CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 243 **Date: June 12, 2026**

SUBJECT: Revisions to State Operations Manual (SOM), Chapter 5

I. SUMMARY OF CHANGES: This transmittal includes Revisions Chapter 5.

NEW/REVISED MATERIAL - EFFECTIVE DATE: **June 12, 2026**
IMPLEMENTATION DATE: June 12, 2026

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

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***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Chapter 5 - Complaint Procedures

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(Rev. 243; Issued:06-12-26)

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5000.2 – Overview

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

All the procedures in this chapter are followed when complaints and reported incidents, including referrals from public entities, involve Medicare-certified providers/suppliers, Medicaid-certified providers/suppliers, or CLIA-certified laboratories. The investigation and resolution of complaints are critical certification activities. The CMS, the State Medicaid Agency (SMA), and the State survey agency (SA) are responsible for ensuring that participating providers/suppliers of health care services continually meet Federal requirements. This requires that the SA promptly reviews complaints/incidents, conducts **unannounced** onsite investigations of reports alleging noncompliance, and informs the CMS *location* and/or the SMA any time certification requirements are found to be out of compliance.

Since there are multiple activities associated with the management of complaints and incidents, responsibilities often cut across organizational lines. Thus, the SA must demonstrate clear-cut accountability for each step of the process and a focal coordinating/controlling responsibility to assure timely and appropriate action. The SA's responsibilities cannot be delegated.

5010 - General Intake Process

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

A complaint is an allegation of noncompliance with Federal and/or State requirements. If the SA determines that the allegation(s) falls within the authority of the SA, the SA determines the severity and urgency of the allegations, so that appropriate and timely action can be pursued. Each SA is expected to have written policies and procedures to ensure that the appropriate response is taken for all allegations and is consistent with Federal requirements as well as with procedures in the State Operations Manual. This structure needs to include response timelines and a process to document actions taken by the SA in response to allegations. If a State's time frames for the investigation of a complaint/incident are more stringent than the Federal time frames, the intake is prioritized using the State's timeframes. The SA is expected to be able to share the logic and rationale that was utilized in prioritizing the complaint/incident for investigation. The SA response must be designed to protect the health and safety of all residents, patients, and clients.

Besides the SA, other public entities receive information and/or perform investigations. These entities include the office of the coroner or medical examiner, end-stage renal disease (ESRD) networks, quality improvement networks (QINs), law enforcement, the ombudsman's office, and protection and advocacy systems. At times, these public entities will forward information to the SA if there are concerns about the health and safety of residents, patients, and clients. The SAs are required to manage and investigate these referrals as complaints.

An allegation is an assertion of noncompliance with Federal health and safety regulations. The point of receipt of the allegation is a critical fact-finding and decision-making point. The SA ensures that its complaint telephone number is listed in local directories. Information regarding the care, treatment and services provided to beneficiaries can come from a variety of sources, including beneficiaries themselves, beneficiaries' family members, health care providers, concerned citizens, public agencies, or media reports. Report sources may be verbal or written. In some instances, the complainant may request anonymity.

The SA and *CMS location* ensure the privacy and anonymity of every complainant. Generally, the SA follows the disclosure procedures under chapter 3, §3308. The SA discloses the complainant's identity only to those individuals with a need to know who are acting in an official capacity to investigate the complaint.

In addition to these Federal requirements, the SA abides by any State procedures not in direct conflict with CMS instructions. The SA notifies the *CMS location* if State regulations conflict directly with any part of these complaint procedures.

See also Section 5310.1 for information related to facility-reported incidents.

5010.2 - Information to Provide to Complainant

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The complaint intake process assists the complainant in resolving his/her conflicts. As part of the intake process the SA provides the following:

- Policies and procedures for handling intakes including the scope of the SA's regulatory authority and any considerations pertaining to confidentiality;
- The course of action that the SA or *CMS location* will take and the anticipated time frames;
- Information about other appropriate agencies that could provide assistance including the name and telephone number of a contact person, if available; and
- A SA contact name and number for follow-up by the complainant.

NOTE FOR DEEMED PROVIDERS/SUPPLIERS: If a complaint does not allege condition-level noncompliance, the SA may: 1) advise the complainant to file the complaint to the accrediting organization (AO), or 2) ask for the complainant's permission to release the information to the AO.

5010.3 – Notification to the *CMS Location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

1 – Notification to the *CMS location*

The SA immediately forwards allegations involving the following to the *CMS location*:

- Deemed providers/suppliers;
- Hospital and psychiatric residential treatment facility (PRTF) restraint/seclusion-related deaths;
- EMTALA complaints;
- Fires resulting in serious injury or death in a Medicare/Medicaid-certified facility;
- Federal facilities;
- Religious Non-medical Health Care Institutions (RNHCIs)(evaluation performed by Region I, Boston, only);
- CLIA-certified laboratories holding a certificate of accreditation. (See Chapter 6).
- CLIA-exempt laboratory. (See Chapter 6);
- Blood transfusion-related fatalities (See Chapter 6 and Appendix C);
- Over-utilization or inappropriate utilization of services within the QIO's jurisdiction;
- Civil rights violations; or
- Medicare or Medicaid fraud

2 – Special Cases

The SA considers whether notification to the *CMS location* is appropriate. If a complaint is especially significant, sensitive, or attracting broad public or media attention, the SA informs the *CMS location* immediately. Additionally, the SA needs to consider any other early notice requirements prescribed by other State or Federal policies or interagency agreements.

5050 - CMS Regional Office Responsibility for Monitoring SA Management of Complaints and Incidents

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

CMS *locations* are responsible for monitoring the SAs' management of complaints and incidents to assure that the SAs are complying with the provisions set forth in Federal regulations, the SOM, and CMS policy memoranda. As part of the monitoring process,

the SAs will be evaluated in accordance with the criteria set forth by the State Performance Standard Review. Many States have State laws and regulations that specify how to manage complaints and incidents. Whenever possible, State and Federal requirements should be integrated to avoid unnecessary duplication. CMS *locations* should accept State requirements that meet or exceed the intent of the Federal requirements. At a minimum, it is expected that noncompliance with Federal requirements resulting from a complaint or reported incident will receive follow-up and be documented in the Aspen Complaints Tracking System (ACTS).

5060 – ASPEN Complaints/Incidents Tracking System (ACTS)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SA collects information related to complaints and facility-reported incidents and uses a system to track and monitor the receipt and disposition of complaint and incident intakes.

The ASPEN Complaints/Incidents Tracking System (ACTS) is designed to track, process, and report on complaints and incidents reported against health care providers and suppliers regulated by CMS. It is designed to manage all operations associated with complaint/incident processing, from initial intake and investigation through the final disposition.

The ACTS must be used for the intake of all allegations against Medicare/Medicaid-certified providers/suppliers and CLIA. The ACTS is a Federal system and data entered into ACTS is subject to Federal laws governing disclosure and the protection of an individual's right to privacy.

A complaint/incident record is created in ACTS based on how the allegation is received by the SA or *CMS location*. For example, if one person calls with ten allegations about one provider/supplier, this is counted as one complaint record. If six people call with the same allegation, this is counted as six telephone calls and is counted as six complaint records. If one letter is received with one or many allegations and is signed by 20 people, this is counted as one complaint record.

5060.1 - Data Entry

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SAs and *CMS location*s are required to enter into ACTS:

- All complaints gathered as part of Federal survey and certification responsibilities, regardless if an onsite survey is conducted [i.e., complaints related to noncompliance with the Federal condition(s) of participation (COPs), condition(s) for coverage (CFCs), condition(s) for certification, requirement(s) for participation (RFPs), or EMTALA requirement(s)]; **and**

- For nursing homes, all self-reported incidents that are reported under Federal law and the requirements for participation [i.e., reporting to law enforcement of crimes occurring in LTC facilities – §1150B of the Social Security Act and §483.12(b)(5); alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property – §483.12(c)(1) and (4)]. For non-long term care providers/suppliers, all self-reported incidents that require a Federal onsite survey.

The information recorded in ACTS reflects the allegation furnished by the complainant/provider/supplier at the time of the intake. At a minimum, if the intake information requires an onsite survey and the allegation may involve both Federal and State licensure requirements, a Federal onsite survey is completed and entered into ACTS.

If an investigation finds one or more violations of Federal requirements, the findings must be cited under the appropriate tags and entered into the Federal system even if the information is entered into a State licensure data system. Since this information is essential to the effective management of the survey and certification program, it is important that SAs complete the required fields in ACTS in a timely manner.

Exhibit 23 defines the required fields in ACTS.

Tracking of Referrals in ACTS

The SAs are required to enter into ACTS all referrals from public entities that allege noncompliance with the Federal requirements. For reporting purposes, the SAs should enter these cases as complaints (i.e., Intake Type=Complaint, Intake Subtype=Federal COPs, CFCs, RFPs, EMTALA). In order to more quickly identify which of these cases stem from a referral, the SAs are expected to check the appropriate category under the "Source" field. For example, for referrals from the coroner's office, states would check "Coroner" under the "Source" field for the intake.

Tracking of State Monitoring Visits (See Section 5077) in ACTS

When a State Monitoring Visit results in a Federal deficiency, the SA will identify the survey in ASPEN as "complaint" and create an intake and survey record in ACTS. The data should be entered into ACTS as follows:

- Intake Type = Complaint;
- Intake Subtype = Federal COPs, CFCs, RFPs, EMTALA;
- Source = State SA;
- Priority = can vary; and
- Allegation Type = State Monitoring.

5070 - Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

This section does not apply to clinical laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). See Sections 5500 – 5590 for CLIA information.

An assessment of each complaint or incident intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of Federal requirements and his/her knowledge of current clinical standards of practice.

From a complainant's allegation(s) or an allegation from a facility-reported incident, the SA/CMS Location identifies potential concerns where the provider/supplier may not be in compliance with Federal requirements. The SA/CMS Location must review the allegation(s) for all requirements that apply and should be investigated. These requirements will be specific to each health care entity. The surveyor then investigates each of those areas of concern and health care entity type.

The role of the surveyor is not to validate whether the events contained in the allegation had occurred, but it is to determine whether the facility is in compliance with the Federal requirements for Medicare/Medicaid-certified providers/suppliers. If CMS or the SA believes that the complaint or facility-reported incident should also be investigated under the jurisdiction of another entity, referrals should be made as appropriate (e.g., law enforcement for criminal activity, State licensing boards for health care practitioners, the Medicare Administrative Contractor (MAC) for billing issues).

In the case of nursing homes, in situations where a determination is made that immediate jeopardy may be present and ongoing, the SA must start the on-site investigation within three business days of receipt of the initial complaint or incident report. Receipt of the initial complaint or incident report means when the report is received by the SA, whether it is received by the SA directly, or another State agency under arrangement or contractor that is receiving the report on behalf of the SA from the complainant or facility. Also, if a complaint or facility-reported incident is received after business hours, then it is considered to be received on the next business day, for purposes of calculating the investigation timeframe. For example, if a complaint is received on Saturday and the SA office is closed during the weekend, then the following Monday will be used to calculate the investigation timeframe.

For non-long term care providers/suppliers, in situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to start the on-site investigation within two business days of receipt of the complaint or incident report, or, in the case of a deemed provider or supplier, within two business days of *CMS location* authorization for investigation. The same process applies to EMTALA

complaints or a survey related to a report of a hospital or CAH Distinct Part Unit patient death associated with the use of restraint or seclusion. The SA's investigation must be initiated within two business days of *CMS location* authorization for investigation.

Generally, an alleged event occurring more than 12 months prior to the intake date would not require a complaint investigation. However, the SA is not precluded from conducting a Federal investigation (with appropriate *CMS location* authorization, where required) to determine current compliance status based on the concerns identified in the complaint.

For nursing homes, an onsite survey may not be required if there is sufficient evidence that the facility does not have continuing noncompliance and the alleged event occurred before the last standard survey.

For all intakes concerning deemed status providers or suppliers where the intake involves allegations of substantial noncompliance (in other words, the allegation would result in a condition-level deficiency citation if found to be true and uncorrected), the SA must submit a request for *CMS location* approval of a complaint validation survey (i.e., substantial allegation validation survey). The SA must obtain *CMS location* approval before conducting a substantial allegation validation survey. The *CMS location* will authorize the SA to conduct the survey by issuing electronically via *iQIES* a Form CMS-2802, which will indicate the specific conditions for which the SA must assess compliance. The *CMS location* must authorize assessment of compliance for a whole condition and not just for particular standards within a condition, unless the Form CMS-2802 for the applicable provider/supplier type permits selection of a specific standard, e.g., Life Safety Code.

All allegations of EMTALA violations related to a hospital (which also includes cancer, children's, long term care, psychiatric and rehabilitation hospitals) or CAH, regardless of whether the hospital or CAH is deemed, must be referred to the *CMS location*. The *CMS location* will determine whether the SA will conduct an EMTALA investigation.

In cases where the SA or *CMS location* has noted a pattern of similar complaints about a specific provider or supplier, each of which on its own merits would be triaged at a medium or low level, the SA or *CMS location* has the discretion to assign a higher triage level to a current intake based on the noted pattern, in order to ensure timely investigation of the provider's/supplier's compliance with the applicable requirements or Conditions.

CMS expects SAs to prioritize complaints at the appropriate level that is warranted. The timeframes in Section 5075 below represent maximum timeframes for investigation; the SA is not precluded from investigating complaints and facility-reported incidents within a shorter timeframe. In addition, the SA is not precluded from taking other factors into consideration in its triage decision. For example, the SA may identify a trend in allegations that indicates an increased risk of harm to residents or the SA may receive corroborating information from other complainants regarding the allegation.

See also Section 5310.2 for requirements for nursing home facility-reported incidents.

5075.1 - Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

General Provisions

The regulations at 42 CFR 489.3 define immediate jeopardy as, "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." Appendix Q contains the Guidelines for Determining Immediate Jeopardy. Intakes are assigned this priority if the alleged noncompliance indicates there was serious injury, harm, impairment or death of a patient or resident, or the likelihood for such, and there continues to be an immediate risk of serious injury, harm, impairment or death of a patient or resident unless immediate corrective action is taken. In addition, for nursing homes, facility-reported incidents are assigned this priority if immediate jeopardy may have occurred, regardless of whether an immediate risk may continue to exist. Examples of intakes that are assigned this priority include, but are not limited to, the following:

- All intakes alleging abuse of a resident/patient/client *that involve serious injury, harm, impairment, or death of a resident/patient/client or likelihood for such,* and it is uncertain that they are adequately protected.
- For nursing homes, all intakes *where a resident was discharged* to an unsafe *setting, or in a manner that place the resident at risk for serious harm (e.g. the resident still has medical needs but they cannot be supported in the setting they were discharged to).*
- Intakes alleging EMTALA noncompliance may also be assigned this priority.
- Any hospital self-reported incident of patient death associated with use of restraint or seclusion which the *CMS location* determines requires an on-site investigation is also assigned this priority.

When the SA or *CMS location* makes the determination that a complaint or incident report suggests an immediate jeopardy may be present, the investigation is to be initiated in accordance with Section 5075.9.

See also Section 5310.2A for additional guidance related to nursing home facility-reported incidents. (Note: Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.)

Fires Resulting in Serious Injury or Death

Fires resulting in serious injury or death are prioritized as "immediate jeopardy". The following actions are taken when a report of a fire resulting in serious injury or death in a Medicare/Medicaid certified facility is received from any source:

The SA

- Enters the complaint or self-reported incident into *the CMS system* (Priority = IJ, Allegation Category = Life Safety Code);
- Informs the appropriate *CMS location* of fire resulting in serious injury or death no later than one working day after receipt of the intake;
- Compiles information as needed to present a comprehensive picture of the situation surrounding the fire;
- Takes appropriate action necessary to assist the Medicare/Medicaid-certified provider/supplier to protect and/or relocate residents or patients from further harm; and
- Performs the Life Safety Code investigation.

The *CMS location*

- Informs CMS Central Office (CO) *Division of Emergency Preparedness and Life Safety Code (DEPL)* of the fire and planned actions, sending a copy of the alert to the Life Safety Code specialist;
- Consults with the CO *DEPL* to determine whether there is an indication for CO *DEPL* participation in the survey for program evaluation purposes;
- Reports any findings and actions taken by the SA to the CO *DEPL* at the end of the on-site survey; and
- At its discretion, may accompany the SA during the on-site survey.

The CO

- Consults with the *CMS location* to determine whether or not issues are present that indicate further investigation to determine the adequacy of current standards and their application; and
- In certain cases, CO *DEPL* staff may accompany *CMS location* and/or state personnel on the on-site survey.

5075.2 - Non-Immediate Jeopardy - High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Nursing Homes:

Intakes are assigned a "high" priority if the alleged noncompliance with one or more requirements may have caused harm that negatively impacts the individual's mental, physical and/or psychosocial status and are of such consequence to the person's well-being that a rapid response by the SA is indicated. Usually, specific rather than general information (such as: descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.) factors into the assignment of this level of priority.

Note: Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.

NOTE: Exhibit 22 provides additional guidance to distinguish between the priorities of "immediate jeopardy" and "non-immediate jeopardy - high" for nursing home complaints/incidents.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for information related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, or EMTALA requirements, if found to be true and uncorrected, would not represent an IJ, but would result in a determination of substantial noncompliance, i.e., at least one condition-level deficiency.

Intakes assigned this priority require an onsite survey to be initiated within 45 calendar days after intake prioritization for non-deemed providers/suppliers, and within 45 calendar days after authorization of the investigation by the *CMS location* for deemed status providers/suppliers. The *CMS location* has the discretion to request the onsite survey be initiated in less than 45 calendar days.

5075.3 - Non-Immediate Jeopardy - Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Nursing Homes:

Complaints are assigned a "medium" priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2). Facility-reported incidents are assigned a "medium" priority if the alleged noncompliance with one or more requirements caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s) (Severity Level 2) and the

facility has not provided an adequate response to the allegation or it is not known whether the facility provided an adequate response. *Please see Section 5075.9 for maximum time frames related to Federal onsite investigation of complaints/incidents.*

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for surveyor guidance related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Condition for Coverage or Condition for Certification is limited in manner and degree and/or caused, or may cause, harm that is of limited consequence and does not impair the individual's mental, physical and/or psychosocial status or function. In other words, the incident or complaint, if found to be true and uncorrected, would not result in a determination of substantial non-compliance, i.e., there would not be any condition-level deficiency.

For non-deemed providers/suppliers, intakes assigned this priority are scheduled in accordance with section 5075.9 for investigation no later than when the next on-site survey occurs.

For deemed providers/suppliers, the SA (or *CMS location*, if the *CMS location* handled the intake) advises the complainant that the allegation does not meet the criteria for a Federal investigation and refers the complainant to the applicable accrediting organization(s)(AOs) in accordance with the provisions of section 5100.2.

5075.4 - Non-Immediate Jeopardy – Low Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Nursing Homes

Intakes are assigned a "low" priority if the alleged noncompliance with one or more requirements may have caused no actual harm with a potential for minimal harm (Severity Level 1). *Please see S*ection 5075.9 *for maximum time frames related to Federal onsite investigation of complaints/incidents.*

In addition, facility-reported incidents are assigned a "low" priority if the alleged noncompliance with one or more requirements may have caused no actual physical and/or psychosocial harm but there is the potential for more than minimal harm to the resident(s)(Severity Level 2) and the facility has provided a potentially adequate response to the allegation.

NOTE: Please refer to Tag F610 in Appendix PP of the State Operations Manual for information related to facility responses to alleged violations, including facility investigation, resident protection, and corrective actions.

The SA reviews these intakes for tracking of possible trends in order to determine if there are common themes that suggest areas for focused attention when the next on-site survey occurs. If the SA identifies a trend that suggests similar concerns, the SA either investigates the concerns during the next standard or complaint survey or initiates a complaint survey.

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with one or more standards within a Condition of Participation, Coverage or Certification may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage.

For non-deemed providers/suppliers, the SA reviews these intakes for tracking of possible trends in the nature of complaints in order to determine if there are common themes that suggest areas for focused attention when the next on-site survey occurs. Individual investigations of each intake are not required, although the SA has the discretion to conduct a complaint survey if trending suggests a number of similar problems that might warrant an on-site investigation.

For deemed providers/suppliers, the SA (or *CMS location*, if the *CMS location* handled the intake) advises the complainant that the allegation does not meet the criteria for a Federal investigation and refers the complainant to the applicable accreditation organization(s)(AOs) in accordance with the provisions of section 5100.2.

5075.5 - Administrative Review/Offsite Investigation (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Nursing Homes

The SA conducts the review/offsite investigation and may confirm the findings at the next on-site survey.

Offsite investigations are rare and are not permitted unless approved in advance by CMS. For example, if a complaint is received related to arbitration agreements, prohibition on third party guarantee of payment, or prohibition on charges for services covered under Medicaid, CMS may approve an offsite review of these or other documents to assess compliance and cite noncompliance and require corrections, as necessary.

Non-long Term Care Providers/Suppliers

For non-long term care providers/suppliers, both deemed and non-deemed, administrative review or offsite investigation is generally not permitted. Exceptions are usually limited to the following types of cases:

- *CMS location* review of alleged noncompliance with provider agreement requirements found in 42 CFR Part 489, such as:
    - Alleged discrimination against Medicare beneficiaries, or
    - Failure of a hospital to accept Medicare-like payment rates for treatment provided to a patient referred by an Indian Health Service or tribal facility.
- *CMS location* review in the case of a CAH:
    - Of a notice by the MAC of failure of a CAH to maintain an average annual per patient length of stay not exceeding 96 hours, or
    - Whether a relocating CAH or an existing hospital seeking to convert to CAH status satisfies the CAH location requirements.

The *CMS location* documents in the provider/supplier file the results of such administrative review or offsite investigation. Note: depending on *CMS location* practice, such administrative review cases may or may not be entered into *iQIES*.

5075.6 - Referral – Immediate (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Intakes are assigned a "Referral – Immediate" priority if the nature and seriousness of a complaint/incident or State procedures requires the referral or reporting of this information for investigation to another agency, board, or ESRD network **without delay**.

For example, if a complaint has criminal implications and the complainant has not reported the incident to law enforcement, the SA must report the suspected crime to law enforcement immediately (NOTE: In such cases, the referral is recorded in the Contact/Refer tab under the *iQIES* intake). This priority may be assigned **in addition to** one of the priorities in sections 5075.1 through 5075.5.

When the SA refers the complaint/incident to another agency or entity (e.g., law enforcement, Ombudsman, licensure agency, etc.) for action, the SA must request a written report on the results of the investigation by the outside entity. Referral to an outside entity does not relieve the SA of the responsibility to assess compliance with Federal conditions or requirements, when applicable. The timeframes for investigation are not altered by the referral. (Expressed requests by law enforcement that the SA defer an onsite investigation should be discussed with the CMS *location*, as appropriate.)

5075.7 - Referral – Other (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Intakes are assigned a "Referral – Other" priority when they are referred to another agency, board, or ESRD network for investigation or for informational purposes. This priority may be assigned **in addition to** one of the priorities in sections 5075.1 through 5075.5.

When the SA refers the complaint/incident to another agency or entity (e.g., law enforcement, Ombudsman, licensure agency, etc.) for action, the SA must request a written report on the results of the investigation by the outside entity. Referral to an outside entity does not relieve the SA of the responsibility to assess compliance with Federal conditions or requirements, when applicable. The time frames for investigation are not altered by the referral. (Expressed requests by law enforcement that the SA defer an onsite investigation should be discussed with the CMS *location*, as appropriate.)

5075.8 - No Action Necessary (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Intakes are assigned a "No Action Necessary" priority if the SA or *CMS location* determines with certainty that no further investigation, analysis, or action is necessary.

For example, no action is necessary if the allegation is not related to any Federal COPs, CFCs, conditions for certification, RFPs, or EMTALA requirement(s); or situations in which a previous survey investigated the exact same event(s) and either did not find noncompliance, or noncompliance was previously identified and subsequently corrected by the provider/supplier.

This category would also be used for intakes concerning an event that occurred more than 12 months in the past, unless the SA (or the *CMS location*, in the case of a deemed status provider/supplier) determines that a complaint investigation is nevertheless warranted.

Nursing Homes

The following are examples of reports that require no further action or investigation by the SA/*CMS location*:

1) Facility-reported incidents that are not reportable events under Federal law or regulations;

2) Facility-reported incidents involving lost items, which are found and no theft is suspected; and

3) The alleged event occurred before the last standard survey and there is sufficient evidence that the facility does not have continuing noncompliance since the last standard survey.

NOTE: Sufficient evidence that the facility does not have continuing noncompliance may be indicated by a recent survey that reviewed the concern, no additional complaints or facility reported incidents have been received regarding the same issue, and interview with the Long-term Care Ombudsman which reveal no concerns.

5075.9 - Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

	Intake Prioritization			
Provider Type	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium	Non-IJ Low
Nursing home complaints	SA must initiate an onsite survey within 3 business days of receipt of the initial report.	SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.	SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.	SA must track/trend for potential focus areas during the next onsite survey, or initiate a new complaint survey.
Nursing home incidents	With inadequate resident protection, SA must initiate an onsite survey within 3 business days of receipt of the initial report. With potentially adequate resident protection, SA must initiate an onsite survey within 7 business days of receipt of the initial report. See Section 5310.2A.	SA must initiate an onsite survey within an annual average of 15 business days of receipt of the initial report, not to exceed 18 business days.	With an inadequate facility response, SA must initiate an onsite survey within 45 calendar days of receipt of the initial report.	With a potentially adequate facility response, SA must track/trend for potential focus areas during the next onsite survey, or initiate a new complaint survey.
Non-deemed non-long term care providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt.	SA must initiate an onsite survey within 45 calendar days of prioritization	SA must investigate no later than when the next onsite survey occurs	SA must track/trend for potential focus areas during the next onsite survey.
Deemed providers/suppliers	SA must initiate an onsite survey within 2 business days of receipt of *CMS location* authorization	SA must initiate an onsite survey within 45 calendar days of receipt of *CMS location* authorization.	Complainant is referred to the applicable accrediting organization(s)	Complainant is referred to the applicable accrediting organization(s)
EMTALA	SA must initiate an onsite survey within 2 business days of receipt of *CMS location* authorization.	SA must initiate an onsite survey within 45 calendar days of receipt of *CMS location* authorization	N/A	N/A
Death associated with restraint/seclusion-Hospitals	SA must initiate an onsite survey within 2 business days of receipt of *CMS location* authorization.	N/A	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 business days of receipt.	N/A	N/A	N/A

5077 - State Monitoring Visits

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

"State monitoring visits" refers to visits by the SA to oversee a provider's/supplier's compliance status:

- During bankruptcy, in those cases in which CMS has authorized such visits.
- After a change of ownership, as authorized by the CMS *location*.
- During or shortly after removal of immediate jeopardy when the purpose of the visit is to ensure the welfare of the residents/clients/patients by providing an oversight presence, rather than to perform a structured follow-up visit.
- In other circumstances, as authorized by the CMS *location*.

See Section 5060 for data entry requirements for this type of visit.

5080.1 - Report to the Complainant

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SA/CMS *location* provides the complainant a written report of the investigation findings as a summary record of the investigation.

The following principles guide preparation of the report to the complainant:

- Acknowledge the complainant's concern(s);
- Identify the SA's regulatory authority to investigate the complaint/incident and any statutory or regulatory limits that may bear on the authority to conduct an investigation;
- Provide a summary of investigation methods (e.g., on-site visit, written correspondence, telephone inquiries, etc.);
- Provide date(s) of investigation;
- Provide an explanation of your SA's decision-making process (NOTE: CMS and the SA should avoid using terms such as "substantiated" and "unsubstantiated");
- Provide the complainant with information regarding whether or not noncompliance was identified during the complaint investigation. (**NOTE**: To the extent possible, the summary should not compromise the anonymity of

individuals, or include specific situations that may be used to identify individuals, when anonymity has been requested or is appropriate in the judgment of the SA);

- Identify where the complainant may find the Statement of Deficiencies and Plan of Correction (e.g., posted at the nursing home, Nursing Home Care Compare, request the CMS-2567 from the SA);

- Describe how the complainant may request a copy of the investigation report, subject to Federal and State disclosure requirements (e.g., see 42 CFR §488.325 and FOIA requirements at 45 CFR Part 5); and

- Identify appropriate referral information (i.e., other agencies that may be involved).

5080.2 - Survey Exit Conference and Report to the Provider/Supplier

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Generally, the SA conducts an exit conference with the provider/supplier at the completion of the on-site portion of the complaint investigation survey. The SA informs the provider/supplier of the survey findings, including a general description of any deficiencies found. The description should be detailed enough to inform the provider/supplier of the types of activities that require the provider's/supplier's corrective action. However, the SA must not comment on the scope and severity of the deficiencies identified for long term care facilities. For non-long term care providers/suppliers, the SA must not comment on manner and degree, that is, whether the deficiencies identified were condition- or standard-level. Surveyors must also not make reference to any "Tags" related to deficiencies identified in non-long term care as this identifies condition- or standard-level. Instead identify the regulatory grouping where concerns exist. See Section 2724 for additional information about presenting findings during the Exit Conference.

For non-long term care providers/suppliers, the SA must not provide a list of patients interviewed, observed, or whose medical records were reviewed, and does not identify specific patients whose cases are associated with specific deficiencies. (The provider/supplier has the right to request a copy of any documentation the surveyors copy to support deficiency findings; therefore the provider/supplier should have enough information after the exit conference to begin corrective actions.)

The SA informs the provider/supplier that survey findings will be documented on Form CMS 2567, which will be sent to the provider/supplier and subsequently will be made available to the public under the disclosure of survey information provisions. For deemed providers/suppliers, the SA informs the provider/supplier that the *CMS location* will be consulted and (depending on *CMS location* practice), either the *CMS location* or the SA will inform the facility of the results of the survey investigation via the Form CMS 2567.

The SA/*CMS location* sends to the provider/supplier a written report of the investigation findings as a summary record of the investigation. At a minimum, this would include the Form CMS 2567 and applicable notices. For surveys of deemed providers/suppliers (not including EMTALA surveys), the *CMS location* sends a copy of the written report to the applicable accrediting organization(s), following the procedures specified in Section 5110. At the *CMS location*'s or SA's discretion, the materials may be sent to the accrediting organization via e-mail.

(See Section 5300.5 for guidance on the exit conference for long term care facilities, Section 5440.5 for EMTALA investigations, as well as the provider/supplier-specific appendices of the SOM, and Appendix V of the SOM concerning EMTALA.)

NOTE: Sections 5300 to 5390 relate to nursing homes.

5100.1 - Basis for Investigation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Sections 1864(c) and 1865 of the Social Security Act (the Act) provide the basis for conducting substantial allegation validation – i.e., complaint investigation - surveys of deemed providers/suppliers. Before the SA may conduct a complaint investigation survey at a deemed provider/supplier, it must receive authorization to do so from the *CMS location*. In accordance with 42 CFR 488.7, the *CMS location* may authorize a complaint investigation only in response to a "substantial allegation" of noncompliance. A "substantial allegation of noncompliance" is defined at 42 CFR 488.1 as a complaint from any of a variety of sources, including complaints submitted in person, by telephone, through written correspondence, or in news media articles, that, if substantiated, would have an impact on the health and safety of patients, and that raises doubts as to a provider's or supplier's compliance with any Medicare condition. In other words, the complaint, if verified and uncorrected at the time of the survey, would result in a condition-level deficiency citation. The SA survey conducted in response to a substantial allegation is one type of validation survey.

NOTE: Deemed status is irrelevant for EMTALA complaints. Hospitals and CAHs may not be deemed to be in compliance with EMTALA requirements at 42 CFR 489.24 and the related requirements at 42 CFR 489.20, since these requirements are not part of an approved Medicare hospital or CAH Medicare accreditation program. SAs must refer all EMTALA-related allegations concerning a hospital or CAH to the *CMS location*, regardless of whether the hospital or CAH is deemed or not. The provisions of Section 5100 do not apply to EMTALA investigations.

The SA must notify the *CMS location* of all complaints/incidents it receives which, if substantiated, would by their manner and degree suggest condition-level noncompliance. The *CMS location* authorizes the SA to conduct a complaint investigation if it concurs that the nature of the allegation, if it were true and uncorrected, suggests condition-level

noncompliance. If the *CMS location* does not concur that the allegation rises to this level, either the *CMS location* will change the prioritization of the intake in ACTS to the appropriate level or it will instruct the SA to do so. Regardless of who makes the change in ACTS, the *CMS location* instructs the SA to refer the complainant to the applicable accrediting organization, following the procedures in section 5100.2

The *CMS location* communicates its authorization to conduct a complaint investigation of the deemed provider/supplier by completing the applicable Form CMS 2802 (See Exhibit 33) in ACTS, indicating which Conditions of Participation or Conditions for Coverage or Certification are to be investigated by the SA. Absent *CMS location* authorization, the SA may not conduct a Federal complaint investigation of the deemed provider/supplier. The SA may have authority under State law to conduct its own non-Federal investigation.

The *CMS location* completes the Form CMS 2802 in ACTS even if the SA received an initial verbal authorization from the *CMS location* to initiate the complaint survey of a deemed provider/supplier. Since ACTS allows the *CMS location* to authorize a complaint survey electronically it is not necessary for the *CMS location* to send a signed hard copy of the Form CMS 2802 to the SA via fax or U.S. Postal Service. Once the SA receives the authorization, it may begin its complaint investigation of a deemed provider/supplier. Whether the survey is of one or all Medicare conditions, it will be treated as a complaint survey under ACTS rather than a re-certification survey, since the complaint/incident is the basis for the survey.

If the *CMS location* learns directly of a complaint/incident concerning a deemed provider/supplier, it will review the complaint/incident to assign a priority consistent with Section 5075. If the complaint/incident is found to be a substantial allegation of noncompliance, prioritized for investigation as either immediate jeopardy or non-IJ high, the *CMS location* authorizes the SA to conduct a complaint investigation or, in a limited number of cases, the *CMS location* conducts the complaint investigation.

There may be occasions during the course of a State-only activity in a deemed provider/supplier when State surveyors observe a situation they believe may constitute IJ or other substantial noncompliance with a Medicare condition. In such circumstances, the State must contact the *CMS location* by telephone or e-mail, explain the situation, and request authorization to conduct a Federal complaint survey. CMS authorizes the investigation as a complaint validation (i.e., substantial allegation validation) survey if it concurs that there may be condition-level noncompliance. The complaint is entered into ACTS at the earliest possible opportunity.

5100.2 – Initial Response to Complainant

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

- If the SA concludes that a complaint represents a substantial allegation of noncompliance (i.e., it is appropriately triaged as an IJ or non-IJ high), it requests authorization in ACTS from the *CMS location* to conduct a survey. If the *CMS location* authorizes a survey, the SA acknowledges receipt of the complaint by a letter

to the complainant, and advises that a SA investigation will be initiated. The acknowledgment letter also advises that the complainant may also wish to file a complaint with the applicable accrediting organization (AO), naming the AO and attaching a current list of AOs and their contact information. This list may be found at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Complaint-Contacts.pdf

- If the SA concludes that a complaint does not represent a substantial allegation of noncompliance (i.e., it is appropriately triaged as non-IJ medium or low) the SA sends the complainant a letter indicating that the complaint does not meet the criteria for a Federal on-site investigation of an accredited health care facility. The letter also advises the complainant which AO(s) accredit the provider/supplier for Medicare participation purposes and provides the above AO contact information, should the individual wish to pursue a complaint with the AO.

If the *CMS location* directly receives a complaint, it is responsible for sending the complainant a letter which acknowledges the receipt of the complaint and advises the complainant in the same manner as indicated above for complaints received by the SA**.**

5110.1 - Substantial Compliance

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If a condition-level deficiency is not cited at a survey, the provider/supplier is in substantial compliance with the Federal requirements. The SA certifies its survey findings in ACTS within 30 calendar days after the completion of the survey. A Form CMS 2567 is prepared in all cases. Even if no deficiencies were cited, the Form CMS 2567 is issued with a statement that a survey was conducted to evaluate compliance with the listed requirements identified on the CMS-2802 and that no deficiencies were identified in these areas.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review to determine if the *CMS location* concurs with the SA's finding of substantial compliance.

- For all cases not selected for review of the Form CMS 2567, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

- For cases selected for review of the Form CMS 2567:

    - If the *CMS location* concurs with the finding, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562

and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

- If the *CMS location* does not concur with the SA's findings of substantial compliance, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for a survey finding substantial noncompliance. (See Section 5110.2 or 5110.3, as applicable.)

The *CMS location* either issues a notice or authorizes the SA in ACTS to issue the provider/supplier a notice of its compliance status. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567containing the survey findings. The notice indicates that the provider/supplier was found to be in substantial compliance even though there may, or may not, also be standard-level deficiencies cited. In such circumstances, the provider/supplier is not required to submit a plan of correction for any cited standard-level deficiencies, but may choose to do so because the Form CMS 2567 is available to the public. The SA and *CMS location* do not review any plan of correction the provider/supplier submits; no revisit survey is conducted. **The *CMS location* promptly sends a copy of the notice letter and Form CMS 2567 to the applicable AO(s).** At the *CMS location*'s or SA's discretion, the materials may be sent to the AO via e-mail.

5110.2 - Condition-Level, IJ

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

1. IJ Removed while the SA is On-site

If deficiencies pose an IJ and the IJ is removed while the SA is on-site, deficiency citations are made at the condition-level. Follow the procedure for condition-level noncompliance, non-IJ, in Section 5110.3 below.

Note: The Form CMS 2567 must state at the beginning that an IJ was cited, regardless of the fact that it was removed while the SA was on-site. An entry in ASPEN/ACTS must also be made by the *CMS location* indicating that there was an IJ citation before the survey can be uploaded to the national database, the CMS National Reporting System (CASPER). The ASPEN/ACTS systems will prompt the *CMS location* whenever a survey includes condition-level deficiencies to indicate whether there was also an IJ.

Details of the IJ situation and the actions taken by the provider/supplier to remove the IJ must also be documented on the Form CMS 2567. Even though the IJ was removed while the SA was on-site, the provider or supplier must still be cited for condition-level noncompliance for the applicable Condition of Participation, Condition for Coverage, or Condition for Certification that is cited for non-compliance related to the IJ. The documentation must also include the date the surveyors verified that the IJ was removed prior to completion of the survey.

2. IJ not Removed while the SA is On-site

If condition-level deficiencies pose an IJ and the IJ is not removed while the SA is on-site, the SA certifies its findings in ACTS within 2 working days after the completion of the survey.

If the *CMS location* concurs with the SA's findings, the deemed provider/supplier is placed on a 23 calendar-day termination track. The *CMS location* sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which is 23 calendar days after the date of the *CMS location*'s notice, and requests submission of an acceptable plan of correction to the *CMS location* within 5 calendar days of the notice. The provider/supplier is advised it will be surveyed after receipt of an acceptable plan of correction and prior to the termination date. The notice also contains a statement that "removes" the "deemed status" of the provider/supplier and places it under SA jurisdiction.

The *CMS location* sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

Note: Although deemed status technically has been removed and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility, so long as it continues to accredit the provider/supplier under its approved Medicare accreditation program.

When the *CMS location* receives a timely and acceptable plan of correction from the provider/supplier, it directs the SA to conduct either a full survey or an IJ follow-up survey, which is a focused, revisit-type survey, before the scheduled termination date in order to confirm that the IJ has been removed and that the provider/supplier is in substantial compliance. See Section 5110.3 for a discussion of factors the *CMS location* should consider when deciding whether a full survey is needed. If the *CMS location* authorizes a full survey, see Section 5110.4 for procedures to follow, except that the full survey must be conducted prior to the 23-day termination date.

i. No Acceptable Plan of Correction Submitted

No revisit is necessary if the provider/supplier fails to submit a timely and acceptable plan of correction. CMS will proceed to terminate a provider/supplier if it does not submit a timely and acceptable POC. See SOM Section 3254F. The public notice must be published 15 calendar days prior to the termination date. The *CMS location* notifies the applicable Medicare Administrative Contractor

(MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

The *CMS location* sends a copy of the termination letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

ii. Post-IJ First Revisit: IJ Not Removed

At least 5 calendar days in advance of the scheduled termination date, the SA certifies to the *CMS location* in ACTs its findings, based on on-site verification, that the IJ has not been removed, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into the CMS National Reporting System (CASPER). The termination of the provider's/supplier's Medicare agreement is processed in ASPEN.

The *CMS location* sends the provider/supplier a final termination letter and publishes a public notice, in accordance with the termination process in Section 3010B. The provider/supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

iii. Post-IJ First Revisit: IJ Removed, Substantial Compliance

The termination action is rescinded if the IJ has been removed and substantial compliance has been achieved prior to the effective date of the termination, i.e., there are no condition-level deficiencies identified during the follow-up survey by the SA. The SA certifies its findings to the *CMS location* via ACTS at least 5 calendar days in advance of the scheduled termination date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur with the SA's finding, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

When substantial compliance is achieved, the *CMS location* either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice of its compliance status, restoring its deemed status. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 containing the survey findings.

In addition, the *CMS location* sends a copy of the notice letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

Although the follow-up survey found the provider/supplier to be in substantial compliance, it may have resulted in citation(s) of standard-level deficiencies of the Form CMS 2567. Because deemed status has been restored, the provider/supplier is not obligated to submit a plan of correction to the SA, nor are any further revisits conducted. The provider/supplier may voluntarily choose to submit a plan of correction because the Form CMS 2567 will be made available to the public. The SA and *CMS location* do not review any plan of correction the provider/supplier submits; no further revisit survey is conducted.

iv. Post-IJ First Revisit: IJ Removed, Substantial Noncompliance Remains

If the IJ has been removed but substantial noncompliance (i.e., condition-level deficiencies), remain, the SA certifies its findings to the *CMS location* in ACTS within 10 working days after the survey completion date. The SA certifies that the IJ has been removed and recommends rescission of the 23 calendar-day IJ termination action, but continuation of the termination action on a 90 calendar-day termination track.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* gives the provider/supplier up to 67 additional calendar days, or a total of 90 calendar days (23 plus 67) to achieve substantial compliance. The resulting revised termination date is 90 calendar days after the date of the *CMS location*'s original 23-day notice. The *CMS location* sends the CMS Form 2567 from the follow-up survey to the provider/supplier with notice of

the new termination date, and requests that an acceptable POC be provided to the SA within 10 calendar days of the notice.

Post-IJ Second Revisit: The SA conducts the second revisit survey by the 60th calendar day after the date of the *CMS location*'s original 23-day termination notice. Unlike the post-IJ first revisit survey, advance authorization from the *CMS location* is not required.

(i) Post-IJ Second Revisit Survey Findings: Substantial Compliance

The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the *CMS location* its findings via ACTS and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or the *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue a notice to the provider/supplier of its compliance status and that its deemed status is restored. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

***i.* Post-IJ Second Revisit Survey Findings: Substantial Noncompliance**

If the second revisit shows that the provider/supplier fails to demonstrate substantial compliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies to the *CMS location* its

findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider/supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider/supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The *CMS location* sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

5110.3 - Condition-Level, Non-IJ

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the provider/supplier fails to demonstrate substantial compliance, i.e., condition-level deficiencies are identified by the SA, but they do not pose an IJ, the SA certifies its findings to the *CMS location* via ACTS within 10 working days after the survey completion date.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* **either** places the deemed provider/supplier on a 90 calendar-day termination track **or** it requires a full survey after a complaint survey.

In determining whether to exercise its discretion to require a full survey for deemed providers and suppliers, the *CMS location* may consider factors including, but not limited to, the following:

- The manner and degree of noncompliance identified as a result of the complaint investigation;
- The provider's/supplier's compliance history;
- Recent changes in the provider's/supplier's ownership or management;
- The length of time since the provider's/supplier's last accreditation survey;

- The availability of SA resources at the time required to conduct a full survey; and/or

- The advantages associated with conducting a more extensive survey compared to the advantages associated with the faster enforcement (and thus a faster potential corrective action) that result when proceeding directly to enforcement action after the complaint survey.

Paragraph a) below discusses the procedures when the *CMS location* does not require a full survey after the complaint survey; paragraph b) discusses the procedures to follow when the *CMS location* directs the SA to conduct a full survey.

a) No full survey – proceed directly to termination track based on the complaint survey

If the *CMS location* places the deemed provider/supplier on a 90 calendar-day termination track as a result of the complaint investigation, it sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which will be 90 calendar days after the date of the *CMS location*'s notice. The *CMS location* requests submission of an acceptable plan of correction to the SA within 10 calendar days. The notice also contains a statement that "removes" the "deemed status" of the provider/supplier and places it under SA jurisdiction.

The *CMS location* sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

NOTE: Although deemed status has technically been "removed" and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility so long as it continues to accredit the provider/supplier.

The SA conducts a complaint survey revisit after the SA has received a timely and acceptable plan of correction, but no later than the 45th calendar day after the notice to the provider/supplier.

1) No Timely, Acceptable Plan of Correction Submitted

If the provider/supplier fails to submit a timely and acceptable plan of correction to the SA and as a result the SA is unable to conduct a timely revisit before the termination date, the SA notifies the *CMS location* and the *CMS location* may

proceed with termination. See SOM Section 3254F. The *CMS location* publishes a public notice 15 days prior to the termination date. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* approves the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into the CMS National Reporting System (CASPER). The provider's or supplier's Medicare agreement is terminated in ASPEN.

Additionally, the *CMS location* sends a copy of the notice of termination letter to the applicable AO(s).

2) First Revisit Survey Findings: Substantial Compliance

The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the first revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the *CMS location* in ACTS its findings and recommends that the termination action be rescinded.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review to determine if the *CMS location* concurs with the SA's finding of substantial compliance.

- For all cases not selected for review of the Form CMS 2567, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

- For cases selected for review of the Form CMS 2567:

    - If the *CMS location* concurs with the finding, the *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

    - If the *CMS location* does not concur with the SA's findings of substantial compliance, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are

made, follows the procedures for a survey finding substantial noncompliance. (See Section 5110.2 or 5110.3, as applicable.)

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue a notice to the provider/supplier of its compliance status and that its deemed status is restored. The *CMS location* or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

3) First Revisit Survey Findings: Substantial Noncompliance

If the SA finds during the first revisit survey that the provider/supplier is not in substantial compliance with one or more Medicare conditions, the SA consults with the *CMS location* on its findings and whether to conduct a second revisit. If the *CMS location* agrees that condition-level deficiencies remain, the *CMS location* considers whether the survey findings warrant a second revisit or proceeding immediately to termination. Generally the *CMS location* authorizes a second revisit, but the *CMS location* has discretion to make an exception, based on the facts of the situation. For example, if the SA and *CMS location* determine that an immediate jeopardy was present during the first revisit, the *CMS location* might find it prudent to proceed to termination without a second revisit.

If the *CMS location* agrees that condition-level deficiencies remain and does not authorize a second revisit, the *CMS location* and SA follow the procedures outlined in paragraph 3ii. below.

If a second revisit is authorized by the *CMS location*, the SA sends the provider/supplier the Form CMS 2567 for the first revisit with notice that substantial noncompliance remains, the 90-day termination date remains in effect, a new acceptable plan of correction is required, and that an additional revisit will be conducted prior to the termination date. The SA conducts the second revisit no later than 60 calendar days after the date of the termination notice.

i. Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA), the SA certifies its findings to the *CMS location* via ACTS within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice letter of its compliance status and that its deemed status is restored. The *CMS location* or SA, as applicable, forwards this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the *CMS location* sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

ii. Second Revisit Survey Findings – Substantial Noncompliance

If the second revisit survey shows that the provider/supplier fails to demonstrate substantial compliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies its findings to the *CMS location* via ACTS within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider/supplier a final termination letter and publishes a public notice at least 15 calendar days prior to the termination date, consistent with the requirements of Section 3012. The provider/supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System. The provider's or supplier's Medicare agreement is terminated in ASPEN.

Additionally, the *CMS location* sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

b) Full Survey After the Complaint Survey

If the *CMS location* directs the SA to conduct a full survey following the complaint survey, it sends the Form CMS 2567 for the complaint survey to the provider/supplier in addition to a notice letter indicating that it is "removing" the provider's/supplier's deemed status and that a full survey will be conducted on an unannounced basis. The provider/supplier is not required to submit a plan of correction in response to the complaint survey findings, but may choose to do so.

The *CMS location* completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

Additionally, the *CMS location* sends a copy of the notice letter and Form CMS 2567 for the complaint survey to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

NOTE: Although deemed status technically has been removed and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility so long as, since it continues to accredit the provider/supplier.

The full survey must be conducted within 60 calendar days after the *CMS location*'s notice to the provider/supplier of the complaint survey results and removal of deemed status. The *CMS location* and SA follow the procedures in Section 5110.4.

5110.4 - Full Survey after Complaint Survey with Condition-level Deficiencies, When Authorized by the *CMS location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the *CMS location* authorizes the SA to conduct a full survey after the complaint survey, the timeframes and procedures described in this section apply.

Timeframe

The full survey must be conducted within:

- 23 days after the *CMS location*'s notice to the provider/supplier, if the complaint survey involved an IJ that was not removed while the survey team was on-site; or

- 60 calendar days after the *CMS location*'s notice to the provider/supplier in all other cases.

Procedures following the full survey with findings of:

a) Full Survey Findings: Substantial Compliance

If the SA full survey finds the deemed provider or supplier to be in substantial compliance, the SA and *CMS location* follow the same procedures and timeline as at Section 5110.1. In addition, since the *CMS location* had removed deemed status, the *CMS location* either issues a notice, or authorizes the SA to issue a notice to the provider or supplier of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

b) Full Survey Findings: Condition-Level, IJ

1. **IJ Removed while the SA is On-site**

If deficiencies pose an IJ and the IJ is removed while the SA is on-site, deficiency citations are made at the condition-level. Follow the procedure for condition-level noncompliance, non-IJ, in Section 5110.4c below.

Note: The Form CMS 2567 must state at the beginning that an IJ was cited, regardless of the fact that it was removed while the SA was on-site. An entry in ASPEN must also be made by the *CMS location* indicating that there was an IJ citation before the survey can be uploaded to the national database, the CMS National Reporting System (CASPER). The ASPEN systems will prompt the *CMS location* whenever a survey includes condition-level deficiencies to indicate whether there was also an IJ.

Details of the IJ situation and the actions taken by the provider/supplier to remove the IJ must also be documented on the Form CMS 2567. Even though the IJ was removed while the SA was on-site, the provider or supplier must still be cited for condition-level noncompliance for the applicable Condition of Participation or Condition for Coverage that is cited for non-compliance related to the IJ. The documentation must also include the date the surveyors verified that the IJ was removed prior to completion of the survey.

2. **IJ not Removed while the SA is On-site**

If condition-level deficiencies pose an IJ and the IJ is not removed while the SA is on-site, the SA certifies its findings to the *CMS location* within 2 working days after the completion of the survey.

If the *CMS location* concurs with the SA's findings, the deemed provider/supplier is placed on a 23 calendar-day termination track. The *CMS location* sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which is 23 calendar days after the date of the *CMS location*'s notice, and requests submission of an acceptable plan of correction to the *CMS location* within 5 calendar days of the notice.

The *CMS location* sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

When the *CMS location* receives a timely and acceptable plan of correction from the provider/supplier, it directs the SA to conduct an IJ follow-up survey before the rescheduled termination date in order to confirm that the IJ has been removed and that the provider/supplier complies with the conditions previously cited for noncompliance.

2.1 First Revisit after Full Survey with IJ

i. No Acceptable Plan of Correction Submitted

No revisit is necessary if the provider/supplier fails to submit a timely and acceptable plan of correction. CMS will proceed to terminate a provider/supplier if it does not submit a timely and acceptable POC. See SOM Section 3254F. The public notice must be published 15 calendar days prior to the termination date. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The SA and *CMS location* complete the processing in ASPEN of the survey kit and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint survey package into CASPER, the CMS National Reporting System.

The *CMS location* sends a copy of the termination letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

ii. First Revisit Survey Findings: IJ Not Removed

At least 5 calendar days in advance of the scheduled termination date, the SA certifies to the *CMS location* its findings, based on on-site verification, that the IJ has not been removed, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the SA and *CMS location* complete the processing of the survey kit in ASPEN and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into the CMS National Reporting System (CASPER). The termination of the provider's/supplier's Medicare agreement is processed in ASPEN.

The *CMS location* sends the provider/supplier a final termination letter and publishes a public notice, in accordance with the termination process in Section 3010B. The provider or supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

iii. First Revisit Survey Findings: IJ Removed, Substantial Compliance

The termination action is rescinded if the IJ has been removed and substantial compliance has been achieved prior to the effective date of the termination, i.e., there are no condition-level deficiencies identified during the first revisit survey by the SA. The SA certifies its findings to the *CMS location* at least 5 calendar days in advance of the scheduled termination date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects several Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur with the SA's finding, the *CMS location* discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

When substantial compliance is achieved, the *CMS location* either issues a notice, or authorizes the SA to issue the provider/supplier a notice of its compliance status, restoring its deemed status, along with a copy of the Form CMS 2567containing the survey findings.

In addition, the *CMS location* sends a copy of the notice letter to the applicable AO(s). At the *CMS location*'s discretion, the copy may be sent to the AO via e-mail.

Although the revisit survey found the provider/supplier to be in substantial compliance, it may have resulted in citation(s) of standard-level deficiencies of the Form CMS 2567. Because deemed status has been restored, the provider or supplier is not obligated to submit a plan of correction to the SA, nor are any further revisits conducted. The provider or supplier may voluntarily choose to submit a plan of correction because the Form CMS 2567 will be made available to the public. The SA and *CMS location* do not review any plan of correction the provider/supplier submits; no further revisit survey is conducted.

iv. First Revisit Survey Findings: IJ Removed, Substantial Noncompliance Remains

If the IJ has been removed but substantial noncompliance (i.e., condition-level deficiencies), remains, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date. If the *CMS location* concurs that the IJ has been removed but that condition-level deficiencies remain, the *CMS location* considers whether the survey findings warrant a second revisit or proceeding immediately to termination. At this point the provider/supplier will have been surveyed three times, including the preceding complaint survey, with continued substantial noncompliance found in each survey and at least one IJ. Generally the *CMS location* authorizes a second revisit, but the *CMS location* has discretion to make an exception, based on the facts of the case, including the risks to patients associated with the remaining deficiencies versus providing the provider/supplier further opportunity to correct its problems in a timely manner.

If the *CMS location* does not authorize a second revisit, it follows the procedures in paragraph ii above.

If the authorizes a second revisit, the *CMS location* gives the provider/supplier up to 67 additional calendar days, or a total of 90 calendar days (23 plus 67) from the date of the notice of the IJ, to achieve substantial compliance. The resulting revised termination date is 90 calendar days after the date of the *CMS location*'s original 23-day termination notice. The *CMS location* provides the provider/supplier the Form CMS 2567 for the revisit with notice of the new termination date, and requests that an acceptable POC be provided to the SA within 10 calendar days of the notice.

2.2 Second Revisit after Full Survey with IJ

The SA conducts the second revisit survey no later than 60 calendar days after the date of the *CMS location*'s 23-day termination notice to the provider or supplier.

i. Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA) during the second revisit survey, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey kit into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* also either issues a notice, or authorizes the SA to issue the provider/supplier a notice, of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the *CMS location* sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

ii. Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that substantial noncompliance (i.e., condition-level deficiencies) remain, the SA certifies to the *CMS location* its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider or supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider or supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The SA and *CMS location* complete the processing in ASPEN of the survey kit and, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The *CMS location* sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

c) Full Survey Findings: Condition-Level, Non-IJ

If the results of the full survey indicate there is substantial noncompliance (i.e., condition-level deficiencies), but the deficiencies do not constitute an IJ, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* places the provider or supplier on a 90 calendar-day termination track as a result of the full survey. The *CMS location* sends the provider or supplier the Form CMS 2567 and notifies it of the proposed termination action and effective date, which will be 90 calendar days after the date of the *CMS location*'s notice. The *CMS location* requests submission of an acceptable plan of correction to the SA within 10 calendar days of the notice.

Additionally, the *CMS location* sends a copy of the notice of termination letter to the applicable AO(s).

1. **First Revisit: The** SA conducts the first revisit survey no later than the 45th calendar day after the date of the *CMS location*'s termination notice to the provider or supplier.

   i. **First Revisit Survey Findings: Substantial Compliance**

   The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the *CMS location* its findings and recommends that the termination action be rescinded.

   The *CMS location* randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing of the survey kit in ASPEN and then, depending on *CMS location* practice, either the SA or the *CMS location* uploads the survey package into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* either issues a notice, or authorizes the SA to issue a notice to the provider or supplier of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

The *CMS location* sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

ii. **First Revisit Survey Findings: Substantial Noncompliance**

If the SA confirms during the first revisit survey that the provider/supplier is not in substantial compliance with one or more Medicare conditions, the SA consults with the *CMS location* on its findings and whether to conduct a second revisit. If the *CMS location* concurs that condition-level deficiencies remain, the *CMS location* considers whether the survey findings warrant a second revisit or proceeding immediately to termination. At this point the provider/supplier will have been surveyed three times, including the complaint survey, the full survey and the first revisit, with substantial noncompliance found on each survey. Generally the *CMS location* authorizes a second revisit, but the *CMS location* has discretion to make an exception, based on the facts of the case, including the risks to patients associated with the remaining deficiencies versus providing the provider/supplier further opportunity to correct its problems in a timely manner.

If the *CMS location* does not authorize a second revisit, the *CMS location* and SA will follow the procedures outlined in paragraph 2(ii). below.

If the *CMS location* authorizes a second revisit, the SA sends the provider/supplier the Form CMS 2567 for the first revisit with notice that substantial noncompliance remains, the 90-day termination date remains in effect, a new acceptable plan of correction is required, and that an additional revisit will be conducted prior to the termination date.

2. Second Revisit: The SA conducts the second revisit survey no later than 60 calendar days after the date of the termination notice to the provider or supplier.

(i) Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA) during the second revisit survey, the SA certifies its findings to the *CMS location* within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The *CMS location* randomly selects some Form CMS 2567s with standard-level deficiencies for review, to determine if the *CMS location* concurs with the SA's finding of substantial compliance. If the *CMS location* concurs, and

in all other cases where the Form CMS 2567 is not reviewed by the *CMS location*, the *CMS location* completes the processing in ASPEN of the survey kit and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the complaint and revisit surveys into CASPER, the CMS National Reporting System. If the *CMS location* does not concur, the *CMS location* discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The *CMS location* also either issues a notice, or authorizes the SA in ACTS to issue the provider or supplier a notice, of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the *CMS location* sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

(ii) Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that the provider or supplier has substantial noncompliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies to the *CMS location* its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The *CMS location* reviews the SA's findings, and if it concurs with the SA's recommendation, the *CMS location* sends the provider/supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider or supplier is terminated from the Medicare program. The *CMS location* notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The *CMS location* completes the processing in ASPEN of the survey kit and then, depending on *CMS location* practice, either the SA or *CMS location* uploads the survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The *CMS location* sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the *CMS location*'s discretion, the materials may be sent to the AO via e-mail.

5130 – Deemed Provider/ Supplier Refusal of Complaint Investigation Surveys

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SA informs the provider/supplier that refusal to allow a complaint investigation survey is a basis for termination and exclusion from the Medicare program, in accordance with Section 1128(b)(12) of the Social Security Act. The SA notifies the *CMS location* immediately of a refusal to allow a complaint investigation survey.

5140 - Complaints Involving HIV-Infected Individuals

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

As direct recipients of Federal funds, providers and suppliers are subject to provisions of Section 504 of the Federal Rehabilitation Act of 1973. Symptomatic and asymptomatic individuals who are infected with the human immunodeficiency virus (HIV), or "AIDS virus," are protected by the Rehabilitation Act as "individuals with handicaps." Therefore, HIV-infected individuals who are provided services, are employed, or are to be employed by providers and suppliers in Federally-conducted or financed programs or activities would be treated like anyone else in the workforce, so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

A provider participating in the Medicare or Medicaid programs cannot discriminate against individuals who are HIV-infected so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others and so long as the provider provides comparable services and care to non HIV-infected individuals.

The SA or the *CMS location* refers discrimination complaints to the Office of Civil Rights (OCR), which is the authority to determine whether Medicare or Medicaid providers and suppliers comply with this non-discrimination statute.

5170.1 - Background

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The Medicare hospital restraint and seclusion requirements are found under the Patients' Rights provisions at 42 CFR 482.13(e),(f) and (g).

Hospitals are required to report a death associated with the use of restraint/seclusion to their CMS *location* in accordance with 42 CFR 482.13(g)(1).

The interpretive guidelines found in the Hospital Appendix A at 42 CFR 482.13(e) – (g) discuss in detail what is considered a restraint or seclusion, the requirements governing hospital use of restraint or seclusion, and these reporting requirements.

5170.2 - Responsibilities

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

***CMS Location*s**

The *CMS location* receives Hospital Restraint/Seclusion Death Reports which hospitals are required to submit in accordance with 42 CFR 482.13(g)(1). The *CMS location* is responsible for communicating with hospitals in its region whether the required reports are to be submitted electronically by facsimile and/or e-mail, providing appropriate addresses or fax numbers, or whether it will also accept mail submissions.

The *CMS location* is also responsible for data entry of reports received into the Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) Hospital Restraint/Seclusion Death Module and for maintenance in ACTS of information related to disclosures to Protection and Advocacy Agencies. (See Process discussion below.)

Each *CMS location* designates one contact person and a backup person who serves as the hospital point of contact regarding reporting, and who is responsible for coordinating the review of reports received, and authorization of complaint surveys when appropriate.

State Agencies (SAs)

Hospitals report patient deaths associated with restraint or seclusion to their CMS *location*, not to the SA. Any hospital patient restraint or seclusion death report received by a SA directly from a hospital (or other source) must be forwarded immediately by the SA to its *CMS location*.

The SA conducts a complaint investigation related to a patient death associated with a hospital's use of restraints or seclusion only when the *CMS location* authorizes the investigation. The investigation must be completed no later than five working days after *CMS location* authorization.

SAs assist *CMS location*s in educating the hospitals in their State about their obligation to report to their *CMS location* any death that meets the reporting requirements found at 42 CFR 482.13(g)(1). Upon request, SAs are to provide hospitals with the applicable *CMS location* contact information, as well as the hospital reporting procedures contained in this policy.

The SAs respond to requests from Protection and Advocacy (P&A) organizations, or any other parties, for information on survey findings related to specific cases identified by the requestor. The SAs handle these requests in accordance with standard CMS policy on disclosure of Federal survey information.

5170.3 - Process

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* evaluates the information required to be reported by the hospital or CAH DPU under 42 CFR 482.13(g)(1) to determine whether the situation might involve a violation of 42 CFR 482.13(e) through 42 CFR 482.13(g) and authorizes an on-site investigation if there appears to be a possible violation.

Using the information provided by the hospital or CAH DPU in the worksheet, the *CMS location* evaluates whether the case warrants an on-site investigation. If the *CMS location* determines that the restraint/seclusion death report requires on-site investigation, within two business days of receiving the report, the *CMS location* enters the reported information into the ACTS restraint/seclusion module and immediately notifies the SA to authorize a complaint survey to investigate the hospital's or CAH DPU's compliance with the Patient's Rights requirement at 42 CFR 482.13(e), (f), and (g), including the reported case. The SA accesses the ACTS restraint/seclusion module to see the information reported by the hospital or CAH DPU prior to conducting the on-site investigation. The SA is expected to be onsite to initiate the investigation within two business days of receipt of survey authorization from the *CMS location*.

Notice to Protection and Advocacy Organizations

At the same time that the *CMS location* notifies the SA that it authorizes the on-site survey, consistent with the ACTS Notice of a Modified or Altered System of Records (SOR) (71 FR 29643, May 23, 2006, SOR 09-70-0565), the *CMS location* also provides written notification, by mail or email, to the appropriate Protection and Advocacy Organization (P&A) within the State where the hospital is located, only if the P&A has a current Data Use Agreement (DUA) with CMS. The *CMS location* may contact CMS Central Office for a list of P&A's with current DUAs. The names and addresses for each State's P&A can be located at the following website, at the drop down menu entitled "Get Help in Your State:" www.ndrn.org . **Notification is provided only in those cases for which an on-site survey is authorized.**

The *CMS location* provides the following information to the P&A: hospital or CAH DPU name, hospital or CAH DPU address, name of the deceased, and a copy of the restraint/seclusion death report submitted by the hospital or CAH DPU. **An entry must be made on the intake in ACTS indicating the name of the P&A to which the restraint/seclusion death report data was sent and the date it was sent.**

The P&A must have an approved CMS Data Use Agreement (DUA), Form CMS-R-0235, (Exhibit 292) in place before restraint/seclusion death report data may be disclosed to it. In order to get an approved DUA, the P&A must complete and submit a signed CMS DUA, Form CMS-R-0235, including an initialed DUA ACTS SOR- P&A Attachment (Exhibit 293) to the Director, Division of Information Security and Privacy Management (DISPM), Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. DISPM will review the DUA,

assign a unique DUA identifier and expiration date to it, and return a signed copy to the P&A, including an expiration date. CMS Central Office Survey and Certification will maintain and make available to *CMS location*s a list of P&As with DUAs.
When completing the Form, P&As must note the following in particular:

- Line 5 of the DUA must state "Restraint/Seclusion Hospital Death Reports." The "Years" and "System of Record" columns should be left blank;

- Line 12 must state "CMS DUA: ACTS SOR Attachment – P&A;"

- The DUA must be signed by the P&A official whom the P&A designates as "Custodian," i.e., the individual who will have actual possession of and responsibility for the data released under the DUA; and

- A P&A may designate more than one Custodian, but if it does so, each individual must complete and sign a Multi-Signature Addendum Form (Exhibit 294).

When approved, the DUA will have an expiration date. DISPM will alert an organization with a DUA of its upcoming expiration date and will give the organization the option of requesting a one-year DUA extension via e-mail, or to close the DUA with a DUA destruction certificate. DISPM has set up a DUA resource email box which accepts all expired DUA resolution requests at DataUseAgreement@cms.hhs.gov.

Custodians may be added or deleted over the life of the primary DUA. To add a new Custodian under an existing DUA, the P&A must submit the following to CMS/DISPM: a letter from the P&A describing the activities planned for the new Custodian and the length of time over which the Custodian will serve, and a Multi-Signature Addendum signed by the appropriate official from the P&A. The Multi-Signature Addendum must show the DUA number of the existing primary P&A DUA. The P&A must assign a case number to all Multi-Signature Addendums beginning with "1" and adding consecutively thereafter. CMS/DISMP will use this number to track the number of Custodians in each P&A. When a P&A seeks to delete an existing Custodian, it must send the CMS/DISPM a letter to this effect. CMS/DISPM will strike out the name of the deleted Custodian from the DUA or Multi-Signature Addendum that added that Custodian, dating and initialing the deletion.

The DUA process described in this section applies to disclosure of hospital and CAH DPU restraint/seclusion death reports by CMS to P&As in those cases where the P&A did not first make a request specific to an identified patient; a DUA is not required for other disclosures of information in ACTS to a P&A when permitted in accordance with the ACTS System of Records Notice.

- A P&A may request information about an on-site survey by submitting its request to the SA. The SA will process this request and release information to the P&A in accordance with standard CMS policy for disclosure of Form CMS 2567, Statement of Deficiencies and Plan of Correction.

If the P&A identifies a particular patient, hospital, and approximate date or dates when the patient was in that hospital or CAH DPU, and if the P&A makes a request for additional information, beyond the Form CMS 2567, related to use of restraint or seclusion on that patient, the request is forwarded to the *CMS location*. The *CMS location* may, in accordance with the ACTS System of Records Notice, release additional information to the P&A.

NOTE: Sections 5200 to 5240 relate to all non-deemed provider/supplier types, excluding nursing homes (SNFs/NFs).

5200.1 - General Procedures

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

For complaint surveys on non-deemed providers/suppliers, the SA uses the appropriate survey protocol and interpretive guidelines. A focus survey is conducted on the specific regulatory requirements related to the allegation. Based on an initial assessment or other observations, if significant problems are identified, the SA expands the scope of review as necessary to determine compliance or noncompliance. The SA does not refer complaints regarding non-deemed providers/suppliers to the *CMS location*.

If deficiencies are cited, the SA documents the deficiencies on Form CMS-2567 and obtains an acceptable POC. If non-compliance with the Medicare conditions is identified, the SA will follow the appropriate termination procedures and document and report as required. (See SOM Chapter 3, §§3010-3028 for termination procedures.)

5200.2 - Special Procedures for Psychiatric Hospitals

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The special conditions for psychiatric hospitals cannot be deemed to meet the Medicare requirements. The remaining conditions for hospitals apply to psychiatric hospitals, and a hospital may be deemed to meet those conditions.

When the SA receives a complaint allegation against a psychiatric hospital under the general conditions of participation, it must determine whether or not the hospital is deemed. If the hospital is deemed, the SA follows the appropriate survey protocol for deemed facilities. If the hospital is not deemed, the SA investigates the complaint if appropriate under these procedures listed above in §5200.1.

If the complaint allegation concerns the special conditions for psychiatric hospitals, the SA may conduct an investigation if it has appropriate qualified personnel or refer it to the *CMS location*. If the complaint is referred to the *CMS location*, the *CMS location* will evaluate and refer it to the CO as required.

5210- Processing of Complaints Originating with or Investigated by the *CMS location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* establishes procedures and clear organizational accountability to ensure that complaints are properly evaluated, documented, acknowledged, and handled timely and appropriately. The *CMS location* uses ACTS to ensure timely and appropriate action on all allegations originating with or investigated by the *CMS location*. The extent and nature of the *CMS location* involvement with a given complaint varies depending on the nature of the allegation and the receiving organization.

Most complaints originate through the SA and are recorded and controlled by the SA. When a complaint is filed directly with the *CMS location*, the *CMS location* assumes those initial SA responsibilities.

5220- Investigation Conducted Directly by the *CMS location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

This less frequent class of complaints includes allegations retained by the *CMS location* or forwarded to the *CMS location* by the SA for investigation. The *CMS location*'s responsibilities vary based on the type of complaint.

The *CMS location* uses the appropriate survey protocol and interpretive guidelines for the provider/supplier. These procedures apply when a direct *CMS location* investigation is conducted, such as for Federal facilities, Religious Non-Medical Health Care Institutions (RNHCIs), or special situations. When directly investigating, the *CMS location* begins by ensuring that it or the SA has met all initial data collection and acknowledgement requirements.

If the allegation involves an IJ, the *CMS location* investigates within two working days. Otherwise, the *CMS location* schedules the investigation based on the severity of the allegation. (See §5075.9 for time frames related to Federal onsite investigations.)

5230 - Special *CMS location* Processing

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The following types of allegations are subject to special *CMS location* handling:

1. Over-Utilization or Inappropriate Utilization of Services- The *CMS location* refers to the local QIO for investigation, and documents the provider's files as for other allegations. The *CMS location* acts, as necessary, on any findings returned by the QIO;

2. Civil Rights Violations- The *CMS location* refers to the regional OCR for investigation. The *CMS location* documents the provider's files as for other

allegations. The *CMS location* acts as necessary on any findings returned by OCR; and

3. Medicare/Medicaid/CLIA fraud- The *CMS location* refers to the *CMS location* of the Inspector General/DHHS for investigation. The *CMS location* documents the provider's files as for other allegations.

In each of the above instances, the *CMS location* ensures that the complainant and SA are notified of any findings.

5300 - Investigation of Complaints for Nursing Homes

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Section 42 CFR 488.332 provides the Federal regulatory basis for the investigation of complaints about nursing homes.

The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements if its review of the allegation concludes that:

- A deficiency in one or more of the requirements may have occurred; and
- Only a survey can determine whether a deficiency or deficiencies exist.

The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

Complaint investigations follow, as appropriate, the pertinent survey tasks, and information gathered is recorded on the appropriate survey worksheets. However, if the documentation required is minimal, use Form CMS-807 to record information during the complaint investigation. Record deficiencies on Form CMS-2567 and/or, the "Statement of Isolated Deficiencies Which Cause No Harm with Only a Potential for Minimal Harm for SNFs and NFs" . The completed Form CMS-2567 must be made a part of the complaint record.

If necessary, a specialized team may be used to investigate complaints. Team members may include, but are not limited to, an attorney, auditor, and appropriate health professionals. The specialized team is not necessarily composed of qualified surveyors. However, specialized team members provide unique talents and expertise that assist at least one qualified surveyor in identifying, gathering, and preserving documented evidence. Further information regarding the composition of the survey team is provided in Chapter 7.

The timing, scope, duration and conduct of a complaint investigation are at the discretion of the SA, except when a determination is made that immediate jeopardy may be present

and ongoing or a higher level of actual harm may be present. If the complaint concerns conditions on a certain day (e.g., on weekends), or on a certain shift (e.g., 11 p.m. - 7 a.m.), the SA should make an attempt to investigate it at the relevant time. In most cases, the following tasks, or portion of tasks, should be performed during a complaint investigation.

~~Ab~~breviated surveys must be conducted on two consecutive calendar days from the day of entrance. Exceptions to this guidance would be an emergency situation as deemed by the state agency or a competing IJ at another location requiring the survey team's immediate attention. Additionally, the surveyor or survey team should plan to be onsite for a minimum of five hours after entrance, unless the investigation can be completed in less than five hours.

5300.5 - Task 7: Exit Conference

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Conduct an Exit Conference related to a complaint survey in accordance with the process described in the Exit Conference section located in the Long-Term Care Survey Process (LTCSP) Procedure Guide (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html). Do not inform the nursing facility of confidential information unless the individual who provided the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected, notify the facility orally and in writing that there *was noncompliance related to the* complaint because deficiencies existed at the time that the complaint situation occurred. (See SOM Chapter 7, Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities, for specific information about citing past noncompliance.)

If *there was no noncompliance related to the* complaint, notify the facility of this decision.

5310.2A-Immediate Jeopardy Priority

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

In cases where the initial report indicates the following, the SA must initiate an onsite survey within three business days of receipt of the initial report:

1) The alleged noncompliance may have caused, or may likely cause, serious injury, harm, impairment, or death to a resident, and
2) The facility has not implemented adequate protection for all residents or the SA has not received sufficient evidence to conclude that residents are adequately protected.

For these cases, the SA will enter into *iQIES*: Intake Type=Incident; Priority = IJ; and Investigate Within X Days = 3 Working Days.

In cases where the initial report indicates the following, the SA must initiate an onsite survey within seven business days of receipt of the initial report:

1) The alleged noncompliance may have caused, or may likely cause, serious injury, harm, impairment, or death to a resident, and

2) The facility has potentially implemented adequate protection for all residents.

For these cases, the SA will enter into *iQIES*: Intake Type=Incident; Priority = IJ; and Investigate Within X Days = 7 Working Days.

NOTE: See Appendix Q of the State Operations Manual for guidance related to immediate jeopardy situations.

Depending on the nature of the allegation, the facility would be expected to take immediate action(s) to ensure the protection of residents. Information provided by the facility may assist the SAs in determining whether there are potentially adequate protections provided to the resident. Examples of such information include, but are not limited to:

- Monitoring of the alleged victim and other identified residents who are at risk, such as conducting unannounced management visits at different times and shifts;
- Evaluation of whether the alleged victim feels safe and if he/she does not feel safe, taking immediate steps to alleviate the fear, such as a room relocation, increased supervision, etc.;
- Providing social services (e.g., emotional support and counseling) to the resident, as needed;
- Immediate assessment of the alleged victim and provision of medical treatment as necessary;
- Provision of goods and/or services that are necessary to avoid serious injury, harm, impairment, or death to a resident;
- Immediate notification of the alleged victim's physician and the resident representative, when there is injury or a change in condition or status;
- If the alleged perpetrator is staff- Removal of access by the alleged perpetrator to the alleged victim and other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents

- If the alleged perpetrator is a resident or visitor- Removal of access by the alleged perpetrator to the alleged victim and, as appropriate, other residents and assurance that ongoing safety and protection is provided for the alleged victim and other residents

- Notification of the alleged violation to other agencies or law enforcement authorities, within timeframes as specified under Federal or State law or regulations; and

- Whether administrative staff, including the administrator, were informed and involved as necessary in the investigation.

Below are examples that indicate that a resident(s) may not be protected in the facility:

- The alleged perpetrator continues to have access to the alleged victim and/or other residents;

- Retaliation occurs against a resident who reports an alleged violation;

- A resident who repeatedly fondles other residents is moved to another unit, where he/she continues to exhibit the same behaviors to other residents; and

- A resident with a history of striking a resident is left unsupervised with a resident who has been targeted in the past.

The SA may contact the resident/representative to determine whether adequate protections are provided to the resident

5320.1 - Notification Procedures - Preliminary Determinations

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the State makes a preliminary determination, based on oral or written evidence and its investigation, that resident neglect, abuse, or misappropriation of property has occurred, the State completes the following notification procedures:

1. **Individuals Notified - The State notifies the following individuals in writing within 10 working days of the investigation:**

   a. Individual(s) implicated in the investigation; and

   b. The current administrator of the facility in which the incident occurred.

2. **Notice Information - The following information is included in the notice:**

   a. Nature of the allegation (specific facts);

   b. Date and time of the occurrence;

   c. A statement that the individual implicated in the investigation has a right to a hearing and must request the hearing within 30 days from the date of the notice. Provide the individual with the specific information needed to request a hearing, such as the name and address of a contact in the State to request a hearing;

   d. Statement that if the individual fails to request a hearing, in writing, within 30 days from the date of the notice, the findings are reported to the nurse aide registry or the appropriate licensure authority;

   e. The intent to report findings *upheld* by a hearing in writing to the nurse aide registry and/or to the appropriate licensure authority;

   f. Consequences of waiving the right to a hearing;

   g. Consequences of a finding through the hearing process that the resident abuse or neglect, or misappropriation of property did occur; and

   h. Right of the accused individual to be represented by an attorney at the individual's own expense.

5330 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit for Nursing Homes

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the SA receives information that a suspected crime may have occurred in a facility and there is indication that it has not been reported or the SA cannot verify that a report was made to law enforcement, the SA must report the suspected crime to law enforcement immediately.

Verifying that a complainant, facility, and/or covered individual(s) has made a report to law enforcement would include review and confirmation of the following information:

- Who submitted the report to law enforcement, including name and contact information;

- Who did the reporter contact, including law enforcement entity, name, and contact information;

- Date/Time that the report was filed;
- Any copies of the report made to law enforcement, if available;
- What information was conveyed to law enforcement; and
- The police report number provided by law enforcement.

When the SA or *CMS location confirms noncompliance related to abuse*, the SA or *CMS location* must report the *cited* finding *of noncompliance* to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

NOTE: "Covered individual" is defined in section 1150B(a)(3) of the Act as anyone who is an owner, operator, employee, manager, agent or contractor of the facility (§483.12(b)(5)(i)).

5350 – Data Entry

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SA enters survey information into the *CMS* system, including Forms CMS-670 and CMS-2567.

5360 - Processing of Complaints Originating with or Investigated by the CMS *location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* establishes procedures and clear organizational accountability to ensure that any complaint is properly evaluated, documented, acknowledged, and handled timely and appropriately. The *CMS location* uses ACTS to ensure timely and appropriated action on all allegations originating with or investigated by the *CMS location*.

The extent and nature of *CMS location* involvement with a given complaint varies depending on the nature of the allegation and the receiving organization. The following procedures address the major variants of *CMS location* involvement.

5370 - Pre-Investigation Actions on Allegations Originating Through the *CMS location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Most complaints originate through the SA and are recorded and controlled by the SA. When a complaint is filed directly with the *CMS location*, however, the *CMS location* assumes those initial SA responsibilities.

5380 - *CMS location* Processing of *CMS location* Investigated Complaints

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

This less frequent class of complaints includes allegations retained by the *CMS location* or forwarded to the *CMS location* by the SA for investigation or special processing. The *CMS location* responsibilities vary based on the type of complaint.

1 - Direct *CMS location* Investigation

These procedures apply when a direct *CMS location* investigation is conducted. When directly investigating, the *CMS location* begins by ensuring that it or the SA has met all intake, acknowledgment, and priority assignment requirements in §5010 to §5020.

2 - Conducting the Investigation

The *CMS location* follows the procedures for investigation in §5300.

3 – *CMS location* Certification Actions

When Federal deficiencies are identified, the *CMS location* initiates certification actions as follows:

a. Noncompliance that Constitutes Immediate Jeopardy to Resident Health and Safety - The *CMS location* initiates procedures in accordance with §§7307 to 7309. The *CMS location* performs the SA responsibilities described in these sections.

b. Noncompliance that Does Not Constitute Immediate Jeopardy to Resident Health and Safety - The *CMS location* initiates procedures in accordance with §§7311 to 7316.

c. In Substantial Compliance - The *CMS location* initiates procedures in accordance with §7319.

4 - Reporting

The *CMS location* should report survey information into the *iQIES* system , including Forms CMS-670 and CMS-2567.

5390 – *CMS location* Oversight of Complaint-Related Processes

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

1. The *CMS location* considers any complaint data in targeting look-behind surveys or reviews.

2. The *CMS location* monitors data in summary form - either through a log or data system. See §5060.

These records should include:

- Identification of region or State-wide patterns;
- Pinpointing of problem providers or States;
- Evaluation of SA processing times, workloads, performance, etc.; and
- Identification of overall SA workloads, including *review of complaints where noncompliance was not found* and Medicaid-only complaint volumes.

3. Based on needs identified from oversight activities, the *CMS location* provides SA training and technical assistance.

NOTE: Sections 5400 to 5480.2 relate to alleged EMTALA violations.

5420 - Basis for Investigation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SA enters alleged EMTALA violations into ACTS. The *CMS location* approves or disapproves requests for EMTALA investigations in ACTS.

5430 - *CMS location* Direction of Investigation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

5430.1 - Evaluation of Allegation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* evaluates all complaints and refers to the SA those that warrant SA investigation. The SA or the *CMS location* sends a letter to the complainant acknowledging the complaint and informing the complainant of whether an investigation is warranted. The SA's responsibility is to verify whether a violation of 42 CFR 489.24 and/or the related requirements at 42 CFR 489.20 occurred, and if there were other violations.

5430.2 - Request for Investigation of Allegations

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* gives an initial verbal authorization to the SA to investigate the EMTALA allegation, and then completes Form CMS-1541A in ACTS. If the *CMS location* identifies Medicare conditions or standards it wants the SA to survey, related to the EMTALA allegation at a deemed hospital, the *CMS location* completes Form CMS-

2802 in ACTS. If the *CMS location* identifies conditions or standards it wants the SA to survey related to the EMTALA allegation at a non-deemed hospital, it directs the SA to conduct a survey by completing Form CMS-1541A in ACTS.

5440.2 - Scheduling the Investigation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Allegations of EMTALA violation against a non-deemed or deemed hospital or CAH may represent a probable immediate jeopardy to the next individual who comes to the hospital requesting examination and treatment for an emergency medical condition. Therefore, when triaged as IJ by the *CMS location*, initiate the investigation within two business days after receipt of the authorization from the *CMS location*. The onsite investigation must be conducted on consecutive business days. The survey must be completed promptly and is not to be interrupted by other activities. DO NOT ANNOUNCE ANY INVESTIGATIONS.

Based on review of the complaint allegations by the *CMS location*, the EMTALA complaint may also be prioritized as Non-IJ High. In these situations, the investigation must be initiated within 45 business days of *CMS location* authorization. The onsite investigation must be conducted on consecutive business days. The survey must be completed promptly, should not be interrupted by other activities, and must be unannounced.

5440.3 - Guidelines for Surveyors Conducting Investigations

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Attention to Procedures

The purpose of conducting the investigation is to ascertain whether or not the hospital violated the EMTALA requirements. The survey must be in accordance with applicable survey procedures and policies. Review instructions in Appendix V, before beginning the investigation. The guidelines provide a detailed interpretation of the regulations.

Involvement of Complainants

Complainants, if known, receive a letter of acknowledgment from the SA or *CMS location*. Do not disclose the identity of complainants. When information obtained during the investigation appears to be in conflict with the information supplied by the complainant, consult with the complainant, if this can be done without disclosing the person's identity.

5440.5 - Exit Conference

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

It is usually desirable and appropriate to conduct an exit conference. The surveyor(s) may outline the basic facts uncovered during the onsite investigation. However, the surveyor(s) must inform the hospital that the *CMS location* makes the final compliance determination, and the determination is often made with information obtained after the onsite investigation. Do not reveal the complainant and do not venture an opinion on what determination the *CMS location* might make. The exit conference should include a description of the process that is followed if the *CMS location* determines that a violation has occurred.

5450 - Forwarding Report of Investigation to the *CMS location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Transmit the results of the investigation and your recommendations to the *CMS location* through ACTS within 10 working days following completion of the onsite survey, if it appears there may be an EMTALA violation. If there appears to be no violation, this time frame may be extended to 15 working days, in order to allow the SA additional processing time.

Transmit the following materials to the *CMS location* through ACTS:

- Form CMS-562,"Medicare/Medicaid/CLIA Complaint Form;"
- Form CMS-1541B, "Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report." Recommend one or more of the actions below on the form:
    - **None -** This means the complaint was not substantiated;
    - **In Compliance, but Previously Out of Compliance -** This means that the hospital identified the problem on its own and took effective corrective action prior to the investigation. In addition to this recommendation, document on the Form CMS-2567 when the hospital identified the violation or a similar problem, the corrective action taken, and the date of such action. Also, document that the hospital has had no violations or similar problems for at least the past 6 months;
    - **Recommend Termination (23 calendar day track) -** This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r) and the violation presents an immediate jeopardy to patient health and safety;
    - **Recommend Termination (90 calendar day track) -** This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r), but the violation does not present an immediate jeopardy to patient health and safety;

- **Request Physician Review.** This means that it is recommended that the *CMS location* obtain a medical review of the case;

- **Possible Discrimination.** This means that it is believed that discrimination occurred based on financial status, race, color, nationality, handicap, or diagnosis.

- Form CMS-670, "Survey Team Composition and Workload Report;"

- Form CMS-2567, "Statement of Deficiencies and POC;"

  NOTE: If the hospital had identified the deficiency and took corrective action prior to the investigation, indicate on the Form CMS-2567 that the requirement was not met. However, indicate on the Form CMS-2567 and the narrative report that the hospital took corrective action prior to the investigation, what action was taken, and for how long the hospital has been in compliance.

- Physician Review Outline for Emergency Care Obligations of Medicare Hospital (if physician review was done by SA);

- Complaint investigation narrative;

- Copies of pertinent hospital policies and procedures that relate to the identified deficiencies;

- Summary listing of all patients comprising the sample, including an explanation of how and why the cases were selected for review;

- Summary of interviews.

Transmit the following to the *CMS location* by overnight mail:

- Copies of medical records for substantiated cases, medical records of individuals named in the complaints, and other medical records for which a QIO review is requested;

- Certification of benefits versus risks of the transfer, if this is a transfer case.

5460 - *CMS location* Review of Investigation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Upon receiving the case from the SA, the *CMS location* has 10 working days to review the investigation findings. The *CMS location* requests a 5-day advisory medical review of the case by the QIO to determine if there is an EMTALA violation. The *CMS location* has 5 working days to review the case upon return from the QIO. With this information,

and any other additional information, the *CMS location* determines whether the hospital complied with the EMTALA requirements and determines whether the violation constitutes an immediate jeopardy to patient health and safety.

Prior to determining compliance or noncompliance, the *CMS location* is encouraged to confer with the State Agency, and **may** confer with the hospital's representatives. The *CMS location* shares as much data as possible in accordance with current Privacy Act requirements.

5460.1 - Hospital Is In Compliance - No Past Violation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the *CMS location* determines that the allegation is not substantiated and that the hospital is in compliance with 42 CFR 489.24 and/or the related requirements at 42 CFR 489.20, the *CMS location* notifies the hospital and forwards a copy of the letter to the SA. If the SA received the complaint, it notifies the complainant that the complaint was not substantiated. If the *CMS location* received the complaint, the *CMS location* notifies the complainant.

5460.2 - Hospital Is In Compliance - Past Violation, No Termination

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the *CMS location* determines that the allegation was substantiated, but the hospital had identified the violation on its own, took effective corrective action prior to the investigation, and has had no EMTALA violations for at least the past 6 months, termination action is not initiated. The *CMS location* notifies the hospital via a "Past Violation - No Termination Letter." The SA receives a copy of the letter through ACTS. The *CMS location* or SA sends a letter to the complainant regarding the outcome of the investigation. Although no termination action is taken, the *CMS location* refers past violations of 42 CFR 489.24 to the OIG for assessment of civil monetary penalties (CMPs) if warranted.

5460.3 - Hospital Is Not in Compliance - Immediate Jeopardy to Patient Health and Safety

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the *CMS location* determines that the hospital is not in compliance and the violation represents an immediate jeopardy to patient health and safety, the *CMS location* follows a 23 calendar-day termination process. The termination procedures in §3010 are followed. Uncorrected deficiencies that resulted in a violation of 42 CFR 489.24 may pose an immediate jeopardy to people seeking emergency care. The *CMS location* notifies the complainant that the complaint was substantiated. It also informs the hospital in writing of the specific violations via a preliminary determination letter, and sends the hospital a copy of Form CMS-2567. The SA receives a copy of the letter through ACTS.

5460.4 - Hospital Is Not in Compliance - Situation Does Not Pose an Immediate Jeopardy to Patient Health and Safety

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the *CMS location* determines that the hospital is not in compliance with the EMTALA requirements, but the violation does not pose an immediate jeopardy to patient's health and safety, or the hospital took corrective action after the investigation to remove the immediate jeopardy, the *CMS location* follows a 90 calendar-day termination process. The termination procedures in §3012 are followed. The *CMS location* notifies the complainant that the complaint was substantiated. The *CMS location* informs the hospital, in writing, of the specific violations via a preliminary determination letter and sends the hospital a copy of Form CMS-2567. The SA receives a copy of the letter through ACTS.

Examples of noncompliance that usually do not pose an immediate jeopardy:

1. A transfer which was appropriate, but not signed or dated by the physicians;

2. An appropriate, functioning, central log that on one particular day is not fully completed; and

3. A written hospital policy that is missing, but is nonetheless being implemented.

The fact that the hospital has completed a POC should not be interpreted to mean that the hospital admits violating the EMTALA requirements. However, the hospital is included on the log of facilities with EMTALA violations, with the notation that an acceptable POC was received by CMS, and termination action was stopped.

5465 - Procedures for the 5-day QIO Review of Alleged Violations of 42 CFR 489.24

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Prior to terminating a hospital from the Medicare program because of possible violation(s) of EMTALA, the *CMS location* requests the QIO to assess whether the individual involved was provided an appropriate medical screening examination, stabilizing treatment, or an appropriate transfer as required by EMTALA.

The QIO 5-day review is mandatory if the *CMS location* determines that a case involves a possible violation of 42 CFR 489.24 to support possible termination action against a hospital if in fact it violated EMTALA. The *CMS location* is responsible for providing the QIO with all information relevant to the case that is within its possession and control. The *CMS location* sends the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) to capture this information. The QIO completes the review within 5 working days upon the receipt of *CMS location*'s request. The QIO sends the case file back to the *CMS location* including a copy of the review report. It is not required that the physician reviewer give the hospital and/or the physician an opportunity

to respond to the allegations at this time. If the affected physician and/or hospitals have questions concerning the case, they are to consult with the *CMS location*.

The QIO Review is not required in cases where a delay in effecting a sanction would jeopardize the health and safety of individuals or in situations where medical review is inappropriate (e.g., cases where the individual was denied a medical screening examination). The QIO 5-day review is required to seek medical expertise on whether the individual was adequately screened, examined and treated.

The *CMS location* shall release upon request the 5 day QIO review to the affected physician and/or hospital, after the *CMS location* has made a determination as to whether the hospital violated or is in compliance with EMTALA. In addition, the *CMS location* may release the QIO review to the complainant or his/her representative upon request. The physician reviewer's identity is confidential, therefore, when releasing the QIO report the physician's identity is not to be disclosed unless he or she consents to the release of their identity in accordance with the disclosure regulations at 42 CFR 480.132 and 480.133.

The cases in which the *CMS location* determined that the hospital was in compliance with 42 CFR 489.24 but in violation of 42 CFR 489.20 of the EMTALA regulation do not need to be forwarded to the QIO for review. The *CMS location* takes action as warranted.

5470.1 - Procedures for Termination when the EMTALA Violation is an Immediate Jeopardy to Patient Health and Safety

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

In cases where the *CMS location* determined that an immediate jeopardy existed, after a 5-day QIO advisory review has been completed, the *CMS location* follows the termination procedures in §3010. The processing timeframes are the maximum allowed. The termination procedures are not postponed or stopped unless evidence of correction of the deficiencies or proof that the violation did not exist is provided by the hospital to the *CMS location*. The *CMS location* forwards the supporting documents to the QIO (for a 60 day QIO review) in order to provide a medical opinion on the case. The *CMS location* refers the case to the OIG that has the responsibility for assessment of CMPs against the hospital and/or physician and physician exclusion provisions for violations of 42 CFR 489.24. The case is also referred to the Office for Civil Rights (OCR) because OCR may take action under the Hill-Burton Subpart G Community Services regulations at 42 CFR 124.603(b) (1).

The termination track starts on the date that the *CMS location* makes the determination of noncompliance with 42 CFR 489.24. It is the date of the preliminary determination letter. The letter is forwarded to the hospital by the fastest method available (fax, e-mail or telephone). In addition, a written letter follows up by mail. The preliminary determination letter informs the hospital of:

- The *CMS location*'s findings based on the investigation and the results of medical review;

- The projected termination date (the 23rd calendar day from the date of the preliminary determination letter);

- The date on which the *CMS location* issues a Notice of Termination Letter and notifies the public (at least two calendar days, but no more than four calendar days prior to the termination date); and

- That the hospital may avoid the termination action and notice to the public by either providing acceptable POCs for the deficiencies or by successfully showing that the deficiencies did not exist. In either case, the necessary information must be furnished to the CMS *location* in time for the SA to verify the corrections before the projected termination date.

If, during the resurvey, the SA finds that the provider had implemented systems and processes to ensure that the likelihood of further violation is remote and there is adequate evidence that the provider is in compliance with the requirements, the termination action is rescinded and the provider is put back in compliance.

If, during the resurvey, the SA finds that the provider has not adequately implemented systems and processes to ensure compliance, the *CMS location* gives the hospital an additional 67 days or a total of 90 days (23 plus 67) to achieve compliance.

This allows the hospital time to prove that the corrective action is good for the long-term (i.e., the corrective action is adequate to ensure that no further violations will occur). The *CMS location* directs the SA to conduct a second survey by the 60th calendar day. On the resurvey, the surveyor(s) reviews patients' emergency department (ED) records and other relevant documents for the period since the last survey to assess continued compliance. If the hospital fails to achieve compliance, it is terminated from the Medicare program. The *CMS location* sends the complainant a letter reporting the final results of the investigation.

If the termination takes place and the hospital desires to become re-certified as a Medicare provider, the hospital must provide reasonable assurance that compliance will be maintained. The procedures at §2016 are followed.

5470.2 - Procedures for Termination When the EMTALA Violation is Not Immediate Jeopardy to Patient Health and Safety

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

In cases where the *CMS location* determined that a violation existed but not an immediate jeopardy, after a 5-day QIO advisory review has been completed when it was warranted, the *CMS location* follows the termination procedures in §3012 The processing timeframes are the maximum allowed. The termination procedures are not postponed or

stopped unless evidence of correction of the deficiencies or proof that the violation did not exist is provided to the *CMS location* by the hospital. If warranted, the *CMS location* forwards supporting documents to the QIO (for a 60 day QIO review) in order to provide a medical opinion on the case. The *CMS location* refers the case to the OIG, if warranted, that has the responsibility for assessment of CMPs against the hospital and/or physician and physician exclusion provisions for violations of 42 CFR 489.24 The case is also referred to the Office for Civil Rights (OCR) because OCR may take action under the Hill-Burton Subpart G Community Services regulations at 42 CFR 124.603(b)(1)

The termination track starts on the date that the *CMS location* makes the determination of noncompliance with 42 CFR 489.24 and/or the related requirements at 42 CFR 489.20. It is the date of the preliminary determination letter.

5480.1 - Procedures for Coordinating 60 day QIO Review

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* requests the QIO to provide a medical opinion on EMTALA violation cases within 60 calendar days. The cases referred for 60-day QIO review are outlined in §5480B. The *CMS location* uses the "Model Letter Requesting QIO Review of a Confirmed Violation of 42 CFR 489.24 for Purposes of Assessing Civil Monetary Penalties or Excluding Physicians," (Exhibit 212). The QIO provides the physician and the hospital reasonable notice of its review a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. (Instructions on notice of review and opportunity for discussion, and additional information that follow the regulatory requirements in 42 CFR 489.24(h) are found in §§9100-9150 of the QIO Manual.)

The *CMS location* is responsible for providing the QIO with all information relevant to the case that is within its possession and control. The *CMS location* sends the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) to capture this information. This outline is helpful for organizing the review of the medical record. The specialty of the reviewing physician should be matched to the specialty of the physician who attended the patient and/or the individual's medical condition. If the patient was not seen by a physician, the QIO uses the diagnosis of the patient or the usual physician assignment practice of the hospital to determine the specialty of the physician reviewer.

Within 60 calendar days of receiving the case, the QIO must submit to the *CMS location* a report on its findings. The report provides an expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there are any medical utilization or quality of care issues involved in the case. Upon request, the *CMS location* provides copies of the QIO report to the affected physician and/or hospital after all investigative activity has been completed.

When there was no screening examination or when a delay would jeopardize the health or safety of individuals, QIO Review is not required before the OIG may impose CMPs or exclude a physician from the Medicare program. In addition, if the QIO determines, after a preliminary review, that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, the QIO returns the case to the *CMS location* with its documented opinion. The *CMS location* will close the case and no referral to OIG is necessary.

When the *CMS location* determines that a hospital was non-compliant with the requirements of 42 CFR 489.24, one of its notice requirements is to notify the OIG that the violation was confirmed and that termination action was initiated. (See Exhibit 208.) The *CMS location* completes the notification after receipt of the QIO 60-day review report. If the QIO report does not support an EMTALA violation, the *CMS location* closes the case without referring it to the OIG.

The *CMS location* forwards the following documents to the OIG:

- Form CMS-1541B;
- Form CMS-2567;
- Medical record;
- Summary of interviews;
- Explanation of sample selection;
- Copies of pertinent hospital policies and procedures related to the identified deficiencies;
- Complaint investigation narrative;
- Certification of benefits versus risks of the transfer (if this is a transfer case);
- Copy of the 5 working-day advisory QIO Review, and
- Copy of the 60 calendar-day advisory QIO Review.

The *CMS location* sends the above information and any other pertinent documentation in its possession to the OIG at the following address:

Office of Inspector General
Office of Counsel to the Inspector General
Department of Health and Human Services
Room 5527, Cohen Building

330 Independence Avenue SW
Washington, D.C. 20201

5480.3 - Releasing QIO Assessment

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Upon request, the *CMS location* may release QIO assessment(s) to the physician and/or hospital or the affected individual, or his/her representative. The QIO physician's identity is confidential unless he/she consents to its release. The QIO Review may be released pursuant to the requirements of 42 CFR 480.132 and 480.133.

Sections 5500 to 5590 relate CLIA.

5500 - Complaints Involving Unaccredited Laboratories

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

NOTE: This section applies to complaints against laboratories that hold a CLIA certificate of compliance, certificate of waiver (COW), and certificate of PPM (See §§5540-5590 for complaints regarding accredited laboratories).

A complaint is an allegation that could result in citing noncompliance with CLIA requirements. A complaint may be substantiated or unsubstantiated as a result of an investigation or survey. A substantiated complaint is one resulting in a finding of noncompliance at the time of the investigation, or a finding that noncompliance was proven to exist, but was corrected prior to the investigation. An unsubstantiated complaint is an allegation where sufficient evidence could not be found to conclude that noncompliance with CLIA requirements existed during the investigation or at the time of the alleged violation. A complaint may be received in either the SA or the *CMS location*. The receiving organization should follow the procedures outlined below.

The SA obtains the following information for every complaint:

- Complainant's name, address, and telephone number, unless the complainant requests anonymity;
- Laboratory's name and address; and
- Description of problem, (e.g., personnel, places, and dates of occurrence).

5500.3 - Evaluation

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The SA evaluates any complaint to determine whether it should be investigated by the SA, or whether it should be forwarded to the *CMS location* for investigation or referral to the appropriate authority (e.g., OCR, OSHA, *CMS location*). The SA assesses the complaint to determine if an immediate survey is necessary. While the SA will perform most complaint surveys, complaints involving State-operated facilities are the responsibility of the *CMS location*. When the SA does not have jurisdiction, it should forward the complaint to the *CMS location* within three working days. If referral is not necessary, the SA considers whether or not any special notification is appropriate.

If a complaint is especially significant, sensitive, or attracting broad public or media attention, the SA informs the *CMS location* immediately.

5500.6 - Conducting Investigations in a Laboratory with a Certificate of Waiver

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* authorizes an unannounced complaint survey of a laboratory holding a certificate of waiver only if it is based on a substantial allegation of noncompliance. The fact that a deficiency is not at the Condition-level does not preclude taking adverse action based on provisions contained in 42 CFR 493.1840. As with other laboratories, the SA investigates complaints made against laboratories with a certificate of waiver by means of an onsite survey, by telephone, letter, or by a review of documents.

The SA performs the onsite investigation based on the allegation and determines whether a laboratory is performing only waived tests and if the laboratory is following the manufacturer's instructions for performing the tests (See Appendix C).

5500.7 - Conducting Investigations in a Laboratory with a Certificate for PPM Procedures

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* authorizes an unannounced complaint survey of a laboratory holding a certificate for PPM procedures only if based on a substantial allegation of noncompliance. This survey should not differ from a complaint survey done in any other laboratory performing non-waived testing, as all requirements for moderate complexity apply except routine survey.

Substantial indication that a laboratory is performing tests that do not appear on the PPM procedures test list; e.g., through billing procedures, should prompt a complaint survey of a certificate for PPM procedures laboratory followed by either proper registration or appropriate sanctions.

5500.8 - Post Investigation Actions

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

Following the investigation, the SA records any deficiencies on a Form CMS-2567 and provides it to the facility using regular procedures. Subsequent actions depend on the severity and nature of the deficiencies cited and the facility's willingness or ability to correct them.

When deficiencies are identified, the SA initiates actions as follows:

1. **Condition-Level Deficiencies - Immediate Jeopardy** - Certifies noncompliance and initiates procedures to recommend imposing alternative and principal sanctions.

2. **Condition-Level Deficiencies - No Immediate Jeopardy; Facility Provides an Acceptable POC** - Certifies noncompliance and initiates procedures to recommend imposing alternative sanctions based on the severity and nature of the deficiencies found.

3. **Lower Level Deficiencies - Facility Provides an Acceptable POC** - Certifies compliance based upon an acceptable POC and assembles documentation for *CMS location* review.

4. **Lower Level Deficiencies - Facility Unable or Unwilling to Provide Acceptable POC** - A facility with deficiencies may not participate without an acceptable POC. The SA recommends sanction action to the *CMS location*.

When no deficiencies are identified, no certification action is required.

5520 - Review of CLIA-Exempt Laboratory Complaints

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the *CMS location* receives a complaint against a CLIA-exempt laboratory, the *CMS location* determines what action is appropriate. The *CMS location* may do any of the following:

- Determine the severity of the complaint;

- Send the information to the approved State for their action;

- Conduct a survey (full or partial);

- Investigate the complaint during the course of a validation survey (full survey), if it is conducted within 45 days of the laboratory's licensure survey and the complaint does not present immediate jeopardy concerns.

- If the seriousness of the complaint or the circumstances warrant, the *CMS location* should invoke the Rapid Response Alert Protocol.

NOTE: Transfusion-related fatality investigations must be conducted by the *CMS location*. They may not be delegated to the approved State; however, the approved State may accompany the *CMS location* on the investigation. In either case, there must be coordination and communication between the *CMS location* and the State. Where State laws apply to transfusion-related incidents, the approved State program should follow its established procedures and coordinate with the *CMS location*.

The *CMS location* Reviews the approved State program's complaint activities as part of the overall annual review. The *CMS location* has the discretion to maintain its own complaint tracking system for those that have been forwarded to the approved State program. However, this information should be an integral part of the State's annual review.

If the approved State program receives a complaint against a CLIA-exempt laboratory, the approved State program determines what action is appropriate. If the approved State sanctions a CLIA-exempt laboratory in any way (e.g., licensure is withdrawn), it must notify the *CMS location* within 30 days.

If the laboratory against which the complaint is alleged is accredited, the State must also notify the accreditation organization.

5530 - Conducting Complaint Investigations and Surveys for CLIA-Exempt Laboratories

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* will complete the "Medicare/Medicaid/CLIA Complaint Form," Form CMS-562, for every complaint investigation it performs in a CLIA-exempt laboratory. When an investigation can be conducted via telephone (e.g., personnel credentials), the *CMS location* should do so. The *CMS location* obtains the following information for every allegation:

- Complainant's name and address, unless complainant requests anonymity. Do not disclose the identity of the complainant to the laboratory;
- Laboratory's name and address; and
- Description of problem, involving names, places, and dates.

The *CMS location* follows the same procedures for control and acknowledgement indicated in §5500. Complaints involving potential immediate jeopardy will be investigated by the *CMS location* within 2 working days of receipt. Complaints not involving potential immediate jeopardy are investigated within 45 days. All complaint surveys are unannounced.

If a laboratory representative refuses to permit a complaint survey, the *CMS location* contacts the State and requests that it contact the laboratory to explain the protocol and, if necessary, suggest that the State take enforcement action against the CLIA-exempt laboratory. The *CMS location* conducts the complaint survey in accordance with the survey protocol and uses the appropriate survey forms specified in Exhibit 63 and the outcome-oriented protocol found in Appendix C.

Initially, the *CMS location* focuses the survey only on the Condition(s) or requirement(s) related to the complaint area(s). If the complaint is substantiated or if additional deficiencies are found during the course of the investigation, the *CMS location* expands the scope of the survey to include additional standards, conditions, and other CLIA requirements. If the complaint is not substantiated, the *CMS location* notifies the laboratory that it is in compliance with the CLIA Condition(s) (Exhibit 243). The *CMS location* also notifies the approved State program of the Condition-level compliance (Exhibit 244).

At the exit conference, the *CMS location* informs the laboratory of the deficiencies found. If the deficiencies pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the *CMS location* notifies the approved State program and the laboratory within two working days by overnight mail and includes a copy of the Form CMS-2567. The *CMS location* directs the State program to take the appropriate enforcement action. (See Exhibits 231 and 228). The *CMS location* follows-up with the State program within 15 working days of its notification to the laboratory to verify that the enforcement action has either been taken against the laboratory or that the laboratory has achieved compliance with CLIA requirements.

If the State program fails to take appropriate enforcement action for an immediate jeopardy case within 23 days of the *CMS location*'s notification, and the laboratory has not achieved Condition-level compliance, the *CMS location* may request CO to either contact the State or attempt other resolution to eliminate the jeopardy.

If the deficiencies do not pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the *CMS location* prepares a Form CMS-2567 and forwards a letter along with the Form CMS-2567 to the laboratory and to the State program within 10 working days of completing the survey. The State program is responsible for taking any enforcement action, if necessary, monitoring the correction of the deficiencies, and providing a report to the *CMS location*. (See Exhibit 231.)

The *CMS location* completes a Survey Team Composition and Workload Report, Form CMS-670, for all complaint surveys and related activity.

If the approved State program fails to take appropriate enforcement action in non-immediate jeopardy situations, the *CMS location* documents its files accordingly and notifies CO. Failure to take and document the necessary enforcement action may subsequently jeopardize current or future approval of the State's laboratory licensure program.

5540 - Complaint Investigations and Surveys of Accredited Laboratories Under CLIA

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

There are a number of entities that must address laboratory complaints including: CMS Central and Regional Offices, the state agencies (including those with state licensure programs), approved states, and accreditation organizations. Each of these entities shares a strong interest in ensuring the quality of patient care and the services provided by laboratories. When the complaint involves more than one of these entities, there should be coordination and communication to ensure an effective and timely resolution of the issue.

The statutory basis for conducting surveys of accredited laboratories based on allegations of noncompliance is found in §353(e)(2)(D) of the Public Health Service Act (PHSA). Since accreditation organization (AO) requirements are equivalent to CLIA requirements, a complaint may affect the laboratory's accreditation status as well.

Complaints are investigated if they meet the following criteria:

- If substantiated, would have an impact on the health and safety of the general public or individuals served by the laboratory, and

- Would raise doubt as to the laboratory's compliance with one or more CLIA Conditions and/or requirements.

The *CMS location* should evaluate the complaint and take appropriate investigatory action. If the seriousness of the complaint or the circumstances warrant, the *CMS location* should invoke the Rapid Response Alert Protocol. Every effort should be made to secure a written form of the complaint, while maintaining anonymity, if requested.

All complaint surveys are unannounced and conducted according to outcome-oriented survey principles (See Appendix C). If an investigation can be conducted by letter or telephone, in lieu of an onsite survey, those means should be utilized.

Upon receipt, all complaints are logged and tracked and the same information as for CMS certified laboratories is collected, monitored and maintained (see Section 5500).

5550 - *CMS location* Direction of Complaint Investigation of an Accredited Laboratory

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

The *CMS location* has primary responsibility for the coordination of all activities involving complaints relating to an accredited laboratory.

This includes:

- Ensuring that all pertinent information concerning the complaint is obtained;
- Assessing the level of severity of the complaint;
- Determining actions required for investigation;
- Determining whether multiple AOs may be involved; and
- When warranted (e.g., in cases potentially involving media coverage, Federal/State Congressional or political interest, legal intervention, etc.), informing and coordination with all affected parties, including AO's, State Agencies and Central Office.

Although the *CMS location* has the lead role in directing the investigation of complaints involving accredited laboratories, all affected entities (i.e., State Agencies, AO's, Central Office) share responsibility in ensuring timely and effective action is taken.

Complaints received by the SA:

If the SA receives a substantial allegation of noncompliance directly from a complainant about an accredited laboratory, it promptly acknowledges receipt of the complaint and advises the complainant that it is being forwarded to the *CMS location* for action. The SA forwards a copy of the acknowledgment letter and the complaint to the *CMS location*. This includes SAs with a State laboratory licensure program.

Complaints received by the *CMS location*:

If the complaint is received directly by the *CMS location*, the *CMS location* will promptly send a letter to the complainant acknowledging the complaint and advising the complainant of the intended course of action, and subsequently the results of any investigation, if appropriate, and of the corrective action taken.

In either case (complaint received by SA or *CMS location*), the *CMS location* evaluates the complaint and has the lead in determining the course of action. The *CMS location* determines whether the *CMS location*, the SA, or the AO, including multiple AOs if circumstances so warrant, will investigate the complaint. The *CMS location* will also determine whether one or multiple AOs may be impacted by the complaint and, if so, alert them of the pending action. In certain instances the *CMS location* may enlist CO support to help determine the most effective course of action.

If the *CMS location* determines that the SA should investigate the complaint, the *CMS location* prepares a "Request for Complaint Investigation or Validation Survey of Accredited Laboratory, Form CMS-2802A," (See **Exhibit 107**) and a "Medicare/Medicaid/CLIA Complaint," Form CMS-562, and forwards them to the SA along with a copy of the complaint and notifies the AO. If the *CMS location* authorizes

the SA to perform a full survey (all specialties and subspecialties covered by the certificate), and the survey can be performed within 90 days of the AO's inspection, the survey can be counted in the SA's validation workload.

If the *CMS location* determines that the complaint involves a potential immediate jeopardy to the individuals served by the laboratory, or to the general public, the SA investigates the complaint within two working days of receiving it from the *CMS location*. Otherwise, the *CMS location* will direct the SA to investigate non-Immediate Jeopardy complaints within 45 days and report their findings to the *CMS location* and AO at the conclusion of the survey.

Complaints investigated by AOs:

If the *CMS location* determines that the accreditation organization should carry out its own investigation, it promptly forwards the complaint to the accreditation organization for immediate attention. The *CMS location* will request to be notified of the results of any investigative action taken. The *CMS location* will then notify the SA and, if warranted, CO.

NOTE: Transfusion-related fatality investigations must be conducted by the *CMS location* or SA. Transfusion-related fatality investigations must not be referred to an accreditation organization for action. However, the AO or multiple AOs, as appropriate, should be notified when such an investigation is taking place.

Complaints received by AOs:

Complaints received directly by AOs will be investigated under each AOs own standards and procedures. If multiple AOs are potentially impacted, the AO receiving the complaint will promptly inform the other AOs and a determination should be reached regarding the need for coordinated action. In cases potentially involving media coverage, Federal/State Congressional or political interest, legal intervention, etc., the SA, *CMS location* and CO should be promptly alerted by the AO receiving the complaint and consulted concerning appropriate action.

5560 - Conducting Complaint Survey of an Accredited Laboratory

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If an onsite survey is warranted, the SA will conduct an unannounced survey of an accredited laboratory based on the substantial allegation of noncompliance. The SA conducts the complaint survey in accordance with outcome-oriented principles (see Appendix C). The SA conducts a focused complaint survey, as instructed by the *CMS location* on Form CMS-2802A. If the SA finds additional deficiencies during the course of the complaint investigation, it may expand the scope of the survey with *CMS location* approval.

At the exit conference, the SA informs the laboratory director of the deficiencies found and the procedures to respond to them. If the deficiencies do not pose an immediate jeopardy to the health and safety of individuals served by a laboratory, or to the general public, the SA prepares a Form CMS-2567 and requests that the laboratory submit a POC for all Condition-level deficiencies. Condition level deficiencies **must** be corrected; those at the standard level are optional. The SA informs the laboratory that the Form CMS-2567 will be made available to the public under the disclosure of survey information provisions. The SA indicates to the laboratory that the "Statement of Deficiencies" (Form CMS-2567) will be forwarded to the laboratory within 10 working days and that the POC must be returned to the SA within 10 calendar days. Upon receipt of the survey information and POC, the *CMS location* makes a determination of whether or not sanctions will be imposed against the laboratory and notifies the AO.

5570 – Forwarding Investigation Report to *CMS location*

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If non-immediate jeopardy is found, the SA will submit the appropriate information as specified in the List of Documents in the Certification Packet (see Exhibit 63) to the *CMS location*, or through an update to ACTS within 45 days of completing the survey and notifies the *CMS location* of the entry. If the laboratory chooses not to submit a POC when deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies to the *CMS location* and AO.

5580 - Accredited Laboratory Found in Compliance Following a Complaint Survey

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If after review of the documentation the *CMS location* determines that the accredited laboratory is in compliance with all CLIA Condition-level requirements, it officially notifies the laboratory and forwards a copy of this letter to the SA and the AO. This letter advises that the accreditation organization may contact the laboratory about correcting any deficiencies below Condition-level.

5590 - Accredited Laboratory Found Not in Condition-level Compliance Following a Complaint Survey

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

If the deficiencies found pose an immediate jeopardy to the health and safety of individuals, the SA prepares the Form CMS-2567, (which is included as part of the List of Documents in the Certification Package, See Exhibit 63) and notifies the *CMS location* and sends Form CMS-2576 to the laboratory within 2 working days. *CMS location* will notify the AO. Based on the information forwarded, and the laboratory's POC, the *CMS location* determines if sanctions are to be imposed against the laboratory. The *CMS location* will then notify the AO.

Should the immediate jeopardy situation be corrected before the adverse action is taken or completed, the SA will advise the laboratory that it will revisit it to inspect all remaining Conditions not in compliance. The *CMS location* will notify the AO.

If non-immediate jeopardy is found, the SA will submit the appropriate information as specified in the List of Documents in the Certification Packet (See Exhibit 63) to the *CMS location*, or through an update to ACTS within 45 days of completing the survey and notifies the *CMS location* of the entry. The POC should also be forwarded to the *CMS location*. If the laboratory chooses not to submit a POC when deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies to the *CMS location* and the *CMS location* will notify the AO and the laboratory that the laboratory is out of compliance and has been placed under SA monitoring jurisdiction (see Exhibit 241). The laboratory is monitored by the SA, *CMS location*, and/or AO until it reaches Condition-level compliance or its certificate of accreditation is revoked. A copy of all correspondence is provided to the accreditation organization by the *CMS location*.

For standard only deficiencies, responsibility rests with the AO to follow-up and pursue corrective action. The laboratory continues to be accredited by its accreditation organization and retains its CLIA certificate of accreditation during this monitoring period; however, it becomes subject to the same CLIA requirements, survey and enforcement procedures as applied to non-accredited laboratories found out of compliance.

CROSSWALK TO THE OLD CHAPTER 5

A crosswalk from sections of the State Operations Manual Chapter Five published 5-21-2004 to the revised chapter five is as follows:

Name of Old Section	Old Section Number	New Section Number	Name of New Section
Management of Complaints and Incidents	5000	5000	Management of Complaints and Incidents
Intake Process	5010	5010	Intake Process
Triage and Priority Assignment	5020	5070	Priority Assessment for Nursing Homes, Deemed and Non-Deemed Providers/Suppliers, and EMTALA
Priority Definitions	5030	5075	Priority Definitions for Nursing Homes, Deemed and Non-Deemed Providers/Suppliers, and EMTALA
Investigation Findings and Reports	5040	5080	Investigation Findings and Reports
CMS Regional Office Responsibility for Monitoring SA Management of Complaints and Incidents	5050	5050	CMS *Location* Responsibility for Monitoring SA Management of Complaints and Incidents
Aspen Complaints/Incidents Tracking System (ACTS)	5060	5060	ASPEN Complaints/Incidents Tracking System (ACTS)
Investigation of Complaints Against Accredited/Deemed Providers and Suppliers	5100	5100	Investigation of Complaints for Deemed Providers/Suppliers
Basis for Investigation of Complaints Against Accredited/Deemed Providers and Suppliers	5110	5100.1	Basis for Investigation
RO Direction of Accredited Hospital Complaint Investigation	5120	5210	Processing of Complaints Originating with or Investigated by *CMS Location*
Conducting an Accredited Hospital Complaint Validation Survey	5130	5050	CMS *Location* Responsibility for Monitoring SA Management of Complaints and Incidents
Forwarding Investigation Report to RO	5140	5050	CMS *ocation* Responsibility for Monitoring SA Management of Complaints and Incidents
Accredited Hospital Found in Compliance Following Complaint Validation Survey	5150	5100	Investigation of Complaints for Deemed Providers/Suppliers
Accredited Hospital Found Not in Compliance Following Complaint Validation Survey	5160	5100	Investigation of Complaints for Deemed Providers/Suppliers
Reinstatement to Accreditation Organization Jurisdiction	5170	5100.2	Post-Survey Procedures
Termination of Accredited Hospital	5180	5100.2	Post-Survey Procedures

Investigating Complaints Involving ESRD Services Provided by Accredited Hospitals	5190	5160	Investigating Complaints Involving ESRD Services Provided by Deemed Hospitals
Investigation of Complaints Against Other Than Accredited/Deemed Providers and Suppliers	5200	5200	Investigating Complaints for Non-Deemed Providers/Suppliers, Excluding Nursing Homes
SA Processing of General, Certification-Related Complaints	5210	5010	General Intake Process
Hospital Restraints/Seclusion Death Reporting and Investigation	5240	5140	Hospital Restraints/Seclusion Death Reporting and Investigation
Complaints Involving HIV-Infected Individuals	5250	5150	Complaints Involving HIV-Infected Individuals
Investigations Involving Alleged EMTALA Violations	5300-5400	5400-5500	Investigations Involving Alleged EMTALA Violations
Complaints Involving Unaccredited Laboratories	5500-5590	5500-5590	Complaints Involving Unaccredited Laboratories

Chapter Five State Operations Manual

Acronyms

(Rev. 243; Issued: 06-12-26; Effective: 06-12-26; Implementation: 06-12-26)

ACTS	ASPEN Complaint Tracking System
AIDS	Auto-immune deficiency syndrome
AO	Accreditation Organization
the ACT	Social Security Act
CFC	Conditions for Coverage
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Civil Monetary Penalties
CMS	Center for Medicare and Medicaid Services
CO	Central Office
CoP	Conditions of Participation
COW	Certificate of Waiver
DED	Dedicated Emergency Department
DHHS	Department of Health and Human Services
EMS	Emergency Medical System
EMTALA	Emergency Medical Treatment and Labor Act
ESRD	End-Stage Renal Disease
FDA	Food and Drug Administration
HHA	Home Health Agency
HIV	Human Immunodeficiency Virus

IJ	Immediate Jeopardy
iQIES	*Internet Quality Improvement & Evaluation System*
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LSC	Life Safety Code
NF	Nursing Facility
NW	Networks
OCR	Office of Civil Rights
OIG	Office of Inspector General
OSHA	Occupational Safety and Health Administration
P & A	Protection and Advocacy Group
PHSA	Public Health Service Act
POC	Plan of Correction
PPM	Provider Perform Microscopy (PPM) Procedures
PRTF	Psychiatric Residential Treatment Facility
QIO	Quality Improvement Organization
RFP	Requirements for Participation
RNHCI	Religious Non-Medical Health Care Institutions
RO	Regional Office
SA	State Agency
SMA	State Medicaid Agency
SNF	Skilled Nursing Facility
SOM	State Operations Manual

USC	United States Code