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SURVEY PREPAREDNESS: F880 AND BEYOND

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Changes To COVID-19 Survey Activities And Increased Oversight In Nursing Homes, QSO-22-02-ALL

- Changes to focused infection control (FIC) surveys
  - Not required to FIC surveys within 3-5 days of nursing homes (SNFs) having 3 or more new COVID-19 confirmed cases, or 1 confirmed resident case in a facility that was previously COVID-19-free
  - Prioritize FIC surveys for SNFs reporting new cases and have low vaccination rates
  - Still perform annual FIC surveys of 20% of SNFs
- States allowed to combine revisits with complaint surveys and annual surveys
- Resume recertification surveys by establishing new intervals based on each SNF's next survey, not based on the last survey that was conducted prior to the COVID-19 public health emergency

Prioritization According To Potential Risk To Residents

- Special attention to SNFs with a history of noncompliance or allegations of noncompliance with:
  - Abuse or neglect;
  - Infection control;
  - Violations of transfer or discharge requirements;
  - Insufficient staffing or competency;
  - Special Focus Facilities (SFFs) and SFF candidates; and/or
  - Other Quality of Care Issues (e.g., falls, pressure ulcers, etc.).
- Prioritize investigations of complaints and facility reported incidents (FRIs) triaged as immediate jeopardy (IJ) within two working days, and Non-IJ-High within ten working days
- Investigate backlogged complaints/FRIs at the Non-IJ-Medium level at the next scheduled standard survey:
  - If the complaint/FRI was received *within one year* of the scheduled standard survey date
  - If the allegation involves staff to resident abuse, neglect, or misappropriation of resident property*, regardless of the date that complaint/FRI was received*

New Focus On Staff Competencies

- Do you have specific documentation showing staff have competency in skills and techniques necessary to care for residents' needs?
- Surveyors will be paying special attention to F726 for *sufficient* nursing staff with appropriate competencies
- Annual performance evaluations and competencies for aides and professional staff, including PRN and agency
  - Consider including competency checklists in onboarding packets

Other Continuing "Heightened Areas Of Concern"

- Antipsychotic medications
  - "focus efforts on identifying the inappropriate use of antipsychotic medications and emphasize non-pharmacologic approaches and person-centered care practices"
- Unplanned weight loss
- Loss of function/mobility
- Depression
- Abuse/neglect
- Pressure ulcers

Enhanced Enforcement F880

Scope & Severity	No Infection Control Deficiencies in Past Year	Infection Control Deficiencies Cited Once In Past Year	Infection Control Deficiencies Cited Twice or More In Past Two Years	Cited for Current Non-Compliance with Infection Control Deficiencies Regardless Of Past History
D/E Not wide-spread potential for harm	• Directed Plan of Correction	• Directed Plan of Correction • DDPNA* with 45-days to demonstrate compliance • Per Instance CMP up to $5000 (at State/CMS discretion)	• Directed Plan of Correction • DDPNA, 30-days to demonstrate compliance with Infection Control deficiencies • $15,000 Per Instance CMP (or per day CMP, as long as the total amount exceeds $15,000)	
F Widespread	• Directed Plan of Correction • DDPNA with 45-days to demonstrate compliance	• Directed Plan of Correction, • DDPNA with 45-days to demonstrate compliance, • $10,000 Per Instance CMP	• Directed Plan of Correction • DDPNA, 30-days to demonstrate compliance • $20,000 Per Instance CMP (or per day CMP, as long as the total amount exceeds $20,000)	

*DDPNA: Discretionary Denial of Payment for New Admission; QSO-20-31-All (June 1, 2020)

Enhanced Enforcement F880

Scope & Severity	No Infection Control Deficiencies in Past Year	Infection Control Deficiencies Cited Once In Past Year	Infection Control Deficiencies Cited Twice or More In Past Two Years	Cited for Current Non-Compliance with Infection Control Deficiencies Regardless Of Past History
G/H/I Harm				• Directed Plan of Correction • DDPNA with 30 days to demonstrate compliance • CMP imposed at highest amount option in the CMP analytic tool
J/K/L				• Mandatory remedies of Temporary Manager or Termination • Directed Plan of Correction • DDPNA, 15-days to demonstrate compliance • CMP imposed at highest amount option in the CMP analytic tool

CMPs Increased By Inflation: 2021

Scope/Severity	Per Day	Per Instance
IJ: J/K/L Category 3 with IJ	$6,888 -- $22,584	$2,259 -- $22,584
Category 3 without IJ	$6,888 -- $22,584	$2,259 -- $22,584
Category 2: F/G/H/I	$113 -- $6,774	$2,259 -- $22,584

Grounds to waive disapproval of nurse aide training program increases to $11,292

https://www.cms.gov/files/document/ltc-hha-clia-specific-cmp-adjustments-2021.pdf

Minimize Risk Of Per-Day CMPs

- Document immediate plans of correction following incidents
  - Assess resident(s) involved in the incident
  - Remove alleged perpetrator pending investigation
  - Report to all applicable agencies & law enforcement
  - Assess and protect other residents
  - Educate staff and volunteers (if applicable), ensuring they will not work with residents until they have been educated
  - Implement corrective measures
  - Monitor and audit

Quality Assurance And Process Improvement (QAPI)

- Review incident at QAPI committee to assess root causes and needed system improvements
  - Does your QAPI plan specify *ad hoc* meetings to respond immediately to incidents?
  - How do you document the meetings where these incidents are being analyzed?
  - Is a physician included?
  - What is reported to Board/Governing Body?
- Document for CORRECTED PAST NONCOMPLIANCE

How Far Back Can They Go?

Enforcement Considerations

- "Please note, when imposing an enforcement remedy for past noncompliance, CMS may reach back no further than the 'last standard survey' to do so. This means that a State should not postpone serious complaints that could lead to enforcement and expect to conduct them after the standard recertification survey."

CMS, "Long Term Care Survey Process (LTCSP) Procedure Guide,"

(*Eff*. January 27, 2022)

The New Vax Mandate F888 (F***)

- Already being enforced and citations issued

- Staff must be vaccinated or granted an exemption or have a temporary delay
  - Any staff not in these categories will be counted against your compliance rate

Who Are Staff?

- Staff, regardless of clinical responsibility or patient contact
- Employees
- Licensed practitioners
- Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement (including hospice and dialysis staff, therapists, mental health professionals)
- Adult students/trainees or volunteers
- Administrative staff
- Facility leadership
- Volunteer or other fiduciary board members
- Housekeeping and food services
- Staff that primarily provide services remotely via telework that occasionally encounter fellow staff, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities and others

Note: policies and procedures do not apply to staff who exclusively provide telehealth services or staff who provide support services if those services are provided outside of the facility with no direct contact with residents or other staff

Compliance Deadlines

COMPLIANCE DEADLINES AND STATUS	30 DAYS 1/27/2022	60 DAYS 2/28/2022	90 DAYS 3/28/2022
Elements Necessary to Establish Substantial Compliance	Policies and procedures developed and implemented	Policies and procedures developed and implemented	Policies and procedures developed and implemented
Elements Necessary to Establish Substantial Compliance	100% staff received at least one dose of vaccine except staff with a pending or approved qualifying exemption or a temporary delay recommended by CDC	100% staff fully vaccinated except staff with an approved qualifying exemption or a temporary delay recommended by CDC	100% staff fully vaccinated except staff with an approved qualifying exemption or a temporary delay recommended by CDC
Noncompliance But No Enforcement If . . .	Vax rate above 80% and a plan to achieve 100% staff vaccination rate within 60 days	Vax rate above 90% and a plan to achieve 100% staff vaccination rate within 30 days	

What Will Surveyors Look For?

- Process or plan for vaccinating all eligible staff
- Process or plan for providing exemptions and accommodations to those who are exempt
- Process or plan for tracking and documenting staff vaccinations, including booster doses, contraindications, exemptions and temporary delays
- Process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19
- Contingency plan for staff who are not fully vaccinated for COVID 19
  - Prioritize contingency plans for staff who have no shots
  - Include deadlines to obtain first dose
  - Actions you will take if deadline not met, such as actively seeking replacement staff or obtaining temp vaccinated staff

Required Policies And Procedures

(i) Process for ensuring all staff (except for staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements, or for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a first dose of vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents; by January 27, 2022

(ii) Process for ensuring that all staff are fully vaccinated for COVID-19, except for those staff who have been granted exemptions or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations by February 28, 2022;

(iii) Process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated. *This might include*

a. Reassigning staff to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assigning to residents who are not immunocompromised, unvaccinated).
b. Requiring staff to follow additional CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.

c. Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated staff in facilities located in counties with substantial to high community transmission.

d. Requiring staff to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff

Required Policies And Procedures

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

What Should Be On Proof Of Vaccination?

- The employee's name
- The type of vaccine administered
- The date(s) of administration
- The name of the healthcare professional(s) or clinic site(s) that administered the vaccine

Acceptable Proof Of Vaccination

- Record of immunization from a healthcare provider or pharmacy
- A copy of the COVID-19 Vaccination Record Card
- A copy of medical records documenting the vaccination
- A copy of immunization records from a public health, state, or tribal immunization information system
- A copy of any other official documentation containing the type of vaccine administered, date(s) of administration, and the name of the healthcare professional(s) or clinic site(s) administering the vaccine(s)

What About Contractors/Vendors?

- Amend contracts to require:
  - Only vaccinated staff?
  - Attestation?
  - Proof of vaccination status within one hour

- Right now testing is not an option to use in place of obtaining proof of vax status

- What about exempted contractors/vendors/volunteers?

Religious Exemptions (Title VII and PHRA)

- Requests for religious exemptions are generally assumed to be based on sincerely held religious beliefs
  - Per EEOC: "The fact that no religious group espouses such beliefs or the fact that the religious group to which the individual professes to belong may not accept such belief will not determine whether the belief is a religious belief of the employee or prospective employee."
  - If there is objective basis for questioning the religious nature or the sincerity, the facility may request additional factual supporting information
- Objections to the vaccine based on social, political or personal preferences or other non-religious concerns about the vaccine do not qualify for this exemption.
- Must have documented policy and procedure to accept, review and act upon requests for religious objections
- Surveyors will review policies and procedures and ask staff about them
- Surveyors CANNOT review the underlying requests for religious exemptions

CMS Staff Matrix

COVID-19 Staff Vaccination Status for Providers

Complete this form or provide a list containing the same information required in this form.

Section I: *Complete based on the Day 1 of the survey:*

Total # of staff:

partially vaccinated staff (5):

completely vaccinated staff (6):

pending exemption (8 and 9):

granted exemption (8 and 9):

temporary delay/new hire (10):

not vaccinated without exemption/delay (11):

Note: The sum of the #'s for columns 5, 6, 8 through 11 should equal the total # of staff.

					Vaccinated			Not Vaccinated			
Staff Name	Direct facility hire (DH), Contracted hire (C), Other (O)	Title	Position	Assigned work area	Partially vaccinated	Completely vaccinated	Booster dose	Pending (P) or Granted (G) medical exemption	Pending (PN) or Granted (GN) non-medical exemption	Temporary delay per CDC/ new hire	Not vaccinated without exemption/delay
	1	2	3	4	5	6	7	8	9	10	11

Matrix Instructions

- DH: direct facility hires
- C: contracted hires who provide care, treatment, or other services for SNF and/or its residents under contract or by other arrangement
- O: adult students, trainees and volunteers
- Assigned work area: physical location (e.g., laundry room, kitchen, unit, ward, wing)
  - If staff is PRN/floater/agency, indicate assigned work area on first day of survey
- Total number of staff: all staff in SNF including employees (*regardless of clinical responsibilities or resident contact*), licensed practitioners, adult students, trainees and volunteers, and individuals who provide care, treatment or other services for SNF and/or its residents, under contract or by other arrangement

Surveyor Tasks F888

- The assigned surveyor(s) should coordinate a review of the infection prevention and control *program, policy and procedures for staff COVID-19 vaccination,* antibiotic stewardship program, and the influenza, pneumococcal, *and COVID-19 for residents and staff.*
- *Facility should complete the COVID-19 Staff Vaccination Matrix within **four** hours*
- *Once the matrix is received, the assigned surveyor selects **eight staff** to review for COVID-19 vaccinations.*
  - *2 vaccinated staff (at least one Certified Nurse Aide/CNA and one contractor who provides services, such as hospice and dialysis staff, occupational therapists, mental health professionals, licensed practitioners)*
  - *6 unvaccinated staff, if available*
  - *3 unvaccinated staff (2 CNAs, if available) without exemption or reason for temporary delay.*
  - *1 non-medical exemption.*
  - *1 medical exemption (Note: If there are 2 or more staff with medical exemptions, select 50% of the staff from this category).*
  - *1 whose primary vaccine series has been temporarily delayed.*
- *If you identify any staff that weren't vaccinated and weren't granted an exemption or temporary delay (and weren't listed on the staff matrix), that individual(s) should be added to the staff sample*

Level 4 - Immediate Jeopardy (IJ)

- Noncompliance resulting in serious harm or death:
  - Did not meet the requirement of staff vaccinated or has no policies and procedures developed or implemented; **and**
  - 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death

OR,

- Noncompliance resulting in a likelihood for serious harm or death:
  - Did not meet the requirement of staff vaccinated; **and**
  - 3 or more resident infections in the last 4 weeks that did not result in serious harm or death; **and**
  - One of the following:
    - Any observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE so F880 would also be cited); **or**
    - or more components of the policies and procedures to ensure staff vaccination were not developed or implemented.

OR,

- More than 40% of staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates.

Level 3: Actual Harm That Is Not IJ

- Did not meet the requirement of staff vaccinated; and
- 3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; and
- 1 or more components of the policies and procedures were not developed and implemented

Level 2: No Actual Harm W/Potential For More Than Minimal Harm That Is Not IJ

- Did not meet the requirement of staff vaccinated; and
- No resident outbreaks

OR,

- Did not meet the requirement of staff vaccinated; and
- 1 or more components of the policies and procedures were not developed and implemented

Level 1

- Met the requirement of staff vaccinated; **and**

- 1 or more components of the policies and procedures to ensure staff vaccination were not developed and implemented (must be cited as widespread ("C")

Scope

- Isolated: 1% or more, but less than 25% of staff are unvaccinated (76% — 99% of staff are vaccinated)
- Pattern: 25% or more, but less than 40% of staff are unvaccinated (61% — 75% of staff are vaccinated)
- Widespread: 40% or more of staff are unvaccinated (0% - 60% of staff are vaccinated), OR 1 or more components of the policies and procedures listed above were not developed and implemented

Can We Test Visitors?

- YES . . .but
  - Only if you have the ability to do rapid tests in-house
  - You cannot require visitors to give you proof of vaccination
  - You cannot require visitors to give test results if you do not provide the testing

  - BUT…residents can tell you (and you can care plan) if they want to restrict their own visitors to those who are vaccinated or tested and give you proof

Closing Thoughts

- CMS is expected to issue additional guidance
- Stay tuned

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