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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-35-ALL

DATE: **August 17, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Enforcement Cases Held during the Prioritization Period and Revised Survey Prioritization

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities continue to be prepared in response to the threat of the 2019 Coronavirus Disease (COVID-19).
- **CMS is revising guidance on the expansion of survey activities to authorize onsite revisits and other survey types.**
- **CMS is providing guidance to State Survey Agencies (SAs) on resolving enforcement cases**: CMS is providing guidance on resolving enforcement cases that were previously directed to be held, and providing guidance on Civil Money Penalty (CMP) collection.
- **Expanded Desk Review Authority:** CMS is temporarily expanding the desk review policy to include review of continuing noncompliance following removal of Immediate Jeopardy (IJ), which would otherwise have required an onsite revisit from March 23, 2020, through May 31, 2020.
- **CMS is also issuing updated guidance for the re-prioritization** of routine SA Clinical Laboratory Improvement Amendments (CLIA) survey activities, subject to the SA's discretion, in addition to lifting the restriction on processing CLIA enforcement actions, and issuing the Statement of Deficiencies and Plan of Correction (Form CMS-2567).

Background

On Friday, March 13, 2020, the President declared a national emergency due to the COVID-19

public health emergency (PHE), which triggered the Secretary's ability to authorize waivers or modifications of certain requirements pursuant to section 1135 of the Social Security Act (the Act). Under section 1135(b)(5) of the Act, CMS prioritized surveys by authorizing modification of timetables and deadlines for the performance of certain required activities.

On March 4, 2020, CMS issued QSO-20-12-All announcing a prioritization of surveys. On March 23, 2020, CMS issued the QSO 20-20-All memorandum, which further limited survey activity to focused infection control surveys, investigation of complaints and facility reported incidents alleging immediate jeopardy (IJ) to patient/resident health and safety, and revisit surveys necessary to verify removal of previously identified IJ deficiencies. Due to the inability to perform revisit surveys to verify substantial compliance during this period, the memo also directed that open enforcement actions pending as of March 23, 2020, be suspended, except for enforcement actions for unremoved IJ deficiencies.

In addition, COVID-19 presents a unique challenge for clinical laboratories with the rapid expansion of COVID-19 testing. To allow for the rapid expansion of testing, CMS worked collaboratively with the U.S. Food and Drug Administration (FDA) and U.S. Centers for Disease Control and Prevention (CDC) to provide ongoing technical guidance and assistance regarding COVID-19 testing, and processing of Clinical Laboratory Improvement Amendments (CLIA) certificate applications during the public health emergency to the laboratory community and State agencies.

I. LONG-TERM CARE GUIDANCE

Expansion of Survey Activities

On June 1, 2020, CMS issued the QSO 20-31-All memorandum that provided survey re-prioritization guidance to transition States to more routine oversight and survey activities. Specifically, once a State has entered Phase 3 of the Nursing Homes Reopening guidance, found in QSO 20-30-NH memorandum, or earlier, at the state's discretion, States were authorized to expand beyond the current survey prioritization (Immediate Jeopardy, Focused Infection Control, and Initial Certification surveys) to perform the following surveys (**for all provider and supplier types**):

- Complaint investigations that are triaged as Non-Immediate Jeopardy-High[1];
- Revisit surveys of any facility with removed Immediate Jeopardy (but still out of compliance);
- Special Focus Facility and Special Focus Facility Candidate recertification surveys; and
- Nursing home and Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) recertification surveys in facilities where it has been over 15 months since the last standard survey.

CMS is now **revising** this guidance to authorize additional onsite surveys. In addition to the surveys listed above, States should resume performing the following surveys as soon as they

[1] Defined in State Operations Manual, Chapter 5, Section 5075.2 – Non-Immediate Jeopardy – High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA) at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c05pdf.pdf

have the resources (e.g., staff and/or Personal Protective Equipment) to do so:

- Onsite revisits as specified in the revisit policy in the State Operations Manual (SOM), Chapter 7, Section 7317.2, for surveys with end dates on, or after June 1, 2020;
- Complaint investigations that are triaged as Non-Immediate Jeopardy Medium[2]; and
- Annual recertification surveys required to be conducted within 15 months from a provider's last recertification survey.

Enforcement Guidance

When the QSO 20-20-All memorandum went into effect, CMS locations were directed to suspend enforcement actions, with the exception of unremoved IJs. Because survey resources were focused on those activities related directly to the COVID-19 pandemic and immediate threats to patient/resident health and safety, other surveys, including revisits for compliance necessary to end an ongoing enforcement cycle[3], were suspended. This included stopping the accrual of Denial of Payment for New Admissions (DPNAs) and per day (PD) CMPs.

CMS intends to resolve those enforcement cases that were suspended and provide guidance for closing them out, going forward from the issuance of this memorandum. This process involves four components:

1. Expanding the Desk Review policy for Plans of Corrections (POCs);
2. Processing enforcement cases that were started **BEFORE March 23, 2020**;
3. Processing enforcement cases that were started **ON March 23, 2020, THROUGH May 31, 2020**; and
4. Processing enforcement cases that were started **ON OR AFTER June 1, 2020**.

Expanded Desk Review Policy

Under the QSO 20-20-All memorandum, beginning on March 23, 2020, enforcement cases were held, and providers were permitted to delay the submission of a POC until the survey prioritization period ended. Although QSO-20-31-ALL permitted states to exercise discretion in expanding beyond the current survey prioritization, CMS is now advising states to follow the guidance below to resolve enforcement cases that were started from March 23, 2020 (QSO-20-20) to May 31, 2020:

- All open surveys with cited deficiency tags must have an acceptable POC and supporting evidence in order for the tags to be corrected (unless a POC is not required such as for isolated deficiencies that CMS or the State determines constitute no actual harm with a potential for minimal harm);
- If providers have not submitted a POC, the state survey agency (SA) will contact them requesting submission of a POC;
- Providers will have 10 calendar days to submit their POC for surveys that ended prior to June 1, 2020. POCs for surveys that will end on or after June 1, 2020, will follow the

[2] Defined in State Operations Manual, Chapter 5, Section 5075.3 – Non-Immediate Jeopardy – Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers) at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c05pdf.pdf

[3] Enforcement cycle: An enforcement cycle begins on the completion date of a survey with the citation of a deficiency and ends when the provider returns to substantial compliance with all federal nursing home requirements, or is terminated.

normal POC submission process.
NOTE: Providers who may have difficulty allocating resources, such as staff, materials, or funding to develop and implement a POC because they are **currently** experiencing an outbreak of COVID-19, as defined in QSO 20-31-All,[4] should contact their SA and/or CMS location to request an extension on submitting a POC.

- State surveyors can perform desk reviews for all open surveys that cited any level of noncompliance, including noncompliance that was cited at the IJ level, when the IJ finding has been verified as removed to a lower level of noncompliance, or corrected. The only exception to the expanded offsite review policy is for any unremoved IJs, which still require an onsite revisit. This expanded desk review policy applies only to outstanding enforcement actions that were held, per QSO 20-20-All memorandum, from March 23, 2020, through May 31, 2020.
- Beginning June 1, 2020, all onsite revisits are authorized and should resume, as appropriate, per SOM, Chapter 7, Section 7317.2.

SAs must request facilities to submit evidence that supports correction of noncompliance so that a desk review can be performed based on the latest compliance date on the POC. **NOTE: A desk review cannot be completed without supporting evidence from the facility.** This evidence may include documentation containing dates of training, staff in attendance, and evidence that staff were evaluated for skill(s) competency. It may also include monitoring for policy implementation and successful performance by staff.

To alleviate any concerns related to clearing noncompliance cited at Actual Harm, or remaining noncompliance following removal of IJ without an onsite revisit, SAs have discretion to include the clinical area of concern cleared using the expanded desk review on the next onsite survey conducted. This is done by following the Long-Term Care Survey Process Procedure Guide for adding concerns to the standard or complaint survey to be conducted.

Enforcement Cycles started BEFORE March 23, 2020

With the issuance of QSO 20-20-All on March 23, 2020, CMS locations were directed to suspend enforcement actions. Some of those suspended actions were started before March 23, 2020. There are two scenarios for enforcement actions that started before March 23, 2020:

1. If initial notice of remedies **was sent** prior to March 23, 2020, but not finalized due to the inability to conduct a revisit (*Example: CMS sent the notice informing the provider a Per Day CMP would be or was imposed and began accruing, however, enforcement actions were suspended before the facility's compliance could be determined. The facility was not notified of the total amount of the CMP*):
   - Accruing enforcement remedies such as PD CMPs or DPNAs will run through March 22, 2020, or the date of substantial compliance per the accepted Plan of Correction, if that date is verified at the desk review, whichever date is earlier.
   - CMS will inform facilities of the CMP amount due and proceed to collection.

2. If initial notice of remedies **was not sent** prior to March 23, 2020 (*Example: CMS had not*

[4] Cumulative confirmed cases/bed capacity at 10% or greater, or cumulative confirmed plus suspected cases/bed capacity at 20% or greater, or ten or more deaths reported due to COVID-19.

yet sent a notice prior to the March 23, 2020, suspension of enforcement informing the provider a PD CMP would be imposed):

- Impose remedies in accordance with the Immediate Imposition of Remedies (IIoR) Policy (SOM, Chapter 7, section 7304). If a PD CMP is imposed, the penalty will accrue based on the start date of the CMP[5] and continue through March 22, 2020, or the date of alleged compliance per accepted Plan of Correction, whichever date is earlier.
- CMS will proceed to collect CMPs as appropriate.
  NOTE: CMS policy on the IIoR does not allow for retroactive impositions of DPNA. The only remedies that are permitted to be imposed in this scenario are Per Instance (PI) or PD CMPs.

An enforcement cycle begins on the completion date of a survey with the citation of a noncompliance deficiency and ends when the provider returns to substantial compliance or is terminated. This is sometimes referred to as a 6-month termination track. Until an enforcement cycle is closed with a revisit survey to verify the facility's return to substantial compliance, or a facility is terminated, any subsequent surveys will become part of the original enforcement cycle and, per 42 C.F.R. § 488.454(a), remedies are in effect until a return to substantial compliance. Surveys conducted during the prioritization period would otherwise be added to any open enforcement cycles that started prior to March 23, 2020, despite being put on hold. However, in order to effectuate the direction in QSO 20-20-All to suspend enforcement action, without undue consequences due to inability to conduct revisits (e.g., termination), surveys with an exit date after March 23, 2020, that fell into enforcement cycles with start dates prior to March 23, 2020, will be pulled out of the existing cycles and will establish a separate cycle. This will result in two enforcement cycles, one starting before March 23, 2020, and one starting on March 23, 2020. The resulting cycle starting before March 23, 2020, is subject to the enforcement direction above for Enforcement Cycles started BEFORE March 23, 2020. The resulting cycle starting on March 23, 2020, is subject to the enforcement direction below for Enforcement Cycles started ON March 23, 2020 THROUGH May 31, 2020.

Example:

1. February 28, 2020 survey includes findings of noncompliance at S/S level G.
2. The CMS Location imposes a PD CMP starting on February 28, 2020, of $1,000 PD until substantial compliance.
3. A revisit is not able to be conducted on that survey due to the survey prioritization period.
4. An April 27, 2020 FIC survey included findings of noncompliance at F880 S/S level J (IJ). This enforcement cycle automatically became part of the same 6-month termination cycle as the February 28, 2020 survey, extending the noncompliance cycle.
5. The SA conducts a desk review on the February 28, 2020 survey and finds that the facility was in compliance with the S/S G level tag on April 15, 2020.
6. The PD CMP will run through March 22, 2020.
7. A new enforcement cycle will be created with the IJ level F880 tag. Follow guidance below for enforcement cycles that started during the prioritization period (started BETWEEN March 23, 2020, through May 31, 2020).

[5] *See* 42 C.F.R. § §488.440(a)(1) ("The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State.")..

NOTE: Additional instructions will be given to the SAs and CMS locations with screen shots on how to split cycles – this will prevent complications with upcoming mandatory termination dates due to the inability to conduct revisits.

Enforcement Cycles started ON March 23, 2020 THROUGH May 31, 2020

CMS will impose CMPs for noncompliance cited at the actual harm S/S levels (G, H, or I) and at the IJ levels (J, K, or L) on surveys conducted March 23, 2020, through May 31, 2020. CMS will not impose CMPs for noncompliance cited at lower S/S levels (D, E, or F).

- CMS will impose a PI or PD CMP on the IJ level noncompliance per the CMP analytic tool. If the CMP analytic tool leads to the imposition of a PD CMP, the CMP will only accrue for the period of time the IJ existed until removal was verified with an onsite revisit. For example, if the IJ began on April 1, 2020, and was removed on April 15, 2020, the PD CMP will run from April 1, 2020, through April 14, 2020.
- CMS will impose a PI CMP for noncompliance cited at Actual Harm.
- As indicated above, enforcement cycles may be closed using the expanded desk review policy noted above for remaining noncompliance.

Enforcement Cycles started ON OR AFTER June 1, 2020

Enforcement cycles beginning with noncompliance cited on surveys exiting on or after June 1, 2020, will be subject to regular enforcement processes in the SOM and to the enhanced enforcement for infection control deficiencies outlined in QSO 20-31-All. This includes all special initiatives, such as Special Focus Facilities, late adopters, etc. However, for imposition of Per Day CMPs, if a survey finds that the first day of noncompliance started prior to the survey entrance and/or during the survey prioritization period (March 23, 2020 through May 31, 2020), CMS **should start the PD CMP effective beginning the date of the survey entrance.**

NOTE: As specified in QSO-20-31-All, enhanced enforcement for infection control deficiencies will be applied to surveys exiting on and after June 1, 2020.

CMP Collections

For CMPs that were imposed and became due and payable **during** the prioritization period (March 23, 2020 through May 31, 2020), but were not paid:

- CMS will re-issue the CMP Due and Payable notice with a new due date that is 15 days from the date of the notice, per §488.442.
- If a facility fails to pay due CMPs following the new due and payable notice, CMS will send the CMP to the Medicare Administrative Contractor to offset, and assess interest beginning on the new due date.

NOTE: CMS will reduce a CMP by 35% for facilities whose 60-day time to appeal has passed during the prioritization period, but were unable to notify CMS that they are waiving their right to a hearing. If a facility files or has filed an appeal, CMS will not reduce the CMP by 35%. Consistent with 42 C.F.R. § 498.40(c), an Administrative Law Judge may find that a facility has good cause for failing to timely file a request for hearing and extend the time for filing such a request. Information on a facility's appeal rights are set forth at § 498.5 and the procedures for requesting a hearing are set forth at § 498.40 et seq., including the process for requesting an extension of time to file a hearing request.

II. NON-LONG-TERM CARE GUIDANCE

Expanded Survey Activities

In addition to ongoing focused infection control surveys, States are encouraged to resume normal survey activities, while also addressing the backlog of surveys that were postponed as directed in QSO 20-20-All. Once a state has entered Phase 3 of reopening (based on White House Guidance for State/Regional reopening) or earlier at the state's discretion, States should resume normal survey activities according to guidance in the FY 2020 Mission & Priority Document, while prioritizing their survey backlog as follows (descending in priority):

1. Revisit surveys for past non-compliance that do not otherwise qualify for a desk review;
2. Complaint surveys triaged as non-IJ level or higher that have not been completed;
3. Special Purpose Renal Dialysis Facilities (SPRDFs);
4. Initial surveys of new providers;
5. Past-due recertification surveys with a statutorily required survey interval; and
6. Past-due recertification surveys without a statutorily required survey interval.

During the period of the COVID-19 Public Health Emergency (PHE), surveyors should continue to utilize the COVID-19 Focused Infection Control Survey: Acute and Continuing Care specified in QSO-20-20-All as part of any survey that is conducted.

CMS will provide additional guidance on the timeframe for resumption of validation surveys at a future date.

While CMS recognizes that resumption of surveys will depend on State reopening plans, staffing, and resources, CMS is requesting that states work with their respective CMS locations to discuss plans and proposed timeframes for completion of required surveys postponed due to the COVID-19 PHE.

Accrediting organizations with Medicare-approved programs may resume normal activity based on State reopening criteria. Any variations from the approved reaccreditation survey process must receive CMS approval prior to implementation.

Addressing Prior Enforcement Cases

When the QSO 20-20-All memorandum went into effect, CMS locations were directed to suspend enforcement cycles with the exception of unremoved IJs, to target focused infection control and IJ surveys.

CMS intends to resolve those enforcement cases which were suspended. For non-long term care providers and ICFs/IID, CMS is expanding the desk review policy for Plans of Corrections (POCs).

Expanded Desk Review Policy

Under the QSO 20-20-All memorandum, enforcement cases were held, and providers were permitted to delay the submission of a POC until the prioritization period ended. All open surveys with cited deficiency tags must have an acceptable POC and supporting evidence in order for the tags to be corrected

- Providers have 10 calendar days from the effective date of this guidance to submit their POC for surveys that ended prior to June 1, 2020. POCs for surveys that will end on or after June 1, 2020, will follow the normal POC submission process.
  NOTE: Providers who may have difficulty allocating resources to develop and implement a POC because they are currently experiencing an outbreak of COVID-19 in their area should contact their SA and/or CMS location to request an extension on submitting a POC.
- State surveyors can perform desk reviews for all open surveys that cited any level of noncompliance, including noncompliance that was cited at the IJ level when the IJ finding has been verified as removed or moved to a lower level of noncompliance. The only exception to the expanded offsite review policy is unremoved IJs, which require an onsite revisit. This expanded desk review policy applies only to outstanding enforcement actions which were held per QSO 20-20-All memorandum, from March 23, 2020, through May 31, 2020.
- Beginning June 1, 2020, all onsite revisits are authorized and should resume, as appropriate, per SOM, Chapter 2, Section 2732.

SAs must request facilities to submit evidence that supports correction of noncompliance so that a desk review can be performed based on the latest compliance date on the POC. **NOTE: A desk review cannot be completed without supporting evidence from the facility.** This evidence may include dates of training, staff in attendance, and evidence that staff were evaluated for skill(s) competency when applicable. It may also include monitoring for policy implementation and successful performance by staff.

To alleviate any concerns related to correcting noncompliance cited at IJ, or remaining noncompliance following removal of IJ without an onsite revisit, SAs have discretion to include the clinical area of concern cleared using the desk review on the next onsite survey conducted. For complaints, surveyors should add the area of concern following normal procedures for complaint investigations in SOM Chapter 5.

III. LABORATORY GUIDANCE

COVID-19 Laboratory Survey Activities

CMS is providing updated guidance to State Agencies on the recommended re-prioritization of the CLIA survey activities listed below, subject to the State's discretion and within their unique COVID-19 restrictions and safety precautions. State Agencies should notify their CMS CLIA Operations Branch staff of their specific plans to implement these activities.

The following re-prioritization of CLIA laboratory survey activities is recommended:

1. **Perform on-site surveys**

Except for validation surveys on accredited laboratories and Provider Performed Microscopy Project 2020 pilot surveys, surveyors should continue to take individual laboratory location limitations and restrictions under advisement as they plan their re-prioritization of surveys. Surveyors can also continue to group their survey activities by geographical locations for the most effective use of travel.

- Complaints that represent situations in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public (including, but not limited to injury or harm related to COVID-19);
- Any revisit to resolve current enforcement actions;
- Recertification actions for certificates that have been extended to August 31, 2020, and any other soon to expire certificates;
- Initial certifications; and
- Other complaints per Chapter 5 of the SOM.

NOTE: Validation surveys on accredited laboratories and Provider Performed Microscopy Project surveys will not resume at this time.

2. **Enforcement Actions and PT desk reviews that have been on hold**

Any enforcement actions or PT desk reviews that have been on hold from either before the March 23, 2020 memo or after the memo was issued can now proceed/be processed.

FAQs

The Division of Clinical Laboratory Improvement & Quality (DCLIQ) will follow up with Frequently Asked Questions (FAQs) and additional updates, as needed.

Contact: Questions about a specific enforcement cycle may be addressed with the specific CMS location.

- Long-Term Care questions should be addressed to: DNH_Enforcement@cms.hhs.gov.
- Non Long-Term Care questions should be addressed to: QSOG_EmergencyPrep@cms.hhs.gov.
- CLIA questions should be addressed to: LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

cc: Survey and Operations Group Management