with others.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Psychosocial Outcome and Abuse

- Some residents are unable to express themselves or may not be able to recall what had occurred. However, when a nursing home resident is treated in any manner that does not uphold a resident's sense of self-worth and individuality, it dehumanizes the resident and creates an environment that perpetuates a disrespectful and/or potentially abusive situation for the resident(s).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Applying the Psychosocial Outcome Severity Guide to Tag F600-Abuse

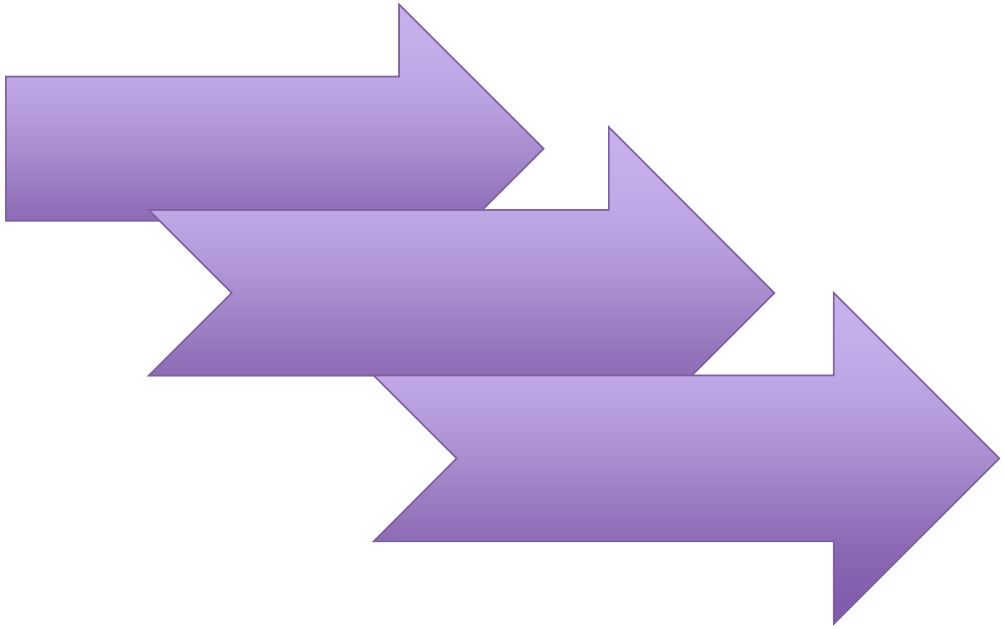
- As described earlier, the below chart that shows how to apply the psychosocial outcome severity guide. As with any other concern, the surveyor must investigate and collect evidence through observation, interview, and record review. Next, the surveyor determines whether the facility is in compliance with Tag F600. If F600 is cited, then the surveyor documents any identified physical and/or psychosocial outcomes to the resident. In addition to the evidence gathered, the surveyor should apply the reasonable person concept, which may reveal that the resident is likely to, or may potentially, suffer a greater psychosocial outcome.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Applying the Psychosocial Outcome Severity Guide to Tag F600-Abuse



Document identified physical/ psychosocial outcomes to the resident

Reasonable Person Concept

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse

Applying the Reasonable Person Concept to Tag F600-Abuse

- In some cases of abuse at F600, there may be instances where there are no:
  - Observed or documented negative psychosocial outcome, or
  - Description of resident impact from the resident's representative or others who know the resident.
- In these situations, Immediate Jeopardy or Actual Harm can be supported through the application of the Reasonable Person Concept.
- In the following slides, CMS provides examples of these types of cases.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Examples of Situations Likely to Cause Immediate Jeopardy

- Examples of abuse that create the likelihood for serious psychosocial harm, or immediate jeopardy to a resident include, but are not limited to:
  - Sexual assault (e.g., rape).
  - Unwanted sexual touching.
  - Sexual harassment.
  - Any staff to resident physical, sexual, or mental/verbal abuse.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Examples of Situations Likely to Cause Immediate Jeopardy

- Examples:
  - Staff posting or sharing demeaning or humiliating photographs or videos of residents.
  - When staff, as punishment, threaten to take away the resident's rights, privileges, or preferred activities, or withhold care.
  - Any resident-to-resident physical abuse that is likely to result in fear or anxiety.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Actual Harm or Above

- In addition, a reasonable person would not expect that they would be harmed in his/her own “home” or a health care facility and would experience a negative psychosocial outcome.
- When investigating incidents in which one resident abuses another resident, surveyors should consider if a reasonable person would likely suffer actual harm as a result of the incident. If so, the incident should not be cited below Severity Level 3 (Actual Harm).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Tag F600-Severity Examples

- See the Interpretive Guidance for further examples.
- Surveyors should review further examples under each severity level in the Interpretive Guidance at F600. These examples further illustrate how to consider the psychosocial outcomes to a resident as a result of abuse and how to apply the reasonable person concept.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Additional Areas

- While the Psychosocial Outcomes Severity Guide does apply to abuse, there are other regulatory areas where surveyors may identify psychosocial outcomes. Some of these areas are listed here, including Quality of Care.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Psychosocial Outcome Severity Guide & Citations at F600-Abuse Additional Areas

- Resident Rights
- Freedom from Abuse, Neglect, and Exploitation
- Comprehensive Resident Centered Care Plans
- Quality of Life
- Quality of Care
- Behavioral Health Services
- Pharmacy Services

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

September 13, 2022

§483.75 Quality Assurance and Performance Improvement

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
Overview of Phase 3 Requirements

- This training will provide an overview of the Quality Assurance and Performance Improvement, also known as QAPI, requirements which went into effect in November 2019.
  - New requirements in F865 for the QAPI plan and program.
  - The relocation of the requirements in F866,New requirements for the QAPI program, including feedback, data collection, analysis, monitoring, and improvement activities.
  - The expansion of Quality Assessment and Assurance (QAA) Committee required members.
  - The new QAPI training requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
Overview of Phase 3 Requirements

- New requirements in F865 for the Quality Assurance and Performance Improvement (QAPI) plan and program.
- Requirements in F866 have been relocated.
- 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.
- New QAPI training requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(a) Quality assurance and performance improvement (QAPI) program. Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must:
  - §483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(a)(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and
- §483.75(a)(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- A quality assurance and performance improvement (QAPI) program takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and improving safety and quality. An interdisciplinary approach encompasses all managerial, and clinical, services, which includes care and services provided by outside (contracted or arranged) providers and suppliers.
- Phase 3 Requirements for 483.75(a) in F865 lay out the requirements of the facility's QAPI program.
- Each facility must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- Each facility must also maintain documentation and provide evidence of its ongoing QAPI program.
- Demonstration of compliance includes, but is not limited to:
  - Evidence of systems and reports demonstrating identification, reporting, investigation, analysis and prevention of adverse events;
  - Data collection and analysis at regular intervals; and
  - Documentation demonstrating development, implementation and evaluation of corrective actions or performance improvement activities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- Additionally, each facility must present its QAPI plan to State and Federal surveyors at each annual recertification survey and upon request during any other survey, and to CMS upon request.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(b) Program design and scope.
  - A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:
    - §483.75(b)(1) Address all systems of care and management practices.
    - §483.75(b)(2) Include clinical care, quality of life, and resident choice.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(b) Program design and scope (continued).
  - §483.75(b)(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.
  - §483.75(b) (4) Reflect the complexities, unique care, and services that the facility provides.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- Phase 3 requirements also specify that Each facility must design a QAPI program that is ongoing, comprehensive and capable of addressing the full range of care and services it provides.
- At a minimum, the program must:
  - Address all systems of care and management practices;
  - Include clinical care, quality of life and resident choice;
  - Utilize the best available evidence to define measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents; and

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- At a minimum, the program must (continued):
  - Reflect the complexities, unique care and services that the facility provides.
- Effective QAPI programs address systems of care and management practices. Systems of care (or care delivery systems) are the processes in place to achieve an expected clinical outcome. Facilities may have many systems of care which intersect and involve multiple disciplines and departments. For example, the system for prevention of pressure ulcers also involves the system for ensuring adequate nutrition, as well as the systems for identification of changes in condition and infection prevention.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- At a minimum, the program must (continued):
- In addition to systems of care, the facility should monitor important management practices such as resident finances and personal funds, admission and discharge practices, and other services that impact quality of life and resident rights. The QAPI program should address quality of life and resident choice by identifying the unique needs and preferences of the varying demographics of residents residing in the facility (i.e., young and/or culturally diverse residents) and seeking ongoing input and feedback from their residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(f) Governance and leadership.
  - The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that:
    - §483.75(f)(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.
    - §483.75(f)(2) The QAPI program is sustained during transitions in leadership and staffing.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(f) Governance and leadership.
  - §483.75(f)(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed.
  - §483.75(f)(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to residents based on performance indicator data, and resident and staff input, and other information.
  - §483.75(f)(5) Corrective actions address gaps in systems and are evaluated for effectiveness.
  - §483.75(f)(6) Clear expectations are set around safety, quality, rights, choice, and respect.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- The governance and leadership requirements are also part of Phase 3.
- The governing body and/or executive leadership (or organized group or an individual who full legal authority and responsibility for operation of the facility) must ensure the QAPI Program:
  - Is defined, implemented and ongoing;
  - Addresses identified priorities;
  - Is sustained through transitions in leadership and staffing;
  - Has adequate resources, including staff time, equipment, and technical training as needed;

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement
F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- QAPI Program (continued):
  - Uses performance indicator data, resident and staff input, and other information to identify and prioritize problems and opportunities;
  - Implements corrective actions to address gaps in systems and evaluates actions for effectiveness; and
  - Establishes clear expectations around safety, quality, rights, choice and respect.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement Investigation and Key Elements for F865

- Surveyors will use the facility task QAPI and QAA Review when determining if the facility meets the requirements for, or investigating concerns related to requirements in F865.
- The Key Elements of Non-Compliance have been updated to include the new requirements discussed.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
Key Elements of Non-Compliance

- The facility failed to do any one of the following:
  - Maintain documentation and evidence of its ongoing QAPI program.
  - Present its QAPI plan to the Federal and/or State surveyors during recertification survey or upon request.
  - Present QAPI evidence necessary to demonstrate compliance with these requirements.
  - Develop, implement and maintain an effective, comprehensive QAPI program, that addresses the full range of services the facility provides.
  - Ensure governing body oversight of the facility's QAPI program and activities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F866 QAPI/QAA Data Collection & Monitoring

- F866
  - Note: Regulatory requirements §483.75(c) and §483.75(c)(1)-(4) have been relocated to F867.
- You may be wondering what happened to F866 the QAPI/QAA Data Collection and Monitoring tag. In the course of writing the Phase 3 guidance, CMS found that the components of F866 and F867 were similar and intertwined, so CMS combined the requirements into one tag. Therefore, the requirements from F866 were relocated into F867.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(c) Program feedback, data systems and monitoring. A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:
  - §483.75(c)(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(c)(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at §483.70(e) and including how such information will be used to develop and monitor performance indicators.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F866 QAPI/QAA Data Collection & Monitoring

- With the exception of the requirements for the QAA Committee to develop and implement plans of action to correct identified quality deficiencies, most of the requirements in F867 are Phase 3 requirements that became effective in November 2019.
- As required in §483.75(a) (F865), the facility must develop and implement written policies and procedures that ensure the care and services it delivers meet acceptable standards of quality in accordance with recognized standards of practice. This is accomplished, in part, by identifying, collecting, analyzing and monitoring data which reflects the functions of each department and outcomes to residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Feedback is one of many data sources which provide valuable information the facility must incorporate into an effective QAPI program. Each facility must establish and implement written policies and procedures for feedback.
- Feedback must be obtained from direct care staff, other staff, residents and resident representatives, as well as other sources, and be used to identify problems that are high- risk, high-volume, and/or problem-prone, as well as opportunities for improvement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Feedback from residents is necessary to understand what quality concerns are important to them, their perspectives, values and priorities, as well as the impact of the facility's daily routines on their physical, mental, and psychosocial well-being. Staff can also provide valuable input into understanding care and service delivery processes.
- A facility should choose the best mechanism for feedback to support their QAPI program. Examples of ways a facility can obtain resident and staff feedback may include, but are not limited to:

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- satisfaction surveys and questionnaires;
- routine meetings, such as care plan, resident council, safety team, or town hall meetings; and
- suggestion or comment boxes.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Effective feedback systems in a QAPI program also include methods for providing feedback to direct care staff, other staff, residents and representatives. This may involve including these individuals in problem solving, various meetings or providing updates and communicating facility system changes.
- In order to ensure care and services are carried out consistently, accurately, timely and according to recognized standards of quality, the facility must collect and monitor data reflecting its performance, including adverse events.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Facility policies and procedures must address how data will be identified, and the frequency and methodology for collecting and using data from all departments. The facility determines what data it will collect to represent its care areas considered to be associated with high-risk, high-volume, and/or problem-prone issues.
- Data collection can be done using several methods, such as audit tools (purchased or developed by the facility), direct observation, interview, or testing. Sources for data may include the Minimum Data Set (MDS) and Quality Measures, medical records, survey results, incident reports, complaints, suggestions and staffing data.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- CMS expects the data collection methodology to be consistent, reproducible and accurate to produce data that are valid, reliable, and support all departments and the facility assessment required in §483.70(e).
- It is not necessary to collect all data at the same frequency, and the facility may develop a schedule for routine data collection. For example, data related to high-risk or problem-prone issues will generally be collected more frequently such as daily, weekly, or monthly, until performance is at a satisfactory level, then collected less frequently (e.g., quarterly or every six months).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(c)(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.
- §483.75(c)(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- The facility must have policies and procedures in place for developing, monitoring and evaluating performance indicators, as well as describe how and with what frequency the facility develops, monitors and evaluates its performance indicators.
- A performance indicator is a measurement of from the data collected, which represents performance in a specific care or service area. Performance indicators enable the facility QAA Committee to establish performance thresholds and goals, identify deviations in performance and evaluate progress. An example of monitoring includes comparing results of facility performance over time, as well as to state or national benchmarks.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Nursing homes must develop and implement written policies and procedures that enable the facility to systematically identify and investigate medical errors and adverse events, including how the facility will analyze and use data relating to errors and events to develop activities to prevent future occurrences.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(D) Program systematic analysis and systemic action.
- §483.75(d)(1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.
- §483.75(d)(2) The facility will develop and implement policies addressing:
  - (i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(d)(2) (continued)
  - (ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems; and
  - (iii) How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- As part of its' QAPI program, each facility is responsible for having systems in place and implementing actions which will improve performance. To ensure improvements are achieved and sustained, facilities should implement corrective actions, measure the success of these actions, and track their performance.
- Additionally, the facility must develop and implement policies and procedures which address how it will use systematic approaches to assist in determining underlying causes of problems which impact larger systems. These approaches may include root cause analysis, reverse tracker methodology, or health-care failure and effects analysis.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Policies and procedures must also address how the facility will develop corrective actions that will make changes at the systems level to prevent quality of care, quality of life, or safety problems, as well as how the facility will monitor the effectiveness of its performance improvement activities to ensure improvements are sustained.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(e) Program activities.
- §483.75(e)(1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.
- §483.75(e)(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(e)(3) As part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at §483.70(e). Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- As part of its QAPI program activities, the facility must establish priorities for performance improvement activities that focus on resident safety, health outcomes, autonomy, choice and quality of care, as well as high-risk, high-volume, and/or problem-prone areas. When determining priorities, the facility must also consider the incidence, prevalence and severity of problems or potential problems which it has identified.
- If systemic concerns, such as repeat survey deficiencies, have not been identified or prioritized by the facility's QAA committee, this may indicate that the committee is not effectively performing its required functions.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- In addition to the improvement activities the facility has identified as priorities, the facility must also track medical errors and adverse resident events. When the facility identifies medical errors or adverse resident events, the facility must analyze the cause of the error or event, implement corrective actions to prevent future events, and conduct monitoring to ensure it has achieved the desired outcome and keeps the outcome going.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- As part of the facility's performance improvement activities to reduce medical errors and adverse events, feedback and learning must be provided throughout the facility. Educating staff, residents, resident representatives and family members on medical errors and adverse events, such as what to look for and preventive measures, are important factors in reducing and preventing medical errors and adverse resident events.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- The facility must conduct distinct performance improvement projects, based on the scope and complexity of facility services and available resources, identified as a result of the facility assessment required at §483.70(e). While the number and frequency of improvement projects may vary, each facility must conduct at least one improvement project annually that focuses on high-risk or problem-prone areas, identified by the facility through data collection and analysis.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- The facility's action plans to address quality deficiencies and improve performance may be implemented in a variety of ways, including:
  - staff training and deployment of changes to procedures;
  - monitoring and feedback mechanisms; and
  - processes to revise plans that are not achieving or sustaining desired outcomes.
- The committee may delegate the implementation of action plans to various facility staff and/or outside consultants.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(g) Quality assessment and assurance.
- §483.75(g)(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:
  - ***

    (iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

F867 Data Collection, Monitoring, Analysis & Improvement

- Functioning under the facility's governing body, the QAA committee is responsible for:
  - Developing and implementing appropriate plans of action to correct identified deficiencies.
  - Regularly reviewing and analyzing data, including data collected under the QAPI program and data resulting from drug regimen reviews.
  - Acting on available data to make improvements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement Investigation & Key Elements for F867

- Surveyors will use the facility task QAPI and QAA Review along with the interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to requirements in F867.
- The Key Elements of Non-Compliance have been updated to include the new requirements discussed.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F686 QAA Committee

- §483.75(g) Quality assessment and assurance.
- §483.75(g)(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:
  - ***

    (iv) The infection preventionist.
- §483.80(c) [Infection preventionist] participation on quality assessment and assurance committee.
- The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F686 QAA Committee

- §483.75(g) Quality assessment and assurance.
- §483.75(g)(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:
  - ***

    (iv) The infection preventionist.
- §483.80(c) [Infection preventionist] participation on quality assessment and assurance committee.
- The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F686 QAA Committee

- F868 contains a new Phase 3 requirement that identifies the infection preventionist (IP) as a required member of the facility's QAA Committee.
  - *The IP must report on the facility's infection prevention and control program, and on incidents such as healthcare-associated infections, identified under the program on a regular basis. Reporting may include, but is not limited to, facility process and outcome surveillance, outbreaks and control measures, communicable illnesses such as TB or influenza and the Antibiotic Stewardship Program. In order to be considered an active participant, the infection preventionist should attend each QAA meeting.*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F686 QAA Committee

  - *If unable to attend, another staff member should report on the infection preventionist's behalf, but this does not change or absolve the IP's responsibility to fulfill the role of QAA committee member or reporting on the facility's infection prevention and control program.*
- For concerns related to the infection preventionist's responsibilities and qualifications, refer to F882 Infection preventionist qualifications and role.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
QAPI & QAA Reviews (CMS 20058)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Quality *Assurance & Performance Improvement (QAPI)* and *Quality Assessment &* Assurance (QAA) Review

This review should occur at the end of the survey, after completion of investigation into all other requirements. However, identification of systemic concerns to be reviewed during the QAPI and QAA review should begin with Offsite Preparation and occur throughout the survey.

Offsite: Make note of concerns identified during offsite preparation, which will be further investigated during the survey (*e.g.* repeat deficiencies, ombudsmen concerns, and complaints/facility-reported incidents). These represent possible systemic issues, which if validated during the survey, should be cited under the relevant outcome tag, and incorporated into the *QAPI and* QAA review for investigation.

Team Meetings: During end of day team meetings, the survey team discusses potential systemic issues or shared concerns for further investigation, or those that have been validated for incorporation into the *QAPI and* QAA review.

- ☐ Were any offsite concerns validated during the survey?
- ☐ Were new systemic*, high-risk, or problem-prone* concerns validated (concerns which will likely be cited at pattern or widespread, substandard quality of care*, or any substantiated or actual incidents of abuse, neglect, exploitation, or misappropriation of resident property)* during the survey?
- ☐ Has more than one surveyor identified and validated the same concern?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

483.75 Quality Assurance and Performance Improvement

QAPI & QAA Reviews (CMS 20058)

- As you heard us mention during the training, the facility task QAPI and QAA Review has been updated to include the new requirements and is available in the survey resources folder.
- Surveyors are to use the facility task at the end of the survey, after completion of investigation into all other requirements, to evaluate facility compliance and when investigating concerns related to QAPI and QAA.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
Where to Investigate

- F865: Concerns related to whether a facility has implemented and maintains a comprehensive QAPI program and plan, disclosure of records and governance and leadership.
- F867: Concerns related to how the facility obtains feedback, collects data, monitors adverse events, identifies areas for improvement, prioritizes improvement activities, implements corrective and preventive actions, and conducts performance improvement projects.
- F868: Concerns related to the composition of the QAA committee, frequency of meetings and reporting to the governing body.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement
F944 QAPI Training

- §483.95(d) Quality assurance and performance improvement. A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at §483.75.
- CMS wants to remind you about the new QAPI Training requirements in F944. Please view the CMS Training presentation and Appendix PP of the SOM for additional information.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.75 Quality Assurance and Performance Improvement Summary

- New QAPI and QAA requirements are located in Appendix PP of the State Operations Manual (SOM) located at:

  https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes

- Please remember that this training serves as an overview of the requirements and interpretive guidance, and that the new requirements, additional guidance and examples are included in Appendix PP of the SOM, which is available on the CMS website listed on the slide.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.24 Quality of Life
483.26 Quality of Care

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care Overview

- Overview of changes and updates for the following Quality of Life and Qualify of Care tags:
  - F675 Quality of Life
  - F686 Pressure Ulcers
  - F687 Foot Care
  - F689 Accidents/Supervision
  - F690 Bowel/Bladder Incontinence, Catheter, UTI
  - F694 Parenteral/IV Fluids
  - F695 Respiratory/ Tracheostomy Care and Suctioning
  - F697 Pain Management
  - F700 Bedrails

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F675 Quality of Life

- Technical corrections to address grammar and update references.
- Removed language suggesting automatic citation of F675 at Immediate Jeopardy (IJ) level.
- Added language to direct surveyors to consider impact to resident(s) affected, and to refer to Appendix Q for any concerns which may rise to IJ.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F675 Quality of Life

- F675 Quality of Life: There were technical corrections made to address grammar and update references. The language suggesting automatic citation of F675 at the Immediate Jeopardy (IJ) level was removed and language was added to direct surveyors to carefully consider the impact to the resident or residents affected by a pervasive disregard for quality of life and refer to Appendix Q for any concerns which may rise to the level of immediate jeopardy.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F686 Pressure Ulcers / F687 Foot Care

- No Phase 3 regulations related to F686 and F687.
- Changed guidance to reflect that pressure ulcer risk assessments should occur quarterly (rather than monthly) or whenever there is a change in condition.
- Added new language on following proper infection prevention practices for foot care equipment.
- Added a reference to the infection prevention and control tag related to foot care.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F686 Pressure Ulcers / F687 Foot Care

- There are no Phase 3 regulations for pressure ulcers and foot care.
- The guidance at F686 was changed to reflect that pressure ulcer risk assessments should occur:
  - upon admission,
  - weekly for the first four weeks, and
  - quarterly (rather than monthly),
  - or whenever there is a change in condition. This change reflects the current accepted standard of practice.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F686 Pressure Ulcers / F687 Foot Care

- New language added to the guidance at F687 to address the importance of following:
  - Proper infection prevention and control practices for foot care equipment, with a reference in F687 related to the infection prevention and control tag.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- New guidance on electronic cigarettes (e-cigs):
  - Added guidance in response to increased use of the devices and questions received from nursing home stakeholders.
  - Guidance identifies risks associated with e-cigs:
    - Health effects for the user and others nearby.
    - Nicotine overdose by ingestion or skin contact.
    - Explosion or fire caused by device battery.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- In the Accidents and Supervision tag at F689, new guidance has been added regarding electronic cigarettes, or e-cigarettes.
- This guidance was in response to increased use of e-cigarettes and questions about them from nursing home stakeholders.
- The new guidance identifies risks which are associated with using electronic cigarettes such as the health effects to the user and second-hand aerosol exposure to others in the vicinity of the user, potential nicotine overdose by ingestion or skin contact, and explosion or fire caused by the battery.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- Facilities must **oversee the use of these devices** and include them in **smoking policies.**
- Policies should address:
  - **Unique characteristics and risks of e-cigarettes.**
  - **How use will be supervised.**
  - **Handling of batteries and refill cartridges.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- Surveyors should consider how facilities:
  - Provide for **resident safety;**
  - **Balance safety with resident right** to use the device; and
  - **Protect residents** who do not want to be exposed to second-hand aerosol.
- Updated references related to bedrails.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- CMS expects facilities to oversee the use of these devices and to address them in their smoking policies. The policies should cover the unique characteristics and risks of e-cigarettes, how staff will supervise residents who use e-cigarettes and how to handle the batteries and refill cartridges.
- When evaluating the use of e-cigarettes in nursing homes, surveyors should consider how facilities ensure resident safety while still honoring the resident's right to use the device according to facility policy and how the facility protects residents who do not want to be exposed to the e-cigarette second-hand aerosol.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- New guidance has been added to address safety for residents with substance use disorder.
- Care planning interventions should address risk for a resident leaving to satisfy an addiction to alcohol or illegal or prescription drugs.
- Facilities are responsible for identifying and assessing a resident's risk for leaving and developing interventions to address the risk.
- A resident who leaves the facility with facility knowledge of the departure, despite facility efforts to explain the risks of leaving earlier than planned, would likely be against medical advice.
- A resident who leaves the facility without staff knowledge of the departure would be considered an elopement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- F689 added new guidance to address **safety for residents with substance use disorder.**
- Residents with substance use disorder may be at **increased risk for leaving the facility** to satisfy an addiction to alcohol or illegal or prescription drugs.
- **Care planning interventions** should address this risk. Facilities are responsible for knowing if a resident leaves the building.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- A resident who leaves the facility with facility knowledge of the departure, despite facility efforts to explain the risks of leaving earlier than planned, would likely be an Against Medical Advice (AMA) discharge.
- Documentation in the medical record should show that facility staff attempted to provide other options to the resident and informed the resident of potential risks of leaving AMA.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- Documentation should also identify the
  - time the facility became aware of the resident leaving the facility.
- A resident who leaves the facility without staff knowledge of the departure would be considered an elopement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- For residents with a history of substance use:
  - Facility staff should assess residents for the risk for illicit substance use in the facility and have knowledge of signs and symptoms of possible substance use.
  - Facility staff should be prepared to address emergencies related to substance use.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- For residents with a **history of substance use:**
  - Facility staff should be **prepared to address emergencies** related to substance use by
    - maintaining knowledge of administering **opioid reversal agents** like naloxone,
    - **initiating CPR** as appropriate, and
    - **contacting emergency medical services** as soon as possible.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- Surveyors should be aware that the **occurrence of an overdose** does not necessarily mean that noncompliance exists.
- If evidence shows a **facility took steps to increase its monitoring** of a resident, and despite this effort, the resident overdosed between checks, then noncompliance with 483.25(d) may not be present.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F689 Accidents/Supervision

- Facilities should **assess whether residents have a risk for using illicit substances** in the facility and staff should have knowledge of signs and symptoms of possible substance use.
- Facilities should be **prepared to address emergencies** related to substance use by maintaining knowledge of administering opioid reversal agents like naloxone, initiating CPR as appropriate, and contacting emergency medical services as soon as possible.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F690 Bowel/Bladder Incontinence, Catheter, UTI

- No Phase 3 regulations.
- F690 regulatory tag is specific to bowel incontinence, not bowel management.
- Clarified that any issues related to bowel management, such as constipation or impaction should be referred to F684.
- Technical Correction – corrects the Urinary Tract Infection parameter to 10 to the fifth power rather than 105.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F694 Parenteral/IV Fluids

- Added guidance on **frequency of assessment** of an **IV Catheter** including factors which affect the frequency such as:
  - Ability of resident to **report symptoms.**
  - **Type of infusion**—is it an irritant or vesicant?
  - **Location of IV**; and
  - **Facility policy.**
  - New language on infection control practices when accessing or using I.V.
  - Clarified the need to document continued need for IV Catheter.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F694 Parenteral/IV Fluids

- For the guidance on Parenteral and Intravenous or IV Fluids at F694, new guidance has been added related to the frequency of assessment. An exact assessment timeframe is not specified but the guidance provides factors which could affect how the frequency of assessment is determined such as:
  - The resident's ability to report symptoms such as pain or redness.
  - The type of infusion a resident is receiving—is it an irritant or vesicant?
  - The location of the I.V.—is it placed in an area of flexion such as the antecubital space.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F694 Parenteral/IV Fluids

- Where it is more likely to dislodge?
- New language was added on proper infection control practices when accessing or using a residents .IV.
- The guidance clarifies that facilities should document the reason for keeping a resident's I.V. when it is no longer being used for IV fluid or medication.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F695 Respiratory/Tracheostomy Care and Suctioning

F695 Respiratory/Tracheostomy Care and Suctioning

- No Phase 3 regulations, only guidance clarification.
- Clarified that mechanical ventilation guidance only applies to facilities who choose to offer this service.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F697 Pain Management

F695 Respiratory/Tracheostomy Care and Suctioning

- Added language regarding use of opioids within the current opioid crisis and to align with the efforts of other government agencies.
- Recommend use of CDC resources on use of opioids for chronic pain.
- 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.
- Guidance describes side effects of opioids and addresses prevention of opioid overdoses by administering naloxone.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F697 Pain Management

F697 Pain Management

- The pain management guidance at F697 has been updated to address opioid use which meets the pain needs of residents within the context of the nation's current opioid crisis. The guidance recommends use of the Centers for Disease Control and Prevention website for resources on use of opioids in treating chronic pain.
- Facilities should assess residents for history of past addiction or opioid use disorder and related treatment in order to implement strategies to adequately address the resident's pain which may include continuation of medication assisted treatment, if appropriate, non-opioid pain medications, and non-pharmacological approaches.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F697 Pain Management

F697 Pain Management

- Medication-assisted treatment is defined in the guidance as the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorder.
- The guidance describes the side effects of opioids and addresses the prevention of opioid overdoses by administering naloxone.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F700 Bedrails

F700 Bed Rails

- The guidance for bedrails clarified to include **the "use"** of bedrails in addition to installation.
- Added links to resources and guidance related to appropriate alternatives to bedrails.
- Clarified that there is **no requirement** that **bedrails be removed or disabled when not in use.**
- Added guidance that **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.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F700 Bedrails

F700 Bed Rails

- F700 now contains links to resources and guidance related to appropriate alternatives to bedrails such as:
  - roll guards,
  - foam bumpers,
  - lowering the bed, and
  - using concave mattresses to reduce rolling off the bed.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F700 Bedrails

F700 Bed Rails

- The guidance also states that **alternatives must be appropriate** for the intended use of the bedrail and made an allowance for when no alternative exists. In such cases, the medical record must include:
  - **Purpose of bedrail** and notation that no appropriate alternative exists.
  - **Assessment of the resident** and the **bedrail for entrapment risk.**
  - **Assessment of the risks versus benefits** which must be reviewed with the resident and resident representative with informed consent given.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F700 Bedrails

F700 Bed Rails

- Clarification was added that there is no requirement that bedrails be removed or disabled when not in use.
- The guidance emphasizes that facilities must have a process for determining whether beds (and their rails) are appropriate for the residents residing in them.
- This includes determining if the rail can be moved to the down position, and if it can, does that pose any type of risk to the resident such as tripping or entrapment?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F700 Bedrails

F700 Bed Rails

- Also included is guidance which states that if bedrails are determined to be inappropriate for a resident but are left on the bed in the down position, raising the rail even episodically to provide care may be considered noncompliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.24 Quality of Life/483.25 Quality of Care
F700 Bedrails

F700 Bed Rails

- Any use of bedrails must meet the requirements to:
  - assess the resident,
  - obtain consent,
  - evaluate appropriateness and
  - routinely provide maintenance of the bed and bed rail.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

483.10 Resident Rights

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F557	Respect, Dignity/Right to have Personal Property	Added language related to mental health and substance use disorders throughout guidance	Significant
F561	Self Determination	Reinsertion of "facility policy on resident smoking" language which was inadvertently removed.	Significant
F563	Right to Receive/Deny Visitors	Added language related to mental health and substance use disorders throughout guidance; Added language related to visitation during infectious outbreaks or pandemics.	Significant
F578	Request/Refuse/ Discontinue Treatment; Formulate Adv Dir	Corrected tag reference under Key Elements of Noncompliance	Technical
F582	Medicare/Medicaid Coverage/Liability Notice	Revisions based upon new Skilled Nursing Facility Advance Beneficiary Notices (SNFABN)	Significant

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights

- CMS revised five tags under the Resident Rights section. F557, F561, F563 and F582 had significant revisions. Additionally, CMS made technical edits to F578 to correct a tag reference under the Key Elements of Noncompliance.
- Some of the added language pertains to mental health and substance use disorders.
- After receiving stakeholder and provider feedback, CMS felt it was important to incorporate this in guidance, since there are a growing number of nursing home residents living with these conditions.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

F557 Respect, Dignity/Right to have Personal Property

- Addition of guidance related to:
  - Staff searches.
  - Signs, symptoms, and triggers of possible substance use.
  - Referral to law enforcement.
  - References to F689 and F740.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

F557 Respect, Dignity/Right to have Personal Property

- For F557, CMS added additional guidance related to the need for resident or, if applicable, the resident's representative's **consent for staff** searches of a resident's body or personal possessions.
- CMS also added language pertaining to the expectation that facility staff should have knowledge of **signs, symptoms, and triggers of possible substance use.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

F557 Respect, Dignity/Right to have Personal Property

- Knowledge of signs, symptoms, and triggers of possible substance use; such as
  - changes in resident behavior,
  - increased unexplained drowsiness,
  - lack of coordination,
  - slurred speech,
  - mood changes, and/or
  - loss of consciousness, etc.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

- Additionally, if the facility determines **illegal substances** have been brought into the facility by a visitor, **the facility should not act as an arm of law enforcement.**
- Rather, these cases may warrant a referral to **local law enforcement.**
- If during the investigation, concerns arise that are related to the identification of risk and the provision of supervision to prevent accidental overdose, refer to **F689 – Accidents**.
- For concerns related to the **behavioral health services** that are provided, investigate potential non-compliance at **F740 – Behavioral Health Services.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes for Resident Rights

- F561 Self-Determination
  - Re-insertion of previous guidance inadvertently deleted.
  - Prohibition of smoking.
  - Change of policy from smoking to non-smoking.
  - Current residents affected by policy change.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes for Resident Rights

- F561, guidance related to facility smoking policies was inadvertently deleted with the implementation of Phase 2. This language is now being added back into the guidance.
- The focus of this content relates to when a facility wants to change from a smoking to a non-smoking facility.
- The facility should allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents and takes into account non-smoking residents. Residents admitted after the facility changes its policy must be informed of this policy at the time of admission.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

F563 Right to Receive/Deny Visitors

- Addition of guidance related to:
  - Denying access to visitors who have a history of bringing illegal substances into the facility.
  - Visitation during communicable disease outbreaks.
  - Signs, symptoms, and triggers of possible substance use after interaction with visitors.
  - Referral to law enforcement.
  - Staff searches.
  - References to F689 and F740.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

F563 Right to Receive/Deny Visitors

- For F563, CMS added additional guidance related to denying access or providing supervised visitation to individuals who have a history of bringing illegal substances into the facility.
- Information related to visitation during communicable disease outbreaks was also added to the guidance.
- Facilities may need to modify their visitation practices when there are infectious outbreaks or pandemics to align with current CMS guidance and CDC guidelines that enables maximum visitation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes to Resident Rights

- CMS added language related to the need for resident or resident representative consent for staff searches of a resident's body or personal belongings.
- If during the investigation, concerns arise that are related to the identification of risk and the provision of supervision to prevent accidental overdose, refer to F689- Accidents.
- For concerns related to the behavioral health services that are provided, investigate potential non-compliance at F740 – Behavioral Health Services.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes for Resident Rights

F582 Medicaid/Medicare Coverage/Liability Notice

- Revisions based on changes to **Skilled Nursing Facility Advanced Beneficiary Notice of Non-coverage (Form CMS-10055).**
- Clarification provided for:
  - Notice of Medicare Non-coverage (Form CMS-10123).
    - Notification that Part-A coverage is ending.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes for Resident Rights

- F582 Medicaid/Medicare Coverage/Liability Notice
  - Skilled Nursing Facility Advanced Beneficiary Notice of Non-coverage (Form CMS-10055).
    - Transfer of financial liability to the beneficiary.
    - Separate and unrelated from the admission and discharge requirements.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.10 Resident Rights
Key Changes for Resident Rights

- In 2018, the Skilled Nursing Facility Advanced Beneficiary Notice of Non-coverage (or SNFABN) form was revised.
- CMS worked with the Center for Medicare, within CMS, to ensure guidance under F582 remained accurate.
- Some of the previous guidance did not align with the Medicare Claims Processing Manual and revisions were made.
- Additionally, the Center for Medicare helped to simplify the content related to the Notice of Medicare Non-coverage (or NOMNC) form, as well as the SNFABN form. The level of detail in the previous version of the guidance created a lack of clarity and seemed unnecessary.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Staffing

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Nursing Services 483.36

- §483.35 Nursing Service tags were revised at:
  - F725
  - F727
  - F729
  - F732

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Nursing Services 483.36

- Key Changes include:
  - Intent
  - Definitions
  - Procedures
  - Probes
  - Key Elements of Non-Compliance
  - Deficiency

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Nursing Services 483.36

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines
F725	§483.35(a) Sufficient Staff	Added new guidance for the Procedure, Probes, and Deficiency Categorization Examples
F727	§483.35(b) Registered Nurse	Added new guidance for the Procedure, Probes, and Deficiency Categorization
F729	§483.35(d)(4) Registry Verification	Added new guidance for Procedure
F732	§483.35(g) Nurse Staffing Information	Added Procedures and Probes

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Administration 483.70

- §483.70 Administration revised F851.
  - F725
  - F727
  - F729
  - F732
- Key Changes include:
  - Guidance
  - Key Elements of Non-Compliance

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Administration 483.70

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines
F851	§483.70(q) Mandatory submission of staffing information based on payroll data in a uniform format	Guidance and Key Elements of Non-Compliance

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Quality of Care

- Staffing Relevance
  - Direct correlation to quality of care.
  - Coordination of care to meet resident needs.
  - A top concern among residents, families.
  - Putting loved ones in someone else's hands.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Quality of Care

- Why is sufficient staffing so important you might ask? Staffing in nursing homes has a substantial impact on the quality of care and outcomes that residents experience. There is a direct correlation between staffing and quality of care. As a surveyor it is important to understand that direct care staff are those individuals 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. Staffing is an essential component that facilities must consider when coordinating care to meet residents' needs.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Quality of Care

- Sufficient staffing is also a top concern among residents and their families. This is not surprising when CMS considers that families are putting their loved ones in someone else's hands every day to help care and provide for them.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

- §483.70(q) Mandatory submission of staffing information based on payroll data in a uniform format.
- §483.70(q)(1) Direct Care Staff.
- §483.70(q)(2) Submission requirements.
- §483.70(q)(3) Distinguishing employee from agency and contract staff.
- §483.70(q)(4) Data format.
- §483.70(q)(5) Submission schedule.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

Payroll-Based Journal (PBJ)

- It is not a requirement for surveyors to become an expert in PBJ procedures.
- With changes being made to the Long-Term Care Survey Process (LTCSP) **software application,** surveyors will be able to obtain specific PBJ data prior to the recertification survey.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

F851 Payroll-Based Journal (PBJ)

- F851 §483.70(q) is specific to the mandatory submission of staffing information based on payroll data in a uniform format.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

F851 Payroll-Based Journal (PBJ)

- Long-term care facilities **must electronically submit** to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

Revised Guidance F851 Payroll-Based Journal (PBJ)includes that:

- The surveyors can obtain PBJ data from the Certification And Survey Provider Enhanced Reports (CASPER) report to determine if the facility submitted the required staffing information based on payroll data in a uniform format.
- The facility's failure to submit PBJ data as required will be reflected on their CASPER report and result in a deficiency citation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

F851 Payroll-Based Journal (PBJ)

- If concerns were identified based on the CASPER report, or from other any other source, refer to the critical element pathway “Sufficient and Competent Staffing.”
- F851 has key elements of noncompliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

F851 Payroll-Based Journal (PBJ)

- To cite deficient practice at F851, the surveyor's investigation will generally show that the **facility failed to do any one of the following**:
  - Complete data for the **entire reporting period**, such as hours paid for all required staff, each day; or
  - Provide **accurate data**; or
  - Provide data by the **required deadline**.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F851 Payroll-Based Journal (PBJ)

F851 Payroll-Based Journal (PBJ)

- The facility is to submit the required staffing information based on payroll data in a **uniformed format.**
- If the survey team identifies non-compliance, then F851 will be cited.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Looking Back

F851 Payroll-Based Journal (PBJ)

- History of PBJ:
  - 1998: CMS started Nursing Home Compare.
  - Originally based on health inspection data.
  - 2003: Quality measures added.
  - 2008: Five-Star Rating added.
  - CMS continually seeks to improve its value.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing

- CMS has long identified staffing as one of the vital components of a nursing home's ability to provide quality care.
- Over time, CMS utilized staffing data for a myriad of purposes in an effort to more accurately and effectively gauge its impact on quality of care in nursing homes.
- The PBJ data provide unprecedented insight into how facilities are staffed, which can be used to analyze how facilities' staffing relates to quality and outcomes.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Looking Back

- CMS posts staffing information on the CMS Nursing Home Compare website, and it is used in the Nursing Home Five Star Quality Rating System to help consumers understand the level and differences of staffing in nursing homes.
- It provides consumers with an easy way to search for nursing homes that deliver the quality of care they desire.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Electronic Submission of Payroll-Based Staffing Information

- Report staffing levels, turnover, and tenure.
- Auditable back to payroll data.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Electronic Submission of Payroll-Based Staffing Information

- CMS has developed the PBJ system for facilities to submit staffing and census information.
- This system allows staffing and census information to be collected on a regular and more frequent basis than previously collected.
- It is also auditable to ensure accuracy. All long-term care facilities have access to this system at no cost to facilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Electronic Submission of Payroll-Based Staffing Information

- The data, when combined with census information, can then be used to not only report on the level of staff in each nursing home, but also to report on employee turnover and tenure, which can also impact the quality of care delivered to the vulnerable population of nursing home residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Days No RN Staffing

- F727 nursing homes are required to have an RN onsite:
  - at least 8 consecutive hours a day,
  - 7 days a week.
- Some nursing homes do not report any RN hours for some days, particularly on weekends.
- CMS is concerned with recurring instances of days with no RN hours reported.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Days No RN Staffing

- Research shows the presence of an RN is strongly related to the quality of care and outcomes residents experience. Statistics have shown that as the number of RN hours increases, so does performance on the quality measures. Therefore, when there are lower levels or even no onsite RN presence, CMS is concerned about the health and safety of the residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Days No RN Staffing

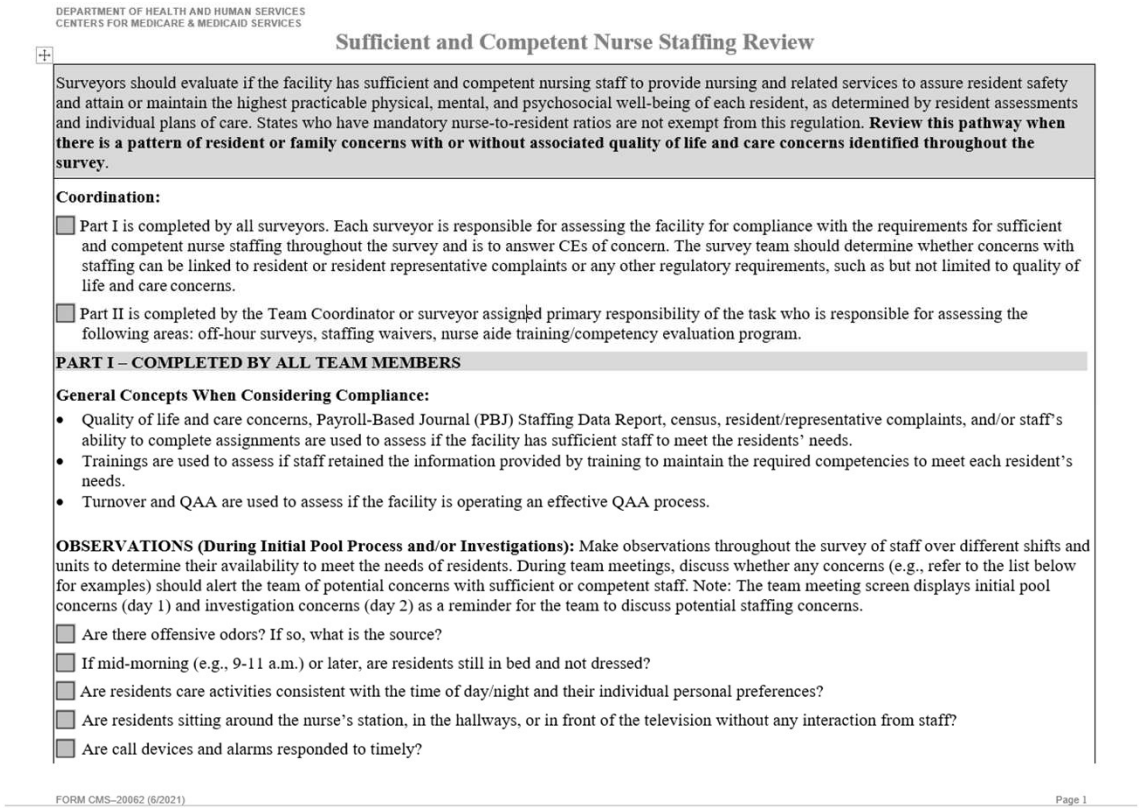
- Since facilities are required to submit the number of hours staff are paid to work each day, the PBJ data show whether or not facilities have an RN onsite each day. While the majority of nursing homes are reporting an RN onsite each day, submitted staffing data show that there are some facilities that don't report an RN onsite, particularly on the weekends. There are risks that the absence of an RN introduces. CMS believes that the presence of an RN onsite every day is extremely important to improving the health and safety of nursing home residents.
- If a facility reports the absence of an RN 4 or more days in a quarter, they will be cited at F727 by the surveyor.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Staffing

Sufficient and Competent Nurse Staffing Review



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Sufficient and Competent Nurse Staffing Review

Surveyors should evaluate if the facility has sufficient and competent nursing staff to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care. States who have mandatory nurse-to-resident ratios are not exempt from this regulation. **Review this pathway when there is a pattern of resident or family concerns with or without associated quality of life and care concerns identified throughout the survey**.

Coordination:

☐ Part I is completed by all surveyors. Each surveyor is responsible for assessing the facility for compliance with the requirements for sufficient and competent nurse staffing throughout the survey and is to answer CEs of concern. The survey team should determine whether concerns with staffing can be linked to resident or resident representative complaints or any other regulatory requirements, such as but not limited to quality of life and care concerns.

☐ Part II is completed by the Team Coordinator or surveyor assigned primary responsibility of the task who is responsible for assessing the following areas: off-hour surveys, staffing waivers, nurse aide training/competency evaluation program.

PART I – COMPLETED BY ALL TEAM MEMBERS

General Concepts When Considering Compliance:

- Quality of life and care concerns, Payroll-Based Journal (PBJ) Staffing Data Report, census, resident/representative complaints, and/or staff's ability to complete assignments are used to assess if the facility has sufficient staff to meet the residents' needs.
- Trainings are used to assess if staff retained the information provided by training to maintain the required competencies to meet each resident's needs.
- Turnover and QAA are used to assess if the facility is operating an effective QAA process.

OBSERVATIONS (During Initial Pool Process and/or Investigations): Make observations throughout the survey of staff over different shifts and units to determine their availability to meet the needs of residents. During team meetings, discuss whether any concerns (e.g., refer to the list below for examples) should alert the team of potential concerns with sufficient or competent staff. Note: The team meeting screen displays initial pool concerns (day 1) and investigation concerns (day 2) as a reminder for the team to discuss potential staffing concerns.

☐ Are there offensive odors? If so, what is the source?

☐ If mid-morning (e.g., 9-11 a.m.) or later, are residents still in bed and not dressed?

☐ Are residents care activities consistent with the time of day/night and their individual personal preferences?

☐ Are residents sitting around the nurse's station, in the hallways, or in front of the television without any interaction from staff?

☐ Are call devices and alarms responded to timely?

FORM CMS–20062 (6/2021) Page 1

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Staffing

Sufficient and Competent Nurse Staffing Review

- The survey team will use the revised CE Pathway Sufficient and Competent Nurse Staffing Review to complete this Mandatory Facility Task for the standard recertification survey.
- This pathway should also be used when surveyors are investigating a stand-alone complaint where concerns with staffing were identified.
- The pathway has been divided into Part 1 and Part 2.
- There are general concepts when considering compliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
Sufficient and Competent Nurse Staffing Review

- Quality of Life and Care Concerns
  - Payroll-Based Journal (PBJ) Staffing Data Report,
  - Census,
  - Resident/representative complaints, and/or
  - Staff's ability to complete assignments

  are **used to assess** if the facility has **sufficient staff** to meet the residents' needs.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Staffing

Sufficient and Competent Nurse Staffing Review

- Trainings are used to assess if staff retained the information provided by training to maintain the required competencies to meet each resident's needs.
- Turnover and QAA are used to assess if the facility is operating an effective QAA Process.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

- Excessively **low weekend staffing.**
- 4 or more days with **no RN.**
- 4 or more days with **less than 24 hours of licensed nursing staff**.
- **1 Star** staffing rating.
- **No data submitted** for the last quarter.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- The **LTCSP software will be updated** to include changes to the survey process to include the PBJ data.
- The survey team will **use this data** to investigate further through observations, interviews, and record review.
- The changes consist of the **following five areas** and are in the form of the **Payroll-Based Journal (PBJ) Staffing Data Report** that surveyors will obtain through the **CASPER reporting system**.
- Those areas are based on **data submitted by the facility** for the last quarter.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 1st Change:
  - Excessively low weekend staffing:
    - This means that the facility has been identified by the PBJ system and triggered for having low weekend staffing. The submitted weekend staffing data is excessively low. This can also trigger a facility to receive an **off-hour survey.**
    - F725 requires sufficient staff, so the team would investigate further.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 2nd Change:
  - Four or more days with no RN:
    - This means that the facility PBJ data shows that within the identified quarter, the facility has had four or more days without an RN. Remember, that according to F727, facilities are required to have an RN onsite for 8 consecutive hours 7 days a week. If four or more days with no RN are identified, the team will investigate further AND cite the facility at F727.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 2nd Change:
  - Four or more days with no RN:
    - Note that the rule of four or more days is used for the purposes of the PBJ Staffing Data Report. The expectation of CMS is that the survey team would consider issuing a citation when a minimum of one day is identified to not meet the nurse staffing requirement for a Registered Nurse.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 3rd Change:
  - Four or more days within the quarter with less than 24 hours per day of licensed nursing coverage.
    - At one point, there were about 1500 nursing homes that reported no licensed nursing staff in a 24-hour period.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 3rd Change:
  - Four or more days within the quarter with less than 24 hours per day of licensed nursing coverage.
    - Per F725, facilities are required to have licensed nursing staff 24 hours a day. If there are four or more days with less than 24 hours of licensed nursing staff, the survey team will investigate further AND cite F725.
    - *"The rule of four or more days"* is used for the purposes of the PBJ Staffing Data Report.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 3rd Change:
  - Four or more days within the quarter with less than 24 hours per day of licensed nursing coverage.
    - The expectation of CMS is that the survey team would consider issuing a citation when a minimum of one day is identified to not meet the nurse staffing requirement for Licensed Nursing Staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 4th Change:
  - One star staffing rating.
    - Different reasons why a facility may have a one-star staffing rating. If this is identified on the PBJ Staffing Data Report, then the survey team should be aware of this low star staff rating as they conduct investigations.
    - For example, surveyors should be alert when interviewing residents about the availability of staff to determine if assistance is provided when needed without having to wait a long time.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 4th Change:
  - One star staffing rating.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

Payroll-Based Journal (PBJ) Staffing Data Report

- 5th Change:
  - The **last of the CASPER report** areas includes:
    - **No data submitted for the last quarter**. If there is no data submitted for the last quarter, it will be assumed that the facility has low staffing. The survey team will investigate further.
    - Surveyors complete the Sufficient and Competent Nurse Staffing Review.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ Staffing Data Report

- Please note: The rule of 4 or more days is used for the purposes of the PBJ Staffing Data Report.
- The expectation of CMS is that the survey team would consider issuing a citation when a minimum of 1 day is identified to not meet the nurse staffing requirement for both a Registered Nurse and Licensed nursing staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

§483.35 Nursing Services

F725 Sufficient Staff

- The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

§483.35 Nursing Services

F725 Sufficient Staff

- §483.35(a)(1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:
  - (i) Except when waived under paragraph (e) of this section, licensed nurses; and
  - (ii) Other nursing personnel, including but not limited to nurse aides.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

§483.35 Nursing Services

F725 Sufficient Staff

- §483.35(a)(2) Except when waived under paragraph (e) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

- Procedure: §483.35(a)(1)-(2)
  - 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.
  - A facility may meet a state's minimum staffing ratio requirement, and still need more staff to meet the needs of its residents.
  - Additionally, the facility is required to provide licensed nursing staff 24 hours a day, 7 days a week.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

- Procedure: §483.35(a)(1)-(2) (continued)
  - The facility is responsible for submitting staffing data through the CMS Payroll- Based Journal (PBJ) system (Refer to F851, §483.70(q)). This data can be obtained through the Certification and Survey Provider Enhanced Reports (CASPER) reporting system. This PBJ Staffing Data Report contains information about overall direct care staffing levels, including nurse staffing. Surveyors will utilize the P B J Staffing Data Report available through CASPER reporting system to identify concerns with staffing.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

- Procedure: §483.35(a)(1)-(2) (continued)
  - The Long-Term Care Survey Process (LTCSP) software application will alert the surveyors of specific dates that require further investigation related to staffing. Surveyors are expected to verify infraction dates indicated on the PBJ staffing data report. If concerns were identified on this report, as well as from other sources, refer to the critical element pathway of Sufficient and Competent Staffing, and the probes noted below.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

- Procedure: §483.35(a)(1)-(2) (continued)
  - Some Investigative Probes in the interpretive guidance have been revised and include but are not limited to:
    - Are the numbers of licensed staff sufficient such that those staff members have enough time to provide direct services to residents as well as to assist and monitor all of the aides they are responsible for supervising?
    - Does the facility have adequate staff to monitor residents at risk for wandering?
    - Does the facility have licensed nursing staff 24 hours a day?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Sufficient Staff

- Procedure: §483.35(a)(1)-(2) (continued)
  - If the surveyor is made aware of the absences of licensed nursing staff in a 24-hour period :
    - Interview direct care staff;
    - Interview the Director of Nursing or Administrator;
    - See Interpretive Guidance at F25 for additional probes.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Deficiency Categorization Example Level 4

- An example of F725 Sufficient Staff, Level 4, immediate jeopardy to resident health and safety includes, but is not limited to:
  - A resident had complained of chest pain and shortness of breath after eating their evening meal. The nursing assistant stated they would inform the licensed nurse. The nursing assistant was informed there would be no licensed nurse until the next morning. At 10:00 p.m. the resident was found unresponsive with minimal respirations by a visiting family member.
  - Because there was no licensed nurse on duty at that time, the nursing assistant called 911.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Deficiency Categorization Example Level 3

- An example of F725 Sufficient Staff, Level 3, actual harm (physical or psychosocial) that is not immediate jeopardy includes, but is not limited to:
- A resident was admitted to the facility with a recently repaired hip fracture and required assistance with ambulation. The resident used the calling device to request assistance to the bathroom. After several minutes no help arrived so the resident attempted to ambulate with a walker to the bathroom without assistance. The resident subsequently fell and was found by nursing assistants. The resident was assisted back to bed by the nursing assistants and complained of pain in the area of the recently repaired hip fracture.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Deficiency Categorization Example Level 3

- An example of F725 Sufficient Staff, Level 3 (continued)
  - There was no licensed nurse on duty to assess the resident for any injuries or provide medication for pain. The next morning the resident complained of increased pain in the area of the repaired hip fracture. After assessment by the day shift licensed nurse the resident was sent to the hospital. The resident was admitted and required surgery to repair the re-fractured hip.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Deficiency Categorization Example Level 2

- An example of F725 Sufficient Staff, Level 2, no actual harm, with potential for no more than minimal harm, that is not immediate jeopardy includes, but is not limited to:
  - Residents complain that they are not allowed choices such as receiving showers consistently on the days or at times they prefer due to inadequate staffing.
  - Review of staffing data submitted via the PBJ system revealed the facility had a one-star staffing quality rating.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F725 Deficiency Categorization Example Level 2

- An example of F725 Sufficient Staff, Level 2 (continued):
  - Follow up interviews with the staffing coordinator revealed that only one CNA was available to provide showers, and therefore residents' preferences for timing of showering could not be met causing anxiety.
  - Refer to the Psychosocial Outcome Guide for additional direction.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)

Staffing

F725 Deficiency Categorization Example Level 1

- Severity Level 1: No Actual Harm with Potential for Minimal Harm

Does Not Apply

- The failure of the facility to provide sufficient staffing including licensed nurses creates a risk that is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Registered Nurse

- §483.35(b) Registered Nurse
  - §483.35(b)(1) Except when waived under paragraph (e) or (f) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.
  - §483.35(b)(2) Except when waived under paragraph (e) or (f) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full-time basis.
  - §483.35(b)(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Registered Nurse

- The intent of this regulation is to ensure that the facility:
  1. Uses the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.
  2. Designates a registered nurse to serve as the director of nursing on a full-time basis.
  3. Permits the director of nursing to serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Registered Nurse

- As previously shared, the facility is responsible for submitting staffing data to the payroll-based journal system (Refer to F851). This data for the purposes of standard and abbreviated surveys can be obtained through the Certification And Survey Provider Enhanced Reports (Casper) reporting system. This report contains information about overall staffing levels as well as licensed nurse staffing, including the 8 consecutive hours required by an RN. If concerns were identified on this report, as well as from other sources, refer to the critical element pathway Sufficient and Competent Staffing, and the probes below.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Registered Nurse

- Procedure Interpretive Guidance changes include but are not limited to:
  - Facilities are responsible for ensuring they have an RN providing services at least 8 consecutive hours a day, 7 days a week. However, per Facility Assessment requirements at F838, §483.70(e), facilities are expected to identify when they may require the services of an RN for more than 8 hours a day based on the acuity level of the resident population. If it is determined the services of an RN are required for more than 8 hours a day, refer to the guidance at F725 related to sufficient nurse staffing for further investigation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Registered Nurse

- Procedure Interpretive Guidance (continued)
  - Facilities may choose to have differing tours of duty (e.g., 8 hour- or 12-hour shifts) for their licensed nursing staff. Regardless of the approach, the facility is responsible for ensuring the 8 hours worked by the RN are consecutive within each 24-hour period.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Registered Nurse

- Probes
  - If there is no RN coverage for at least 8 consecutive hours each day, (e.g., as indicated by the PBJ Staffing Report), corroborate the findings by interviewing:
    - Front Line Staff (i.e., nurse aides, LPNs/LVNs).
    - Director of Nursing or Administrator.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 4

- An Example of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety includes but is not limited to:
  - The annual recertification survey of a facility indicates that it provides care for residents with high acuity needs including residents that receive medications and fluids via central intravenous lines (IV) and ventilator dependent residents. The investigation revealed an RN was not onsite for at least 8 consecutive hours during the day. During the period when there was no RN, the LPN had to perform assessments and maintain central line (IV) infusions, which is out of the scope of practice for an LPN in the absence of supervision of the RN.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 4

- An Example of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety includes but is not limited to (continued):
  - The facility's failure to have an RN on duty for at least 8 consecutive hours a day as required by the regulation, created the likelihood for serious injury, harm, impairment or death. Specifically, the RN was not present to meet the critical needs of these high acuity residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 3

- Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:
  - Investigation of falls occurring in the facility with a census greater than 60 residents revealed the monthly fall evaluation for one resident was not completed with the interdisciplinary team after the resident experienced 2 falls. Interview with the Director of Nursing (DON) revealed this was the DON's responsibility; however, because she had been serving as the charge nurse, there was no time to complete the evaluation for this resident who experienced another fall resulting in a sprained wrist.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 3

- Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to (continued):
  - Record review revealed that the resident experienced a fall after the DON failed to complete the fall evaluation in response to the two initial falls. Staff ultimately determined the resident was falling due to a change in the resident's condition (deteriorating eyesight) that was not timely identified because of the DON's.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 2

- Examples of Severity Level 2 Non-Compliance: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:
  - Review of the PBJ Staffing Data Report revealed concerns related to the facility's requirement to have a Registered Nurse on duty for at least 8 consecutive hours a day. The surveyor verified an RN was routinely on duty for only 7 consecutive hours a day last quarter. No actual harm to residents was identified.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 2

- Examples of Severity Level 2 Non-Compliance: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to (continued):
  - However, there was a potential for more than minimal harm due to the facility's failure to have an RN on duty for at least 8 consecutive hours a day, 7 days a week in order to ensure that all the residents' clinical needs were met either directly by the RN or indirectly by the LPNs or CNAs for whom the RN was responsible for overseeing resident care.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F727 Deficiency Categorization Example Level 1

- Severity Level 1: No Actual Harm with Potential for Minimal Harm

Does Not Apply

- The failure of the facility to provide an RN creates a risk that is more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F729 Registry Verification

- §483.35(d)(4) Registry verification. Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—
  - (i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or
  - (ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F729 Registry Verification

- §483.35(d)(5) Multi-State registry verification. Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act that the facility believes will include information on the individual.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F729 Registry Verification

- §483.35(d)(6) Required retraining. If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F729 Registry Verification

- F729 Interpretive Guidance, there have been additions to the Procedure Section.
  - Procedure
    - If concerns are identified with Nurse Aide Services at F725 and F726, review a minimum of five nurse aide personnel files including any specific staff members with whom concerns were identified.
    - Review the nurse aide personnel folder to determine if the facility received registry verification that the individual has met competency evaluation requirements before the employee's start date unless an exception applies as noted in §483.35(d)(4).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- §483.35(g) Nurse Staffing Information.
- §483.35(g)(1) Data requirements. The facility must post the following information on a daily basis:
  - (i) Facility name.
  - (ii) The current date
  - (iii) The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift:

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- §483.35(g)(1) Data requirements (continued)
  - (A) Registered nurses.
  - (B) Licensed practical nurses or licensed vocational nurses (as defined under State law).
  - (C) Certified nurse aides.
  - (iv) Resident census.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- §483.35(g)(2) Posting requirements.
  - (i) The facility must post the nurse staffing data specified in paragraph (g)(1) of this section on a daily basis at the beginning of each shift.
  - (ii) Data must be posted as follows:
    - (A) Clear and readable format.
    - (B) In a prominent place readily accessible to residents and visitors.
- §483.35(g)(3) Public access to posted nurse staffing data. The facility must, upon oral or written request, make nurse staffing data available to the public for review at a cost not to exceed the community standard.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- §483.35(g)(4) Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- F732 Posted Nurse Staffing Information
- The intent of this regulation is to make staffing information readily available in a readable format to residents and visitors at any given time.
- Interpretive guidance has been revised to include the addition of new procedures and probes. Let's review these together.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- Procedures and Probes §483.35(g)(1-4)
  - Surveyors must determine through information obtained by observations and verified by record reviews the following:
    - The facility post's the following information on a daily basis
      - Facility name.
      - The current date.
      - The total number and actual hours worked by the following categories of licensed nursing staff directly responsible for resident care per shift (Registered nurses, Licensed practical nurses or licensed vocational nurses, Certified nurse aides).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- Procedures and Probes §483.35(g)(1-4) (continued)
  - Resident census:
    - The facility must post the nurse staffing data mentioned above on a daily basis at the beginning of each shift.
    - The data must be posted in a clear and readable format and in a prominent place readily accessible to residents and visitors.
    - The facility must upon oral or written request make nurse staffing data available to the public for review at a cost not to exceed the community standard.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
F732 Nurse Staffing Information

- Procedures and Probes §483.35(g)(1-4) (continued)
  - Resident census (continued):
    - The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ-Related Resources

- CMS PBJ Policy Manual
  https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/PBJ-Policy-Manual-Final-V24.pdf
- CMS PBJ Policy Manual FAQ
  https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/PBJ-Policy-Manual-FAQ-09-26-17.pdf
- CMS Staffing Data Submission PBJ Website
  https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Staffing
PBJ-Related Resources

- CMS Five-Star Quality Rating System Technical Users Guide
  https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/usersguide.pdf
- Questions regarding PBJ policy can be sent to NHStaffing@cms.hhs.gov

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc.

Requirements of Participation (RoP)

483.95 Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Training

- Below are the Training Requirement tags with significant changes. Key changes for these tags will be discussed further in this portion of the training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Training

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F940	Training Requirements	Added new guidance for this stem requirement for all training tags	Significant
F941	Communication Training	Added new guidance for communication	Significant
F942	Resident Rights Training	Added new guidance for training related to Resident Rights/Facility Responsibilities	Significant
F944	QAPI Program	QAPI Program mandatory training	Significant
F945	Infection Control Training	Added new guidance for training related to Infection Control	Significant
F946	Compliance and Ethics	Annual training requirement for organizations with 5 or more facilities	Significant

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Training

F-Tag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F947	In-Service Training for Nurse Aides	Added new guidance for training related to Nurse Aides	Significant
F949	Behavioral Health Training	Added new guidance for training related to Nurse Aides	Significant

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F940 Training Requirements
  - Facilities must develop, implement, and maintain effective training program for:
    - All new and existing staff;
    - All individuals providing services under contract; and
    - Volunteers.
  - Facilities must use the Facility Assessment at F838 to determine the amount and types of training necessary.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F940 Training Requirements (continued)
  - Facilities must develop, implement, and maintain effective training programs for all new and existing staff and that would be anyone who provides services under a contractual arrangement, and volunteers.
  - A facility must determine the amount and types of training necessary based on a facility assessment as specified at §483.70(e).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F941 Communication Training
  - A facility must include effective communications as mandatory training for direct care of staff.
  - Guidance includes description of:
    - Effective communication
    - Direct care staff
  - A facility must include effective communications as mandatory training for direct care staff

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F941 Communication Training (continued)
  - Effective communication is a process of dialogue between individuals. The skills include speaking to others in a way they can understand and active listening and observation of verbal and non-verbal cues.
  - Direct care staff are those individuals 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.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F942 Residents' Rights Training
  - Facilities must develop and implement an ongoing education program on all residents' rights and facility responsibilities for caring of residents as outline in §483.10.
  - Education program should:
    - Support current scope and standards of practice.
    - Incorporate learning objectives, performance standards, and evaluation criteria.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F942 Residents' Rights Training (continued)
  - The guidance for F942 is new for the Phase 3 requirements. CMS drafted language to specify that an ongoing education program must be developed and implemented related to resident rights of every nursing home resident.
  - Additionally, CMS provided surveyors with probes to assist in their investigation. This includes the use of interviews, observations, and record review to investigate concerns with staff knowledge and understanding of resident rights and facility responsibilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F944 QAPI Training
  - §483.95(d) Quality assurance and performance improvement. A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at the §483.75.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F944 QAPI Training (continued)
  - Facilities must conduct mandatory training, for all staff on the facility's QAPI program.
  - The training should also include the staff's role in the facility's QAPI program and how to communicate concerns, problems or opportunities for improvement to the facility's QAA Committee.
  - As updates are made to the facility's QAPI program or goals, the facility's training should also be updated and staff trained on the updates, as appropriate.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F944 QAPI Training (continued)
  - There should be a process in place to track staff participation in the required trainings.
  - It is not required to have an outcome deficiency to be cited for this tag to be cited for deficient staff training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training
  - All facilities must develop, implement and permanently maintain an effective training program for all staff, which includes training on the standards, policies, and procedures for the infection prevention and control program, (as described at the §483.80(a)(2)) that is appropriate and effective, as determined by staff need.
  - Guidance addressing training on written standards, policies and procedures of the Infection Prevention and Control Program.
  - Added probes related to observations, interviews and review of training records.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training (continued)
  - F945 is a new Phase 3 requirement specific to Infection Control. All facilities must develop, implement and permanently maintain an effective training program for all staff, which includes training on the standards, policies, and procedures for the infection prevention and control program, (as described at §483.80(a)(2)) that is appropriate and effective, as determined by staff need.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training (continued)
  - Guidance has been written to address infection control training. It is important to note that changes to the facility's population, community infection risk, national standards, staff turnover, facility's physical environment, or facility assessment may necessitate ongoing revisions to the facility's training program for infection prevention and control.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training (continued)
  - All Training should support current scope and standards of practice through curricula which detail learning objectives, performance standards, evaluation criteria, and addresses potential risks to residents, staff, and volunteers if procedures are not followed. There should be a process in place to track staff participation in and understanding of the required training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training (continued)
  - Surveyors can utilize interviews, observations, and record reviews to determine the following:
    - Did staff observations or did interviews with residents and/or resident representatives indicate a training need? Did Staff report and/or did the training records indicate the staff member did not receive training on the concern identified by the surveyor?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training (continued)
  - What process does the facility have to encourage staff to express concerns and request training in challenging situations? Does the facility respond to staff's concerns and requests for training?
  - Review the training coursework to determine if the content meets professional standards/guidelines and covers facility policy and procedures for infection prevention and control.
  - Does the facility implement the training program and ensure staff are instructed to meet the requirements of §483.80(a)(2), Infection Control, F880?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F945 Infection Control Training (continued)
  - Surveyors should verify that the facility has a mandatory requirement that all facility staff participate in infection prevention and control training, with a process a process in place to track participation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F946 Compliance and Ethics Training
  - The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85 – §483.95 (f)(1) An effective way to communicate the program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.
  - §483.95(f)(2) Annual training if the operating organization operates five or more facilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F946 Compliance and Ethics Training (continued)
  - The operating organization (the individual or entity that operates a facility) for each facility must provide a training program or another practical manner to effectively communicate the standards, policies, and procedures of the compliance and ethics program to its entire staff. There should be a process in place to track staff participation in the required trainings.
  - In addition, for the operating organizations that operate five or more facilities, annual training for staff on the compliance and ethics program must be conducted.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F947 Nurse Aide Training
  - Required in-service training for nurse aides.
  - In-service training must: §483.95(g)(3) Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at §483.70(e) and may address the special needs of residents as determined by the facility staff.
  - Guidance expanded to reflect that the minimum 12-hour nurse aide training, in addition to ensuring competence, and including dementia and abuse training, must address areas of weakness as determined in nurse aide performance reviews.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F947 Nurse Aide Training
  - All facilities must develop, implement and permanently maintain an in-service training program for nurse aides that is appropriate and effective, as determined by nurse aide performance reviews and the facility assessment as specified at §483.70(e).

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F947 Nurse Aide Training (continued)
  - There are a variety of methods that could be used to provide training. For example, nurse aide training may be facilitated through any combination of in-person instruction, webinars and/or supervised practical training hours and should be reflective of nurse aides' performance reviews, in order to address identified weaknesses. When able, each nurse aide should be evaluated based on individual performance, and the facility should develop training that can be utilized and beneficial to all nurse aide staff when applicable.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F949 Behavioral Health Training
  - Facilities must develop, implement, and maintain an effective training program for all staff, which includes, at a minimum, training on behavioral health care and services (consistent with §483.40) that is appropriate and effective, as determined by staff need and facility assessment (as specified at §483.70(e)).
  - CMS drafted language to specify that behavioral health training must be developed, implemented, and maintained for all staff.
  - The training must be appropriate and effective, as determined by need and the facility assessment.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F949 Behavioral Health Training: New Provision for Phase 3
  - Training should include competencies/skills necessary to provide:
    - Person-centered care reflective of resident's goals for care.
    - Interpersonal communication that promotes mental/psychosocial well-being.
    - Meaningful activities which promote engagement/positive relationships.
    - An environment/atmosphere that is conducive to mental/ psychosocial well being.;

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F949 Behavioral Health Training: New Provision for Phase 3 (continued)
  - Individualized, non-pharmacological approaches to care.
  - Care specific to the individual needs of residents diagnosed with a mental, psychosocial, or substance use disorder, a history of trauma, and/or pot-traumatic stress disorder, or other behavioral health condition.
  - Care specific to the individual needs of residents diagnosed with dementia.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
483.95 Training Requirements
Key Changes to Training

- F949 Behavioral Health Training: New Provision for Phase 3 (continued)
  - CMS discussed the competencies and skills that should be included in the behavioral health training.
  - Areas that were discussed include: person-centered care and services, interpersonal communication, meaningful activities, environment atmosphere, and non-pharmacological approaches to care. This also includes the needs of residents diagnosed with a mental, psychosocial, or substance use disorder, a history of trauma, and/or post-traumatic stress disorder, or other behavioral health condition and the needs of residents living with dementia.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

F940 Training Requirements is the general requirement for facilities to

- Develop,
- Implement, and
- Maintain

an effective training program that is based on the Facility Assessment.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements

F940 Training Requirements

- Training must be completed for:
  - new staff,
  - existing staff,
  - contracted individuals and
  - volunteers (consistent with their roles).

  The amount and type of training required should be **reflective** of the **services** and **patient acuity** identified in the **Facility Assessment.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- Requirements of Participation, Phase 3, added a new regulatory group, Training Requirements.
- Below regulations effective as of November 28, 2017.
  - F943 Abuse, Neglect and Exploitation Training.
  - F947 Required In-Service Training for Nurse Aides.
  - F948 Training for Feeding Assistants.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- Below regulations effective as of November 28, 2019.
  - F940 Training Requirements.
  - F941 Communication Training.
  - F942 Resident's Rights Training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

F940 Training Requirements states training topics must include, but not limited to:

- Communication
- Resident's Rights
- QAPI
- Infection Control
- Compliance and Ethics
- Behavioral Health
- Abuse, Neglect and Exploitation Training
- Required In-Service Training for Nurse Aides
- Training for Feeding Assistants

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

F940 Training Requirements

- Cross reference these training topics with the organization's:
  - New staff orientation training topics.
  - Annual mandatory reeducation plan.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- Certain Training Requirements have tags with noteworthy changes.
- HHI to highlight these changes throughout the 8-week course.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes

F-Tag	Tag Subject	Noteworthy Changes
F940	Training Requirements	New guidance.
F941	Communication Training	New guidance.
F942	Resident Rights Training	New guidance.
F944	QAPI Program Training	Mandatory training.
F945	Infection Control Training	Added new guidance for training related to Infection Control.
F946	Compliance and Ethics Training	Annual training requirement for organizations with 5 or more facilities.
F947	Nurse Aide Training	New guidance.
F949	Behavioral Health Training	New guidance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements
Noteworthy Changes

- F940 Training Requirements
  - Facilities must develop, implement, and maintain effective training program for:
    - All **new** and **existing staff**;
    - All **individuals providing services** under contract; and
    - **Volunteers.**
  - Facilities must use the **Facility Assessment at F838** to determine the amount and types of training necessary.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
Communication Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- F941 Communication Training requirement states that facilities must have mandatory training for direct care staff on effective communications.
- Throughout the RoPs, the importance of communication is emphasized, including for communication
    - across all shifts and
    - information sharing between staff, residents and representatives.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- F941 Communication Training
  - Direct care staff need to understand their responsibilities for **reporting change in condition** and **sharing information between team members** for continuity in care provided that is based on individualized interventions.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes 941 Communication Training

- F941 Communication Training
  - Guidance includes description of:
    - Effective Communication.
    - Direct Care Staff.
  - A facility must include effective communications as mandatory training for direct care staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes 941 Communication Training

- F941 Communication Training
  - **Effective communication** is a process of **dialogue** between individuals.
  - The skills include speaking to others in a way they can:
    - Understand.
    - Active listening.
    - Observation of verbal cues.
    - Observation of non-verbal cues.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes 941 Communication Training

- F941 Communication Training
  - Direct Care Staff are those individuals 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."*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes 941 Communication Training

- F941 Communication Training
  - Topics reflect the resident population.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes Training Requirements Regulation – F941

- Training Requirements Regulation
- F-Tag 941 Communication
  - A facility must include **effective communications** as mandatory training for direct care staff.
  - Phase 3 implementation.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes Training Requirements Regulation – F941

- Training Requirements Regulation
- Communication
  - Training all nursing home staff, particularly direct care staff, to be on the **lookout for changes in a resident's condition** and to **effectively communicate those changes** is one tool LTC facilities can employ to
    - improve patient **safety**,
    - create a more **person-centered environment**, and
    - **reduce** the number of **adverse events** or other resident complications.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes Training Requirements Regulation – F941

- Training Requirements Regulation
- Communication
  - Effective communication has been identified as important in reducing unnecessary hospitalizations as well as for improving a nursing home resident's overall quality of life and quality of care.
  - Breakdowns in communications are a known contributor to adverse events of all types.
  - *Effective as stated* in Resident Rights means for some residents the use of auxiliary aids and services.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes Training Requirements Regulation – F941

- Training Requirements Regulation
- Communication
  - CMS believes communications training is **vital**, also that each facility should have the **flexibility to determine**, based on its internal facility assessment and competencies and skill sets needed for employees, **how to structure training** to meet its specific needs.
  - CMS also recognizes that **training needs** are likely to **change over time.**

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
Resident Rights Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- F942 Resident's Rights Training
  - The requirement at F942 notes that facilities must ensure that **all staff members** – not just direct care staff – receive education on **resident's rights** and the **facility's responsibilities** in providing care for its residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- F942 Resident's Rights Training
  - Under F550 Resident's Rights, residents have the right to be **treated with dignity and respect**, and all interactions with residents by staff must assist the residents in:
    - maintaining/enhancing their **self-esteem** and **self-worth**,
    - show **respect** for each resident's **individuality** and
    - incorporate the residents' **goals, choices** and **preferences.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

- F942 Resident's Rights Training
  - May be in place at most facilities, but ensure the curriculum is adequately defined.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F942 Residents' Rights Training

- F942 Residents' Rights Training
  - Facilities must develop and implement an ongoing education program on all residents' rights and facility responsibilities for caring of residents as outline in §483.10.
  - Education program should:
    - Support current scope and standards of practice.
    - Incorporate learning objectives, performance standards, and evaluation criteria.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F942 Residents' Rights Training

- F942 Residents' Rights Training
  - The guidance for F942 in Phase 3 requirements includes language to specify that an ongoing education program must be developed and implemented related to resident rights of every nursing home resident.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F942 Residents' Rights Training

- F942 Residents' Rights Training
  - CMS provides surveyors with probes to assist in their investigation. This includes the use of:
    - interviews,
    - observations, and
    - record review

    to investigate concerns with staff knowledge and understanding of resident rights and facility responsibilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
- New Resident Rights F-Tag Numbering
  - Resident Rights is a person-centered focus.
  - Preceding Resident Rights requirements have remained but expanded and clarified.
  - Many of the regulations from the Quality-of-Life section are relocated to Resident Rights.
  - Resident Rights F-Tags (151-177) re-numbered to reflect the new F-Tags 550-586.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
- New Resident Rights F-Tag Numbering
  - **Provisions** were added to reflect **changes in technology**, such as electronic communication.
  - **Interpretative guidance** revised to:
    - provide **clarity**,
    - additional **direction**, and
    - **examples** of non-compliance.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
- New Resident Rights F-Tag Numbering
  - F551 Resident Representative *
  - F553 Participate in Planning Care
  - F555 Choice of Attending Physician
  - F563 Visitation
  - F564 Visitation Rights
  - F578 Right to Request/Refuse Treatment/ Advance Directive
  - F585 Grievances
  - F586 External Entities

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F551 – Resident Representatives
    - *Previously F152.
    - Resident representative acts within their legal responsibility.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F551 – Resident Representatives
  - Guidance addresses changes and the facility's responsibility to assure the resident representative acts within their legal responsibility.
  - Surveyors are directed to
    - check for the designation of a resident representative and
    - whether the resident's delegation of rights have been followed by facility staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F553 – Participation in Care Planning
    - Previously F154/F280.
    - Resident has the right to participate in care planning process.
    - Facility upholds rights.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F553 – Participation in Care Planning
  - Regulations require that residents:
    - have the right to **participate** in the care planning process,
    - to **receive** those care planned services, and
    - **see the care plan** after significant changes.
  - Guidance addresses ways in which the facility can support these rights and **ways for the surveyor** to determine if these regulatory requirements have been met.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F555 – Choice of Attending Physician
    - Previously F163.
    - Physician must be **licensed to practice.**
  - Regulations require that **physicians** providing care to nursing home residents be **properly licensed** to practice.
  - Guidance addresses the **ways a surveyor can determine** if these regulatory requirements are being met.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F563/F564 – Visitation
    - Previously F172.
    - Resident's right to visitors.
    - Restriction for clinical or safety reasons.
    - Informing of visitation rights.
    - Equal visitation privileges.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F563/F564 – Visitation
  - Clarifies a resident's **right to have visitors**, including the requirement to **inform residents** of their **visitation rights**, and **equal visitation privileges.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F563/F564 – Visitation
  - Facility's responsibility to uphold these rights, as well as explanation of the facility's responsibility when these rights are restricted for clinical or safety reasons.
  - Guidance clarifies clinical and safety restrictions and how the facility must continue to support visiting rights, so as not to infringe on the rights of other residents.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F563/F564 – Visitation
  - Facilities are required to have **written policy and procedures** regarding visitation rights that include any clinically necessary or reasonable restrictions or limitations or safety restrictions or limitations.
  - The facility is responsible for ensuring that **all visitors** enjoy full and **equal visitation privileges** consistent with **resident preferences**.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F578 – Right to Request/Refuse Treatment/Advance Directive
    - Previously F155.
    - Facility's responsibility to assist residents in establishing advance directives.
  - Regulations address the facility's responsibility when it comes to residents establishing an advance directive.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F578 – Right to Request/Refuse Treatment/Advance Directive
    - Guidance addresses ways that a surveyor can determine if these regulatory requirements have been met and provides direction on where to look for other areas of concern.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F585 – Grievances
    - Previously F165.
    - Grievance official responsibilities.
    - Facility's responsibility to inform residents of how to file a grievance, and to maintain records.
    - Grievance policy.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F585 – Grievances
    - Regulations delineate the **grievance official's responsibilities** and the general requirements for providing information on how to file a grievance or complaint.
    - Addresses the **maintenance of grievance records** and the establishment of a **grievance policy** to ensure the **prompt resolution** of all grievances.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F585 – Grievances
    - Guidance includes situations depicting when a facility may not comply and the direction to go for grievances which involve the reporting of alleged violations.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F586 – External Entities
    - Previously F168.
    - Communication with Federal, State, or local officials must be allowed.
  - The new regulations include the facility's responsibility to ensure that **residents are able to communicate freely** with
    - Federal,
    - State, or
    - local representatives.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes §483.10 Resident Rights

- §483.10 Resident Rights
  - F586 – External Entities
    - Previously F168.
    - Communication with Federal, State, or local officials must be allowed.
  - The new regulations include the facility's responsibility to ensure that **residents are able to communicate freely** with
    - Federal,
    - State, or
    - local representatives.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
QAPI Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F944 QAPI Training

- F944 QAPI Training
  - §483.95(d) Quality Assurance and Performance Improvement.
  - A facility must include as part of its QAPI program **mandatory training** that **outlines** and **informs** staff of the **elements** and **goals** of the facility's QAPI program as set forth at the §483.75.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F944 QAPI Training

- F944 QAPI Training (continued)
- Facilities must conduct mandatory training, for all staff on the facility's QAPI program.
  - The training should also include the staff's role in the facility's QAPI program and how to communicate concerns, problems or opportunities for improvement to the facility's QAA Committee.
  - As updates are made to the facility's QAPI program or goals, the facility's training should also be updated and staff trained on the updates, as appropriate.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F944 QAPI Training

- F944 QAPI Training (continued)
  - There should be a process in place to **track staff participation** in the required trainings.
  - It is not required to have an outcome deficiency to be cited for this tag to be cited for deficient staff training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes § 483.95 Training Requirements – F944

- § 483.95 Training Requirements
- F-Tag 944 QAPI Training
  - A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes § 483.95 Training Requirements – F944

- § 483.95 Training Requirements
- F-Tag 944 Quality Assurance and Performance Improvement (QAPI)
  - At § 485.95(d), CMS shall require facilities provide mandatory QAPI training to its staff. This training would outline the elements and goals of the facility's QAPI program.
  - All facility staff should be **aware of what a QAPI program entails** and **how** the facility intends to **implement** and **monitor** their program.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes § 483.95 Training Requirements – F944

- § 483.95 Training Requirements
- F-Tag 944 Quality Assurance and Performance Improvement (QAPI)
  - Given that a facility's QAPI program is meant to encompass **input from facility staff**, it is imperative that staff members are adequately trained on the elements of the facility's QAPI program.
  - CMS shall require facilities to include mandatory training as a part of their QAPI program that educates staff on the **written standards, policies, and procedures for the program.**

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
Infection Control Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training
  - All facilities must develop, implement and permanently maintain an effective training program for all staff, which includes training on the standards, policies, and procedures for the infection prevention and control program, (as described at the §483.80(a)(2)) that is appropriate and effective, as determined by staff need.
  - Guidance addressing training on written standards, policies and procedures of the Infection Prevention and Control Program.
  - Added probes related to observations, interviews and review of training records.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training
  - Guidance addressing **training on written standards**, **policies** and **procedures** of the Infection Prevention and Control Program.
  - Added probes related to **observations, interviews** and **review of training records.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training (continued)
  - Changes to the facility's
    - population,
    - community infection risk,
    - national standards,
    - staff turnover,
    - facility's physical environment, or
    - facility assessment,

    may necessitate **ongoing revisions** to the facility's training program for infection prevention and control.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training (continued)
  - All Training should support current scope and standards of practice through curricula which detail:
    - learning objectives,
    - performance standards,
    - evaluation criteria, and
    - addresses potential risks

    to residents, staff, and volunteers if procedures are not followed.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training (continued)
  - Process in place to track **staff participation** and **understanding** of the required training.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training (continued)
  - Surveyors can utilize **interviews, observations,** and **record reviews** to determine the following:
    - Did staff observations or did interviews with residents and/or resident representatives indicate a training need?
    - Did Staff report and/or did the training records indicate the staff member did not receive training on the concern identified by the surveyor?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training (continued)
  - What **process** does the facility have to encourage staff to express concerns and request training in challenging situations? Does the facility respond to staff's concerns and requests for training?
  - Review the **training coursework** to determine if the content meets professional standards/guidelines and covers facility policy and procedures for infection prevention and control.
  - Does the facility **implement** the training program and **ensure staff are instructed to meet the requirements** of §483.80(a)(2), Infection Control, F880?

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F945 Infection Control Training

- F945 Infection Control Training (continued)
  - Surveyors should **verify** that the facility has a **mandatory requirement** that all facility staff participate in infection prevention and control training, with a **process in place** to **track participation**.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
Compliance and Ethics Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F946 Compliance and Ethics Training

P-R-E-P-A-R-E

Policies and Procedures

Reporting and Investigating

Education and Training

Prevention and Response

Auditing and Monitoring

Responsibility/Oversight of Compliance Officer/Committee

Enforcement, Discipline and Incentives

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F946 Compliance and Ethics Training

- F946 Compliance and Ethics Training
  - The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85 – §483.95 (f)(1) An effective way to communicate the program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.
  - §483.95(f)(2) Annual training if the operating organization operates five or more facilities.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F946 Compliance and Ethics Training

- F946 Compliance and Ethics Training (continued)
  - There should be a process in place to track staff participation in the required trainings.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
Nurse Aide Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F947 Nurse Aide Training

- F947 Nurse Aide Training
  - Required in-service training for nurse aides.
  - In-service training must: §483.95(g)(3)
    - Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at §483.70(e) and may
    - Address the special needs of residents as determined by the facility staff.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F947 Nurse Aide Training

- F947 Nurse Aide Training
  - Guidance expanded to reflect:
    - Minimum 12-hour nurse aide training.
    - To ensuring competence.
    - Including dementia training.
    - Including abuse training.

    Must address areas of weakness as determined in nurse aide performance reviews.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F947 Nurse Aide Training

- F947 Nurse Aide Training (continued)
  - There are a **variety of methods** that could be used to provide training. For example, nurse aide training may be facilitated through any combination of **in-person instruction**, **webinars** and/or **supervised practical training hours** and should be reflective of nurse aides' performance reviews, in order to address identified weaknesses.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F947 Nurse Aide Training

- F947 Nurse Aide Training (continued)
  - When able, each nurse aide should be **evaluated** based on **individual performance**, and the facility should **develop training** that can be utilized and beneficial to all nurse aide staff when applicable.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview
F940 Training Requirements
Noteworthy Changes F947 Nurse Aide Training

- F947 Nurse Aide Training (continued)

"Be sufficient to ensure the continuing competence of nurse aides but must be no less than 12 hours per year.

- *Include dementia management training and resident abuse prevention training.*
- *Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at § 483.70(e) and may address the special needs of residents as determined by the facility staff.*
- *For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired."*

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F947 Nurse Aide Training

- F947 Nurse Aide Training (continued)
- A facility must **not** use any individual working in the facility as a **paid feeding assistant** unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in §483.160.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)
Training Requirements Overview

F940
Behavioral Training Requirements

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F949 Behavioral Health Training

- F949 Behavioral Health Training: New Provision for Phase 3
  - Training should include competencies/skills necessary to provide:
    - Person-centered care reflective of resident's goals for care.
    - Interpersonal communication that promotes mental/psychosocial well-being.
    - Meaningful activities which promote engagement/positive relationships.
    - An environment/atmosphere that is conducive to mental/ psychosocial well being.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F949 Behavioral Health Training

- F949 Behavioral Health Training: New Provision for Phase 3 (continued)
  - Individualized, non-pharmacological approaches to care.
  - Care specific to the individual needs of residents diagnosed with a mental, psychosocial, or substance use disorder, a history of trauma, and/or post-traumatic stress disorder, or other behavioral health condition.
  - Care specific to the individual needs of residents diagnosed with dementia.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F656 Comprehensive Person-Centered Care Plan

- F656 Comprehensive Person-Centered Care Plan
- §483.21(b) (Formerly F279)
  - F656 is where noncompliance with Comprehensive Person-Centered Care plan will be cited, formerly F279.
  - Section 483.21(b) contains requirements for facilities to **develop** and **implement** a comprehensive, person-centered care plan.
  - Previously, failure to implement the care plan was cited at F282, Qualified Professional, but the **word "implement" was added to these requirements.**

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F656 Comprehensive Person-Centered Care Plan

- F656 Comprehensive Person-Centered Care Plan
- §483.21(b) (Formerly F279)
  - The guidance at F656 as been **expanded** to include the **definition** and a **discussion** of Person-Centered, which means to:
  - "**Focus** on the resident as the **locus of control.**"
  - "**Support the resident in making their own choices.**"
  - "**Control over their daily lives.**"

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F656 Comprehensive Person-Centered Care Plan

- F656 Comprehensive Person-Centered Care Plan
- §483.21(b) (Formerly F279)
  - Provisions require the Comprehensive Care Plan describe:
    - Resident goals and preferences.
    - Potential for discharge, including referrals to local contact agency.
    - Discharge plan if applicable.
    - Specialized services from PASRR recommendations or rationale for disagreement.

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP) Training Requirements Overview

F940 Training Requirements

Noteworthy Changes F949 Behavioral Health Training

- F949 Behavioral Health Training
  - Facilities must develop, implement, and maintain an effective training program for all staff, which includes, at a minimum, **training on behavioral health care and services** (consistent with §483.40) that is appropriate and effective, as determined by staff need and facility assessment (as specified at §483.70(e)).
  - CMS drafted language to specify that behavioral health training must be **developed, implemented, and maintained for all staff.**
  - The training must be appropriate and effective, as determined by need and the facility assessment.

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Handouts / Downloads

Harmony Healthcare INTERNATIONAL

Requirements of Participation (RoP)
Handouts/Downloads

1. HHI Blog 7.27.2022 Requirements of Participation (RoP) Phase 3 Revised Guidance 6.29.2022
2. Appendix PP - Guidance for Surveyors -State Operations Manual - June 2022
3. Exhibit 23 ASPEN Complaints-Incidents Tracking System (ACTS) 7.26.2022
4. Exhibit 358 - Sample Form Facility Reported Incidents 7.26.2022
5. Exhibit 359 - Follow-Up Investigation Report
6. F Tag Crosswalk 7.26.2022
7. Psychosocial Severity Guide - Appendix P Section IV E 7.26.2022
8. QSO Memo Guidance - Requirements of Participation (RoP) Phase 3 Dated 6.29.2022
9. State Operations Manual (SOM) Chapter 5 - June 2022

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

HHI Blog 7.27.2022 Requirements of Participation (RoP) Phase 3 Revised Guidance 6.29.2022

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Appendix PP - Guidance for Surveyors - State Operations Manual June 2022

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Exhibit 23 ASPEN Complaints-Incidents Tracking System (ACTS) 7.26.2022

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Exhibit 358
Sample Form for Facility Reported Incidents

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Exhibit 359
Follow-up Investigation Report

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

F Tag Crosswalk 7.26.2022

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

Psychosocial Severity Guide - Appendix P Section IV E 7.26.2022

Harmony Healthcare INTERNATIONAL

Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

QSO Memo Guidance - Requirements of Participation (RoP) Phase 3 Dated 6.29.2022

Harmony Healthcare INTERNATIONAL

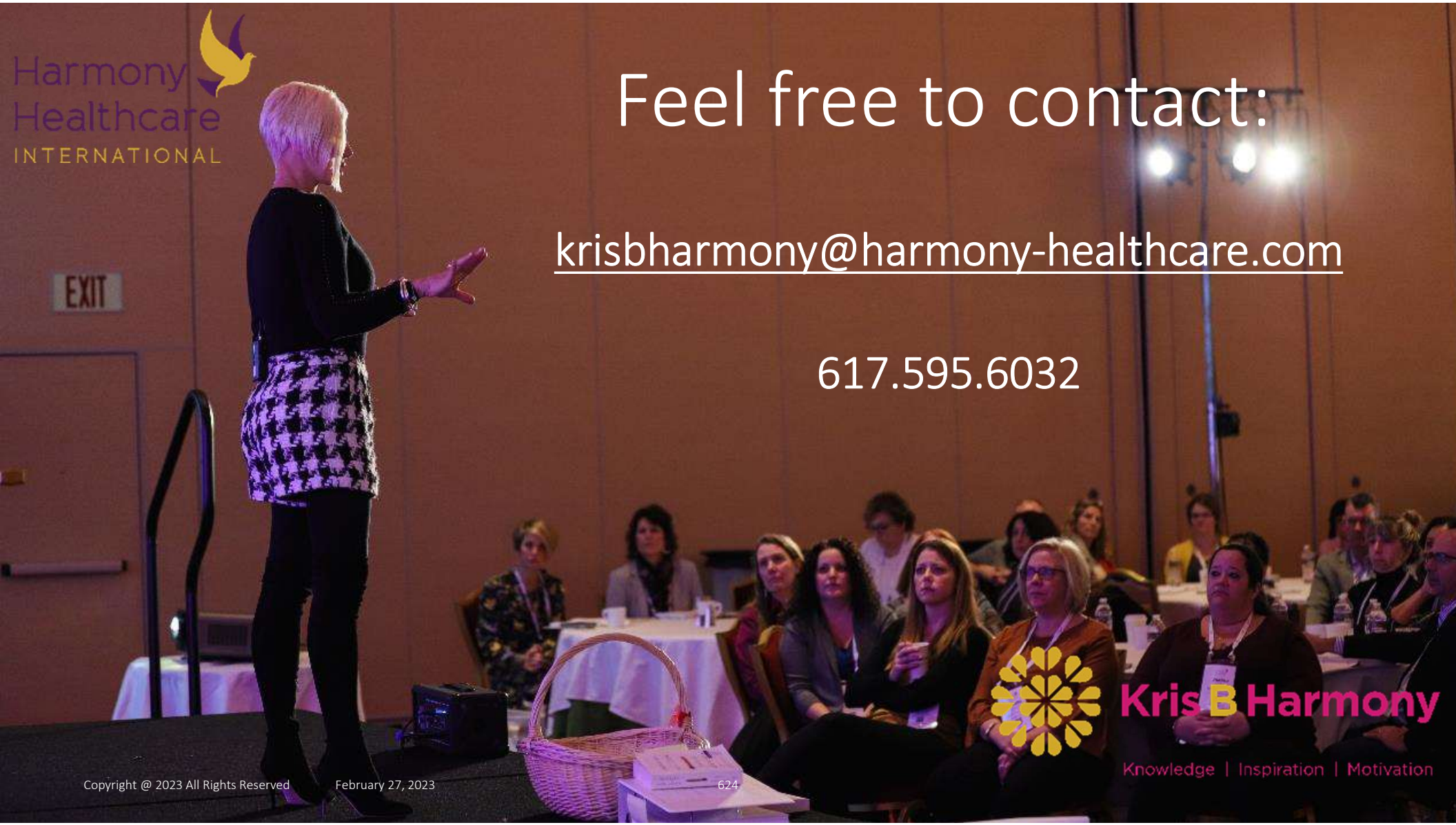
Harmony Healthcare International, Inc. (HHI)

Requirements of Participation (RoP)

Revised Guidance June 29, 2022

State Operations Manual (SOM) Chapter 5 - June 2022

Harmony Healthcare INTERNATIONAL



Connect With Kris

krisbharmony@harmony-healthcare.com

kmastrangelo@harmony-healthcare.com

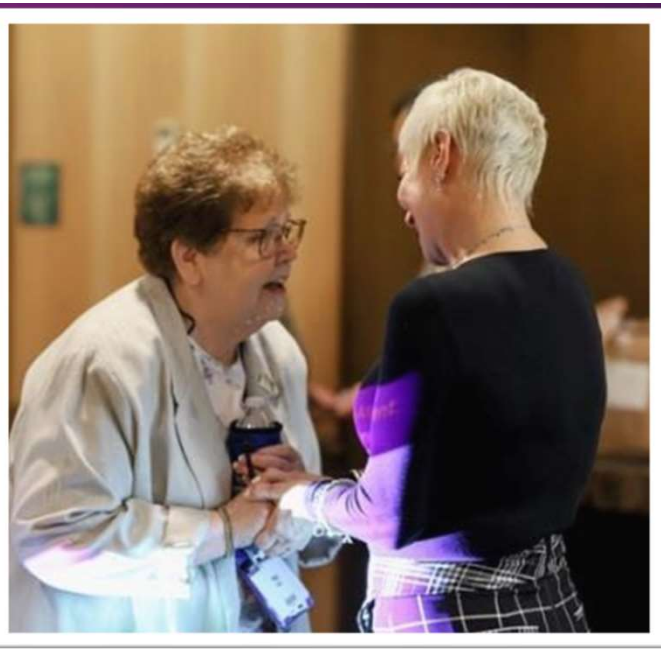
617.595.6032

@KrisBHarmony

@KrisBHarmony

@KrisBharmony

@KrisBHarmony



Connect With HHI and Follow HHI Blog

harmonyhealthcareinternational I @KrisBharmony

harmonyhealthcareinternational I @KrisBharmonyseries

harmonyhealthcareinternational I @KrisBharmony

@harmonyhlthcare I @Krismastrangelo

Harmony Healthcare INTERNATIONAL

About HHI

- HHI founded in 2001.
- Privately owned and operated.
- Female owned business.
- Ranked among Inc. Magazine's top 5,000 fastest growing private companies in America three years in a row.
- HHI active in all 50 states.
- HHI services over 1,000 Skilled Nursing Facilities.
- HHI trains thousands of clinicians every year.

Our Commitment
HHI C.A.R.E.S.

Built on the C.A.R.E.S. platform:

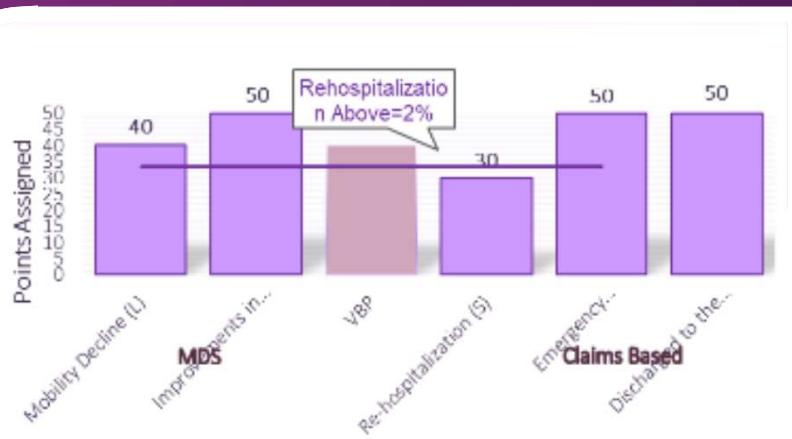
- Compliance
- Audit, Analysis
- Regulatory, Reimbursement, Rehabilitation
- Efficiency, Education
- Survey

Harmony Healthcare INTERNATIONAL

HHI Process

- Prescribed medical record review process that encompasses HHI's core business
- HHI Consultants provide expertise through teaching and training and an extensive chart audit process in order to ensure:
  - MDS Accuracy
  - MDS Supporting Documentation
  - Billing Accuracy
  - Nursing Documentation
  - Therapy Documentation
  - Clinically Appropriate Care

Month	Nov 16	Dec 16	Jan 17	Feb 17	Mar 17	Apr 17
Total Part A Revenue	$189,711.70	$202,597.35	$228,482.48	$176,144.00	$192,332.99	$148,861.18
Rehab Revenue	$181,514.58	$201,631.41	$227,975.42	$175,546.71	$190,248.65	$146,559.14
Therapy Portion	$80,465.58	$83,667.77	$100,444.39	$79,055.93	$86,172.60	$67,534.29
% Therapy Portion	42.4%	41.3%	44.0%	44.9%	44.8%	45.4%
% Therapy of Total Revenue	95.7%	99.5%	99.8%	99.7%	98.9%	98.5%
% Therapy RUG Days (P)	93.9%	99.4%	99.6%	99.5%	98.6%	97.5%
Part A Rate	$442.22	$434.76	$464.40	$465.99	$453.62	$462.30
% of Max Rate	61.9%	60.9%	65.0%	65.3%	63.5%	64.8%
ADC	14.30	15.03	15.87	13.50	13.68	10.73



Complimentary HHI Offerings

- Medicare Part A PDPM Revenue and Risk Analysis
- Five-Star Quality Rating Analysis
  - Staffing Domain
  - Quality Measure Domain
- PEPPER Analysis
- Medicaid RUGS Revenue and Risk Analysis

Harmony Healthcare INTERNATIONAL

https://www.harmony-healthcare.com/harmonyhelp

Knowledge
Support
Available

HarmonyHelp

HarmonyHelp provides resources for the entire interdisciplinary team. Access HHI's vault of information on Compliance, Regulatory, Reimbursement, Survey, Education, Manuals (RAI, Medicare, Billing, ICD-10), PowerPoints, On Demand Training, Toolkits, Forms, Library of Final Rules, Kris's Brain and much more.

The **Knowledge Center** is loaded with **information** that will assist staff with daily responsibilities at the facility.

Manuals I Tools I On Demand WebinarsI
Rules and Regulations

Harmony Healthcare INTERNATIONAL

HHI Consultants

"HHI Consultants are cross-trained on the C.A.R.E.S. platform."

Harmony Healthcare International, Inc. (HHI)

HHI Team

The HHI Consultants

- Accomplished HHI Consultants.
- Located across the country; servicing all regions.
- Administrators, Billing Experts, Nurses, Occupational Therapists, Physical Therapists, and Speech Language Pathologists.
- Cross-trained to communicate effectively with all disciplines.

Harmony Healthcare INTERNATIONAL

The HHI Team

"HHI strives and thrives for Harmony within and outside of the work environment."

HHI employs positive, proactive and polite staff with a life-long desire to learn, teach and assist the health care industry in improving patient care.

The HHI Team has decades of experience and expertise in the healthcare industry.

Harmony Healthcare INTERNATIONAL

HHI
Services and Plans

Gold C.A.R.E.S.
2 Year Service Plan

Platinum C.A.R.E.S.
3 Year Service Plan

List of HHI Services

PDPM Training and Audits | Medicare | Compliance | Rehab Program Development | Seminars | MMQ Audits | Mock RAC Audits | Rehab Certification | Mock Health Inspection Survey | MDS Competency | Talent Management | Denials Management | Compliance Certification | Clinically Appropriate Stay | QAPI | QIS | Medicare Part B Program | MDSC Mentor Program | Case Mix Consulting | Professional Development | Leadership Trainings | Regulatory and Survey Assistance | Five Star | PBJ | Quality Measures | Analysis | Staff Training | Infection Control and More!

Silver C.A.R.E.S.
1 Year Service Plan

A La C.A.R.E.S.
Customized Service Plan

HHI Services
HHI Service Plans

Built on the C.A.R.E.S. platform:

- Platinum C.A.R.E.S.
  - 3-Year Service Contract.
- Gold C.A.R.E.S.
  - 2-Year Service Contract.
- Silver C.A.R.E.S.
  - 1-Year Service Contract.
- A La C.A.R.E.S.
  - Flexible service contract.

Harmony Healthcare INTERNATIONAL

Thank you and have a great day!

C.A.R.E.S.™

HHI C.A.R.E.S. About Care

Compliance | Analysis | Audit | Regulatory | Rehabilitation

Reimbursement | Education | Efficiency | Survey

"HHI C.A.R.E.S. About Care"

Harmony Healthcare INTERNATIONAL