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

Center for Clinical Standards and Quality

Ref: QSO-22-02-ALL

DATE: November 12, 2021

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Changes to COVID-19 Survey Activities and Increased Oversight in Nursing Homes

Memorandum Summary

- **CMS remains committed** to taking critical steps to protect vulnerable Americans to ensure the nation's health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- **CMS is announcing steps to assist State Survey Agencies (SAs) in addressing the backlog of complaint and recertification surveys. These steps include:**
  - Revising the criteria for conducting COVID-19 Focused Infection Control (FIC) Surveys;
  - Guidance for resuming recertification surveys; and
  - Temporary guidance and minor flexibilities related to complaint investigations.
- **CMS is increasing oversight in nursing homes** to allow a more focused review of quality-of-life and quality-of-care concerns.

Background

Since the beginning of the COVID-19 PHE, CMS has remained vigilant in assessing the needs of Medicare/Medicaid beneficiaries, health care providers/suppliers, and the State Survey Agencies (SAs). In the early days of the PHE, in an effort to control the spread of COVID-19, CMS developed a COVID-19 Focused Infection Control (FIC) survey and directed SAs to focus their efforts on infection prevention and control. Additionally, in order to prevent the spread of COVID-19, CMS limited onsite surveys and activities to FIC surveys; complaints and facility-reported incidents alleging immediate jeopardy (IJ) to beneficiary health and safety; revisit surveys needed to verify removal of IJ; and complaints related to infection control (see QSO-20-20-All and QSO-21-13). This temporary suspension and reprioritization of survey activity nationwide resulted in a backlog of complaint and recertification surveys to be investigated.

Also, CMS has taken actions to protect our Nation's most vulnerable citizens and aid the facilities that care for them. Among these actions, for example, CMS has implemented new requirements for COVID-19 testing and education, as well as offering and reporting of

vaccination for nursing home residents and staff. Working with the Centers for Disease Control and Prevention (CDC), CMS has also engaged nursing homes directly through regular provider calls and direct outreach to nursing homes from the Quality Improvement Organizations. These efforts, along with CDC's Long-Term Care Pharmacy Partnerships, and actions by communities and states, have resulted in millions of nursing home residents and staff being vaccinated, and a dramatic decrease in cases and deaths related to COVID-19 in nursing homes.

However, in August 2021, staff vaccination rates remained approximately 20 percentage points lower than resident vaccination rates. Therefore, we remain concerned about the transmission of the virus from unvaccinated staff to residents and are taking additional measures, such as establishing a staff vaccination requirement, to mitigate the spread of COVID-19 and protect residents. On November 4, 2021, CMS issued a regulation requiring that all nursing home staff be vaccinated against COVID-19 as a requirement for participating in the Medicare and Medicaid programs. This requirement also applies to nearly all Medicare and Medicaid-certified providers and suppliers.

Lastly, during the COVID-19 PHE, CMS has issued waivers and flexibilities to expand capacity, enhance staffing, and otherwise assist hospitals and other healthcare providers and suppliers to ensure that sufficient healthcare items and services are available to meet the needs of their communities during the pandemic. This information is available here: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/currentemergencies/coronavirus-waivers.

Discussion

While CMS has always focused on ensuring the health and safety of Medicare/Medicaid beneficiaries, the COVID-19 PHE warranted a more targeted approach for assessing compliance with CMS's infection prevention and control requirements. CMS is taking the following steps which will allow SAs to focus their efforts on identifying concerns for all aspects of quality of care, quality of life, and ensuring health and safety:

- FIC surveys: CMS is rescinding the requirement per QSO 20-31-All to conduct FIC surveys within 3-5 days of an outbreak of COVID-19. SAs may still conduct these surveys when concerns related to managing COVID-19, or infection control practices, arise.
  NOTE: While CMS is changing its policy regarding FIC surveys, there are other policies in QSO 20-31-All that are still in place.
- Resuming standard recertification surveys: SAs will continue to conduct recertification surveys, but do not need to conduct additional recertification surveys to make up for any surveys that could not be completed during the COVID-19 PHE. In other words, SAs will resume the normal survey schedule moving forward, as described in more detail below.
- Nursing Home complaints/facility-reported incidents: CMS is providing SAs with flexibilities to focus on allegations that are more serious.
- Timeframe for clearing backlogs: CMS will collaborate with each State to determine appropriate timeframes for clearing the survey backlog;
- Temporary guidance and flexibilities: As described below, CMS is providing temporary guidance and minor flexibilities for SAs to work through the current backlog of complaints and recertification surveys that is a direct result of the suspension of certain onsite survey activities in an effort to control the spread of COVID-19.

FIC Surveys

CMS will no longer require FIC surveys to be conducted within 3-5 days of a nursing home having 3 or more new COVID-19 confirmed cases, **or** 1 confirmed resident case in a facility that was previously COVID-19-free. However, each survey agency must continue to perform annual FIC surveys of 20% of nursing homes. States should prioritize these surveys for facilities that are reporting new cases and have low vaccination rates. To count toward the required 20%, these FIC surveys must be stand-alone surveys not associated with a recertification survey; the FIC survey may be combined with a complaint survey. States may also conduct these surveys when concerns related to COVID-19 infection control arise. The Critical Element (CE) Pathway and FIC protocol will remain available in the Survey Resource Folder. States that fail to perform these survey activities timely and completely could forfeit up to 5% of their Coronavirus Aid, Relief, and Economic Security (CARES) Act allocation, annually.

Recertification Surveys

SAs conduct unannounced standard recertification surveys, which provide a comprehensive review of the quality of care furnished in a facility. For long-term care (LTC) facilities, these recertification surveys must be conducted no later than 15 months after the previous recertification survey, with a statewide average interval of 12 months or less. The recertification frequency for continuing and acute care providers must follow the CMS Mission and Priority Document. CMS had previously suspended certain routine inspections as part of its response to the COVID-19 PHE to prioritize infection control and immediate jeopardy situations (QSO-20-20-All). CMS later advised states to resume surveys based on the availability of PPE and surveyor staffing (QSO-20-31-All and QSO-20-35-All). At this time, we believe SAs should be able to resume recertification surveys on a regular basis, and should do so by establishing new intervals based on each facility's next survey, not based on the last survey that was conducted prior to the COVID-19 PHE. For example:

> If the SA had scheduled a LTC recertification survey for a facility in April 2020, and was unable to conduct it because of the PHE, but now conducts that survey in August 2021, the next annual recertification survey would be due by the end of October 2022 (i.e., 15 months from completion of the August 2021 survey). We note that Special Focus Facilities are required to be surveyed once every 6 months. In this example, if this facility were an SFF, the next recertification survey would be due by the end of February 2022.
>
> For continuing and acute care providers, for example, if the SA had scheduled a home health agency or hospice program recertification survey in April 2020, and was unable to conduct it because of the PHE, but now conducts that survey in August 2021, the next recertification survey would be due by August of 2024 (i.e., 36 months from completion of the August 2021 survey).

CMS recommends that SAs prioritize recertification surveys according to the potential risk to residents, such as facilities with a history of noncompliance, or allegations of noncompliance, with any of the following:

- 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.).

In addition, CMS is temporarily allowing certain mandatory survey protocol tasks to be discretionary or triggered based on concerns identified during offsite preparation activities such as complaints to be investigated during the survey, or those raised by the ombudsman, and previous patterns of citations. These tasks can also be triggered based on concerns identified during the onsite survey through observations, interviews, and record reviews or if complaint(s) are to be investigated during the recertification survey. The mandatory survey tasks eligible for temporary discretion are the following:

- **Resident Council Meeting:** Surveyors interview up to 40 residents in the initial pool depending on facility census (See Attachment A of the Long Term Care Survey Process (LTCSP) Procedure Guide). If concerns are identified through these interviews (e.g., concerns with visitation or grievances), the survey team should proceed with conducting this task.
- **Dining Observation Task:** This task may be discretionary except it must be completed if a resident is being investigated for nutrition, weight loss, or concerns identified related to dialysis.
- **Medication Storage:** This task may be discretionary except it must be completed if the surveyor identified concerns with medication storage when completing the mandatory task of medication administration observation.

The next (LTCSP) software updates will include numerous upgrades and efficiencies to assist survey teams in preparing for and conducting recertification surveys. Additional details on these upgrades will be released in an upcoming QIES Technical Support Office (QTSO) Memo and surveyor training.

Investigating Complaints with the Recertification Survey

SAs must utilize the efficiencies built into the LTCSP software application to investigate complaints with the recertification survey. Detailed instructions are located in the LTCSP Procedure Guide. In February 2021, CMS modified the existing restrictions for the maximum number of residents named in a complaint that should be included in the initial pool and subsequent final resident sample for the LTCSP.

The current survey process does not restrict the number of complaints/FRIs that may be brought onsite; however, if a survey team is including more than the maximum number of residents with complaints or FRIs, as designated in the LTCSP Procedure Guide, we expect either the size of the survey team to be increased, or the duration of the survey to be lengthened. SAs should review the LTCSP Procedure Guide and trainings available to ensure they are taking full advantage of the available efficiencies in the survey software application.

The trainings are available for surveyors on Quality, Safety, and Education Portal (QSEP): "LTCSP 11.2 Software and Other Updates" recording and the "Offsite Prep/Complaints" computer-based training (CBT) module that demonstrate how to link complaints/FRIs to the LTCSP application.

Complaints/Facility-Reported Incidents (FRIs)

CMS continues to emphasize the importance of complaints and FRIs in identifying serious concerns that are occurring in facilities. Throughout the COVID-19 PHE, CMS has directed the

SAs to prioritize complaints/FRIs triaged as IJ for investigation; on June 1, 2020, CMS expanded the prioritization of surveys to complaints/FRIs triaged as Non-IJ High. CMS is now issuing guidance noted below for SAs to investigate the backlog of complaints/FRIs according to the level of triage. This guidance would remain in effect only for as long as it takes a State to clear any backlog and resume routine operations. The CMS Location will be working closely with each State on their plans to address the backlog and the expected timeframe.

We remind SAs that complaints/FRIs triaged as IJ and Non-IJ-High are required to be investigated within two and ten working days, respectively. SAs should strive to meet these timelines. However, if they cannot meet these timeframes, then the SA should investigate these complaints/FRIs as soon as possible. States should prioritize investigating complaints that pose the highest risk to residents such as IJ, and then schedule investigations for the other triage levels (Non-IJ High/Medium/Low) as appropriate. In order to promote efficiency in addressing the backlog of survey activities, the following describes CMS's instructions for the investigation of backlogged complaints/FRIs:

- LTC Complaints/FRIs triaged as IJ or Non-IJ High – SAs are required to investigate backlogged complaints/FRIs triaged at this level *as soon as possible*.
- Continuing and Acute Care provider complaints triaged as IJ – SAs are required to investigate backlogged complaints as this level *as soon as possible*.
- Continuing and Acute Care provider complaints triaged as Non-IJ High – SAs are required to investigate complaints triaged at this level within an average of 90 calendar days, with no one complaint exceeding 120 calendar days.
- LTC Complaints/FRIs triaged as Non-IJ Medium – SAs may investigate backlogged complaints/FRIs triaged at this level at the *next scheduled standard survey:*
    - If the complaint/FRI was received within one year of the scheduled standard survey date, or
    - If the allegation involves staff to resident abuse, neglect, or misappropriation of resident property, regardless of the date that complaint/FRI was received.

  Alternatively, if the SA does not investigate the Non-IJ Medium backlogged complaints/FRIs during the standard survey, the SA may initiate a complaint survey. This may be helpful in situations where there is a high volume of backlogged complaints/FRIs for review. The resident(s) named in the complaint/FRI *must* be linked to the survey and included in the initial pool and the final sample of the survey. Refer to the LTCSP Procedure Guide. For example, if the SA schedules a standard survey for August 1, 2021, then the SA must investigate all Non-IJ Medium complaints/FRIs that were received since August 1, 2020, if they have not been investigated yet.

  If the Non-IJ Medium complaint/FRI was received over one year prior to the scheduled standard survey date, the SA should review the allegations. If there are complaints/FRIs that indicate a pattern of poor care, the SA should investigate at either the next scheduled standard survey or complaint survey. Otherwise, the SA has discretion to include the resident(s), who is the subject of the allegation, in the standard survey sample. If there is no indication of a pattern of poor care and the SA does not investigate the complaint/FRI onsite, then the SA may close the complaint/FRI in the ASPEN Complaints/Incidents Tracking System (ACTS) by indicating that the complaint/FRI was "Withdrawn/Expired."
- LTC Complaints/FRIs triaged as Non-IJ Low – SAs are not required to investigate backlogged complaints/FRIs triaged at this level and may be closed in ACTS at the next

standard survey. The SA has discretion to include the resident(s), who is the subject of the allegation, in the standard survey sample. For example, the SA may choose to do this when there is a pattern of the same or similar allegations that suggest areas for focused attention. If the SA does not investigate the complaint/FRI onsite, then the SA may close the complaint/FRI in ACTS, by indicating that the complaint/FRI was "Withdrawn/Expired."

- Continuing and Acute Care provider complaints triaged as Non-IJ Medium and Non-IJ Low – SAs are required to follow the maximum time frames outlined in State Operations Manual (SOM), Chapter 5, section 5075.9.

CMS acknowledges that conducting multiple complaint and FRI investigations on standard recertification surveys will likely result in extending the length of time to conduct the surveys. In turn, this may make it challenging for SAs to meet the requirements to conduct a standard survey not later than 15 months after the date of the previous standard survey for each facility, and for maintaining the statewide average interval between standard surveys not exceeding 12 months. In light of these challenges, CMS will work with SAs to establish reasonable expectations for when these requirements should be met based on the size of the backlog and each SA's plan to address it.

Increasing Oversight in Nursing Homes:

Throughout the COVID-19 PHE, CMS and SAs have been unable to have the traditional level of visibility inside nursing homes to assess residents' health and safety, and survey for facilities' compliance. Due to the limitations of oversight during the PHE and changes in how some nursing homes may have operated, CMS is very concerned about how residents' health and safety has been impacted, such as increased weight loss, pressure ulcers, abuse or neglect, and other quality-of-care and quality-of-life issues. Surveyors should be aware that these may be potential areas for further investigation during the survey, such as the following:

Surveying for Nurse Competency

CMS waived certain regulatory requirements that have allowed facilities to alter the manner in which they operate. For example, CMS waived the requirements that a facility may not employ a nurse aide for longer than four months if they did not meet certain training and certification requirements (42 C.F.R § 483.35(d)). We note that CMS did not waive § 483.35(c), which requires facilities to ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

CMS is alerting SAs to pay additional attention to compliance with the requirements for nursing services at § 483.35, which states, "*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).*"

Specifically, surveyors should review the guidance in Appendix PP of the SOM for tag F-726, which guides surveyors to assess compliance with the requirement for nursing staff to have the appropriate competencies. As noted in the SOM, a key component of competency is the ability to identify and address a resident's change in condition. This expectation applies to licensed and

registered nurses as well as nurse aides. These competencies are critical in order to identify potential issues early, so interventions can be applied to prevent a condition from worsening or becoming acute. Without these competencies, residents may experience a decline in health status, function, or need to be transferred to a hospital. Surveyors should refer to the Sufficient and Competent Staffing Critical Element Pathway for further guidance in determining compliance with requirements related to nursing services.

Inappropriate Use of Antipsychotic Medications
Inappropriate use of antipsychotic medications continues to be an area of concern related to quality of care. Nursing homes are required to ensure that each resident's drug regimen is free from unnecessary drugs (§ 483.45(d)). SAs should continue to focus their efforts on identifying the inappropriate use of antipsychotic medications and emphasize non-pharmacologic approaches and person-centered care practices.

Identifying Other Areas of Concern
In addition to the items above, surveyors should assess other care areas where residents' health and safety may be at increased risk, such as unplanned weight loss, loss of function/mobility, depression, abuse/neglect, or pressure ulcers. SAs should use the appropriate critical element pathways to thoroughly investigate these areas to ensure any noncompliance is identified and subsequently corrected.

Contact: For questions related to LTC, contact DNH_TriageTeam@cms.hhs.gov (LTC regulations) or NHSurveyDevelopment@cms.hhs.gov (LTC survey process).
For questions related to NLTC, contact QSOG_LifeSafetyCode@cms.hhs.gov.

Effective Date: Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group