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HOSPICE SURVEY PREPAREDNESS BINDER

Include all of the items below in your "Survey Binder" to have ready for the surveyor to review upon entrance.

Note: The items in **RED** *should be prepared as you near survey and re-ran each Monday morning for the survey binder.*

HOSPICE SURVEY PREPAREDNESS BINDER: Table of Contents

Other information to have ready to share, as requested by the surveyor:

- COVID Vaccine policy, staff and contractors vaccine status and documentation of proof
- Emergency Plan, to include updates regarding Emerging Infectious Diseases (EIDs), emergency training for staff and contractors and emergency plan drills
- Complaint log with oversight by Administrator and documentation of investigation and resolutions
- QAPI
- Contracts for review
- CLIA Waiver

FOR MORE INFORMATION: visit **www.hospicefundamentals.com**

HOSPICE FUNDAMENTALS

KNOWLEDGE • EXPERTISE • COMMON SENSE

Checklist

ELECTION STATEMENT COMPLIANCE

Due to the recent increase in denials related to a missing component in the election statement, use this tool as a checklist to ensure your Prudent Hospice has all of the items on the Election Statement. These items must be on the election form itself, and not just in the patient handbook, or part of another form. The MACs are denying in medical review if a component is missing from the Election Statement itself.

The hospice's election statement must include the following items of information:

- ☐ **Identification** of the particular hospice agency that will provide care to the beneficiary.
- ☐ **The beneficiary or their representative's (as applicable) acknowledgment** that they have been given a full understanding of hospice care, ***particularly the palliative rather than curative nature of treatment.***
- ☐ **The individual's acknowledgement** that the individual has been provided information on the hospice's coverage responsibility and that certain Medicare services are waived by the election. For hospice elections beginning on or after 10/1/2020, this would include providing the individual with information indicating that services unrelated to the terminal illness and related conditions are exceptional and unusual and the hospice should be providing virtually all care needed by the individual who has elected hospice.
- ☐ **The effective date of the election**, which may be the first day of hospice care or a later date, but cannot be a retroactive date. An individual may not designate an effective date that is retroactive.
- ☐ **The beneficiary's designated attending physician (if any).** Information identifying the attending physician recorded on the election statement should provide enough detail so that it is clear which physician, NP or PA was designated as the attending physician. This information should include, but is not limited to, the attending physician's full name, office address, NPI number, or any other detailed information to clearly identify the attending physician.
- ☐ **The beneficiary or their representative's acknowledgement** that the designated attending physician was their choice.
- ☐ **Information** on individual cost-sharing for hospice services.
- ☐ **Notification of the individual's (or representative's) right**to receive an election statement addendum if there are conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.
- ☐ **Information on the BFCC-QIO** , including the right to immediate advocacy and BFCC-QIO contact information
- ☐ **The signature** of the beneficiary or their representative.

Each hospice agency designs and prints its own election statement. CMS has provided examples for developing a hospice election statement Model Example of Hospice Election Statement.

HOSPICE FUNDAMENTALS

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Self-Assessment for Top 10 Survey Deficiencies

	Standard Citations re: POC/Coordination	Questions to Ask	Compliant?
1. 4. 5. 10.	§418.56(b) Standard: Plan of care L-Tag: L543 All hospice care and services furnished to patients and their families must follow an individualized, written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire. Medicare Hospice CoP: §418.56(c) Standard: Content of the Plan of Care L-Tag: L545 The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions Medicare Hospice CoP: §418.56(c)(2) Standard: Content of the Plan of Care L-Tag: L547 A detailed statement of the scope and frequency of services necessary to meet specific patient and family needs. Medicare Hospice CoP: §418.54(e)(2) Standard: Coordination of Services L-Tag: L555 Ensure that the care and services are provided in accordance with the plan of care.	• Were all disciplines involved in creating POC and have frequencies? • Were frequencies beyond "cookie cutter"? What percentage have the same? • Was collaboration shown with the IDG? • Was communication of plan shown to include attending (if any)? • Was plan specific to needs found on assessment? • Did plan incorporate goals and preferences of patient and family? • Were the frequency/discipline and interventions on the POC followed and documented?	
	Standard Citations re: Comprehensive Assessments	Questions to Ask	Compliant?
2.	§418.54I(6) – Drug profile L-Tag: L530 A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following: (i) Effectiveness of drug therapy (ii) Drug side effects (iii) Actual or potential drug interactions (iv) Duplicate	• Was a drug profile (with all four components) completed at SOC and with every comprehensive assessment after? (15 days, 21 during waiver) & with med chg? • How is the DRR documented? Can it be performed remotely if using telehealth?	

Self-Assessment for Top 10 Survey Deficiencies

8.	drug therapy Drug therapy currently associated with laboratory monitoring. Medicare Hospice CoP: §418.54(c)(7) Standard: Bereavement L-Tag: L531 An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.	• Does your EMR contain all four components?** • How do you document the bereavement assessment? Who does this? When is it completed? When is it updated? • Are comprehensive assessments completed within 5 days of the SOC (date of election) and at least every 15 days updated? (21 allowed during waiver period)	
9.	Medicare Hospice CoP: §418.54(b) Standard: Timeframe for completion of the comprehensive assessment L-Tag: 523 The hospice interdisciplinary group, in consultation with the individual's attending physician (if any) must complete the comprehensive assessment no later than 5 calendar days after the election of hospice care in accordance with §418.24.		
	Standard Citation re: Supervision of Aide		
3.	§418.76 (h) Standard: Supervision of hospice aides L-Tag: L629 A registered nurse must make an on-site visit to the patient's home: No less frequently than every 14 days to assess the quality of care and services provided by the hospice aid and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aid does not have to be present during this visit.	• Review records with aides for supervisory visits timeframes • What self-check does your EMR have for supervisory visits? • Waiver allows by phone! Don't miss a one! • Make it a habit- document supervision every visit.	
		•	
	The other two citations in top 10 were volunteers at 5% (waived) and infection control (FOCUS during pandemic!)	•	

Hospice Attachment
Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

L-900
§ 418.60 Condition of participation: Infection control.

(d) *Standard: COVID-19 Vaccination of facility staff.* The hospice must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospice staff, who provide any care, treatment, or other services for the hospice and/or its patients:

(i) Hospice employees;
(ii) Licensed practitioners;
(iii) Students, trainees, and volunteers; and
(iv) Individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following hospice staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the hospice that are performed exclusively outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as

recommended by CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the hospice and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A 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;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(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 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 hospice 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 hospice'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.

GUIDANCE

DEFINITIONS

**"Booster," ** per Centers for Disease Control and Prevention (CDC), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

"Clinical contraindications" refer to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, accessed at https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

"Fully vaccinated" refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

"**Good Faith Effort**" refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

"Primary Vaccination Series" refers to staff who have received a single-dose vaccine or all doses of a multi-dose vaccine for COVID-19.

"Staff" refers to individuals who provide any care, treatment, or other services for the hospice and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the hospice, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the hospice and who does not have any direct contact with patients and other staff specified in paragraph (d)(1).**

"Temporarily delayed vaccination" refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
(https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf)

Background

To protect hospice patients from COVID-19, each hospice must develop and implement policies and procedures as specified in §418.60(d) to ensure that all hospice staff are fully vaccinated against COVID- 19. Per §418.60(d)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who are outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff. For example, this may include a telehealth provider who does not visit the settings where hospice services are provided to patients, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of those settings.

The vaccine may be offered and provided directly by the hospice or, if unavailable through the hospice, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, a hospice that are conducted by "one-off" vendors, volunteers, and professionals. Hospices are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. Hospices should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the hospice (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker's Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

Hospices will be expected to meet the following:

Vaccination Enforcement
CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule**. Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures
The hospice policies and procedures must be implemented and address each of the following components:

The hospice must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary delay, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to "mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated." The requirement is not explicit and does not specify which actions must be taken.

Facilities may also consult with their local health departments to identify other actions that can potentially reduce the risk of COVID-19 transmission from unvaccinated staff.

The hospice must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include type of exemption and supporting documentation) requirements by the hospice; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:
Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:
Certain allergies, or recognized medical conditions may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, hospices should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, accessed at https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the hospice's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

Hospices must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection

until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:
Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each hospice's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the hospice's acceptance or denial of the request. Rather, surveyors will review to ensure the hospice has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:
While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, a facility can address those individually Accommodations can be addressed in the hospice's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations.

Contingency Plans
For staff that are not fully vaccinated, the hospice must develop contingency plans for staff who have not completed the primary vaccination series for COVID-

Contingency plans should include actions that the hospice would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the hospice will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process
Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference
    - Surveyors will ask hospices to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
        - A process for ensuring all required staff have received, at a minimum, the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the hospice and/or its patients;
        - A process for ensuring that all required staff are fully vaccinated;
        - A process for ensuring that the hospice continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the hospice, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
        - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
        - 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;
        - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on an applicable Federal law;
        - A process for tracking and securely documenting information provided by those staff who have requested, and for whom the hospice has granted, an exemption from the staff COVID-19 vaccination requirements;
        - 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—
            - 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
            - a statement by the authenticating practitioner recommending that the staff member be exempted from the hospice's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
        - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

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

- The hospice will provide their process for how the hospice ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:
   - Surveyors will review the policies and procedures to ensure all components are present.
   - Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the hospice that may include:
     - Requiring unvaccinated 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.
     - Reassigning unvaccinated 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., assign to patients who are not immunocompromised, unvaccinated);
     - Requiring at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
     - Requiring unvaccinated 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.

   - Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
     - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated);
     - Contracted staff; and
     - Direct care staff with an exemption

   - There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.) Two of the direct care staff sampled should be contractors.

   - The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.

- For each individual identified by the hospice as vaccinated, surveyors will:
    - Review hospice records to verify vaccination status. Examples of acceptable forms of proof of vaccination include:
        - CDC COVID-19 vaccination record card (or a legible photo of the card),
        - Documentation of vaccination from a health care provider or electronic health record, or
        - State immunization information system record.

    - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the hospice as unvaccinated, surveyors will
    - Review hospice records
    - Determine, if they have been educated and offered vaccination
    - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
        - Request and review documentation of medical contraindication.
        - Request to see employee record of the staff education on the hospice policy and procedure regarding unvaccinated individuals.
    - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.

- For each individual identified by the hospice as unvaccinated due to a medical contraindication:
    - Review and verify that all required documentation is:
        - Signed and dated by physician or advanced practice provider.
        - States the specific vaccine that is contraindicated and the recognized clinical reason for the contraindication with a statement recommending exemption.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE**: Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction *and Good Faith Effort*:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.