State
Operations Manual
Chapter 5 - Complaint Procedures

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(Rev. 250; Issued: 10-16-26)

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5000.1 – Purpose of the Complaint/Incident Process
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

Mission: To protect Medicare/Medicaid beneficiaries from abuse, neglect, exploitation, inadequate care or supervision.

The goal of the Federal complaint/incident process is to establish a system that will assist in promoting and protecting the health, safety, and welfare of residents, patients, and clients receiving health care services. The complaint/incident management system has three objectives.

1. The first objective and priority for the complaint/incident management system is protective oversight. This is accomplished by analyzing the complaint allegations and reported incidents received to identify and respond to those that appear to pose the greatest potential for harming beneficiaries (has caused or is likely to cause, serious injury, harm, impairment or death). Complaints/incidents of this type that allege an immediate threat to the health, safety or welfare of individuals are investigated immediately.

2. The second objective is prevention. Complaints/incidents that do not allege a threat of serious harm are investigated to determine if a problem exists that could have a negative impact on the healthcare services provided. The investigation of these complaints/incidents is designed to identify and correct less serious complaints/incident to prevent the escalation of these problems into more serious situations that would threaten the health, safety and welfare of the individuals receiving the service. These complaints/incidents are also prioritized and investigated based on the seriousness of the allegations.

   Numerous or more frequent complaints/incidents may indicate systemic problems and therefore may be assigned a higher priority for investigation.

3. The third objective is to promote efficiency and quality within the health care delivery system. Complaints/incidents that are not directly related to Federal requirements are forwarded to the appropriate agency(ies) for follow-up and investigation. Complaints/incidents in this category may include but are not limited to Medicare/Medicaid fraud, complaints against individual licensed practitioners, and billing issues.

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.

5010.1 - Information to Collect From Complainant

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA collects information necessary to make important decisions about the allegations. In instances where written or verbal allegations are received, subsequent communication may be necessary to obtain additional information.

Comprehensive information should be collected during the intake process to allow for proper prioritization, including the following:

- Information about the complainant (e.g., name, address, telephone, etc.);
- Individuals involved and affected;
- Narrative/specifics of the complainant's concerns including the date, and time of the allegation;
- The complainant's views about the frequency and pervasiveness of the allegation;
- Name of the provider/supplier including location (e.g., unit, room, floor) of the allegation, if applicable;
- How/why the complainant believes the alleged event occurred;
- Whether the complainant initiated other courses of action, such as reporting to other agencies, discussing issues with the provider, and obtaining a response/resolution; and
- The complainant's expectation/desire for resolution/remedy, if appropriate.

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 locations 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.

5060.2 - Reports

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The ACTS produces a variety of reports that may be used for analysis and evaluation of provider/supplier performance. Complaint/incident reports are generated and displayed through menus that can be accessed in ACTS. Reports may be produced for one provider/supplier, or reports may be combined and present information for multiple providers/suppliers. Report filtering criteria is available through the Report Customization window, which allows the user to select criteria for the report to meet the user's specifications. Refer to the ACTS Procedures Guide for a list and description of the reports available in ACTS.

NOTE:

FOR ADDITIONAL INFORMATION ON SPECIFIC POLICIES RELATED TO:

- **DEEMED PROVIDERS AND SUPPLIERS, EXCLUDING CLIA, SEE SECTION 5100**
- **NON-DEEMED PROVIDERS AND SUPPLIERS, SEE SECTION 5200**
- **NURSING HOMES, SEE SECTION 5300**

- **EMTALA, SEE SECTION 5400**
- **CLIA LABORATORIES, SEE SECTION 5500**
- **ESRD, SEE SECTION 5160 AND SECTION 5170**

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 - Priority Definitions for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

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 Section 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

Investigating nursing home complaints and facility-reported incidents according to section 5075.9 will be implemented no later than October 1, 2023, to provide time for the SAs to prepare given the resource constraints in the SAs.

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.

5078 – Pre-Survey Activities
(Rev. 120, Issued: 09-19-14, Effective: 09-19-14, Implementation: 09-19-14)

To assist in planning the complaint investigation, prior to going on-site the SA should review the provider's or supplier's prior compliance record and, as applicable, quality indicators, ESRD Outcome List and Data or supporting information received from other programs, such as the Ombudsman program or Protection and Advocacy program. This process may require additional contact with the complainant. More information on pre-survey activities may be found in Section 5170 for ESRD facilities, Section 5300.1 for long term care facilities, in the provider/supplier-specific SOM appendices and in Appendix V concerning EMTALA of the SOM.)

5079 – Entrance Conference - Non-Long Term Care Providers/Suppliers
(Rev. 120, Issued: 09-19-14, Effective: 09-19-14, Implementation: 09-19-14)

Onsite complaint investigations must always be unannounced. Upon entrance, advise the provider/supplier CEO or other senior official on duty of the general purpose of the visit. The SA explains the reason for the survey and avoids any impression that a predetermination has been made as to the validity of the allegation. It is important to let the facility know why you are there, but to also protect the confidentiality of those involved in the complaint. Do not release information that will cause opportunities to be lost for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, in the case of a hospital, critical access hospital or ambulatory surgical center, if the complaint is that a patient developed a life-threatening infection in a post-surgical wound, do not tell the facility the exact complaint. Rather, tell them it is a situation related to infection control for surgical patients. Another example, in the case of a long term care facility, would be when a complaint that food that is intended to be

served hot is always served cold. In this case, do not tell the provider the exact complaint. Rather, tell them it is a situation related to dietary requirements.

(See Section 5300.2 for guidance on the entrance conference for long term care facilities as well as the provider/supplier-specific appendices of the SOM, and Appendix V of the SOM concerning EMTALA.)

5080 - Investigation Findings and Reports
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Each SA establishes reporting policies, procedures and formats including report language targeted to specific audiences.

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 <u>not</u> 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 - Investigation of Complaints for Deemed Providers/Suppliers
(Rev. 120, Issued: 09-19-14, Effective: 09-19-14, Implementation: 09-19-14)

Sections 5100 - 5130 apply to all deemed providers and suppliers, with the exception of clinical laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). See Sections 5500 – 5590 for CLIA information, including investigation of complaints related to accredited laboratories.

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 - Post-Survey Procedures
(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

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.

5120 - Life Safety Code Guidance for Deemed Providers/Suppliers

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

In most States, an engineer or other fire safety specialist surveys for compliance with the Life Safety Code (LSC) standard and others survey the remaining standards in the Physical Environment Condition. If the allegation pertains only to LSC requirements, it is not necessary to survey the remainder of the Physical Environment Medicare condition.

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.

5150 - Investigating Complaints Involving ESRD Services Provided by Deemed Hospitals or CAHs

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

Many of the hospitals or CAHs participating in the ESRD program are deemed to meet the Medicare Conditions of Participation on the basis of their accreditation by a CMS-approved Medicare accreditation program. "Deemed status" applies only to the hospital's or CAH's approval as a provider, not to its status as a supplier of ESRD transplantation or dialysis services. The SA investigates all complaints and allegations related solely to ESRD services since ESRD services fall outside the purview of accreditation.

5160 - Investigating Complaints Against ESRD Suppliers

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

1. General

Refer to the guidance for investigation of complaints against non-deemed providers and suppliers. See SOM §5200.

The ESRD Networks are required to have a complaint /grievance resolution system. Networks (NW) and the SA are frequently contacted by the same complainant with the same or similar allegations. If the allegations require an onsite investigation or allege potential risk to patient health or safety, the SA is responsible for the investigation. If the allegations are primarily focused on relationship or communication issues, the NW may assume primary responsibility for the investigation. If the focus of the allegations is a medical practice issue, the SA and NW may need to collaborate on the investigation. The NWs and SA are encouraged to communicate and collaborate to reduce or prevent redundant investigations.

2. Conducting the ESRD Investigation

The SA surveyors must use the ESRD survey protocol in Appendix H to investigate complaints. The allegations of the complaint will determine the tasks needed. For example, an allegation of inadequate patient care staffing would require use of the following tasks, at a minimum:

- Pre survey activities;
- Entrance Conference: Provide an overview of the complaint allegations and the planned agenda for your survey time;
- Tour and observations;
- Patient interviews;

- Staff interviews;
- Record reviews;
- Review of quality management materials; and
- Exit conference.

Conduct each of the identified survey tasks in Appendix H, "Guidance to Surveyors: End-Stage Renal Disease Facilities."

3. Pre-survey Task for ESRD Complaint Investigations

Review the allegations of the complaint to identify needed survey tasks. Review the State Outcomes List and the Dialysis Facility Report to determine if there are data outliers related to the allegations. For example, if the complaint alleges staff members do not wash their hands, the surveyor should review the facility's rate of hospitalization and hospitalizations related to septicemia, and consider this information in the survey process.

To facilitate meeting the requirement of surveying each ESRD facility every 3 years, the SA evaluates all available information (outcome list rank, Dialysis Facility Report, time since last survey, complaint history, NW information, etc.) to determine whether a recertification survey should be conducted at the time of the complaint investigation.

5170 – Hospital Restraints/Seclusion Death Reporting and Investigation

(Rev. 88, Issued: 08-27-13, Effective: 07-19-13, Implementation: 7-19-13)

This section applies to both deemed and non-deemed hospitals, as well as to deemed and non-deemed CAH distinct part psychiatric and rehabilitation units.

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 Locations

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 locations 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 locations 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).

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

5200 - Investigating Complaints for Non-Deemed Providers/Suppliers, Excluding Nursing Homes (SNFs/NFs)

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

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.

5240 - Complaints - HHA Hotline
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Each State has a Medicare home health hotline that can be called by patients who are dissatisfied with the home health services they are receiving or by other individuals with a complaint about a specific HHA. Under the Medicare COPs for Patient Rights at 42 CFR 484.10, HHAs are required to provide their patients with the hotline number for their state. Concerns about an HHA not complying with the COPs, or reports that an HHA is misinforming beneficiaries or inappropriately terminating care for patients, can be referred to the SA for investigation via the home health hotline. Concerned consumers may also call the SA directly. A violation of the COPs or the provider agreement could lead to termination of the HHA from the Medicare program.

As part of the patient rights COPs, the HHA is required to investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is, or fails to be, furnished, and to document both the existence of the complaint and resolution of the complaint.

Surveyors, as part of their investigation of the HHA's compliance of the COPs, may ask to review complaints received by the HHA and the resolution of these complaints. The HHA must permit examination of these records by or on behalf of CMS, or risk termination from the Medicare program.

NOTE: Sections 5300 to 5390 relate to nursing homes.

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.

Abbreviated 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.

5300.1 - Task 1: Offsite Survey Preparation
(Rev. 250; Issued: 10-16-26; Effective: 10-16-26; Implementation: 10-16-26)

Review any information about the facility that would be helpful to know in planning the investigation. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to the ombudsman.

Review the related regulatory requirements or standards that pertain to the complaint. For example, if it is a complaint about abuse, review the requirements at 42 CFR 483.12.

Plan the investigation. Before going to the nursing home, plan what information to obtain during the complaint investigation based on the information already acquired. Consider practical methods to obtain that information.

5300.2 - Task 2: Entrance Conference/Onsite Preparatory Activities
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's Administrator of the general purpose of the visit. The SA explains the reason for the survey and avoids any impression that a predetermination has been made as to the validity of the allegation. It is important to let the facility know why you are there, but protect the confidentiality of those involved in the complaint. Do not release information that will cause opportunities to be lost for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, if the complaint is that food that is intended to be served hot is always served cold, do not tell the facility the exact complaint. Rather, tell them it is a situation related to dietary requirements.

5300.3 - Task 5: Information Gathering
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The order and manner in which information is gathered depends on the type of complaint that is being investigated. Conduct comprehensive, focused, and/or closed record reviews as appropriate for the type of complaint. Generally, it is not necessary to review records and information from more than one year ago. However, the SA is not precluded from doing so if concerns identified during the investigation indicate it is necessary in order to determine current compliance. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Perform information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As information is obtained, use what has been learned to determine what needs to be clarified or verified as the investigation continues.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e.,

what happened to the resident and the outcome, investigate what facility practice(s) or procedures affected the occurrence of the incident.

EXAMPLE

It was verified through the investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (e.g., turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

Record Review: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

EXAMPLE

For a complaint of verbal and physical abuse, review the record to determine the resident's mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident's demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he/she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff involved. In order to maintain the confidentiality of witnesses, change the order of interviews if necessary. It may not always be desirable to interview the person who made the complaint first, as that may identify the person as the complainant to the facility. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines needed for other identified witnesses and revise outlines as new information is obtained.

During information gathering to investigate a complaint about the care and services provided to residents in a nursing home, findings of past noncompliance may be identified. Before considering a citation of past noncompliance with a specific regulatory tag, surveyors must determine if current compliance with the specific regulatory tag exists. Similar to verifying correction of current noncompliance on a revisit, surveyors should use a variety of methods to determine whether correction of the past

noncompliance occurred and continues. This may include, but is not limited to, the following:

- Interviews with facility staff, such as the administrator, nursing staff, social services staff, medical director, quality assessment and assurance committee members, and/or other facility staff, as indicated, to determine what procedures, systems, structures, and processes have been changed.

- Reviewing through observation, interview and record review, how the facility identified and implemented interventions to address the noncompliance. Examples of interventions may include, but are not limited to:

    - The facility's review, revision, or development of policies and/or procedures to address the areas of concerns;

    - The provision and use of new equipment, as necessary;

    - The provision of staff training required to assure ongoing compliance for the implementation and use of new and/or revised policies, procedures, and/or equipment, especially with new and/or temporary staff;

    - The provision of additional staffing, changes in assignments or deployment of staff, as needed; and

    - The provision of a monitoring mechanism to assure that the changes made are being supervised, evaluated, and reinforced by responsible facility staff.

- Evaluating whether the facility has a functioning quality assessment and assurance committee whose responsibilities include the identification of quality issues; providing timely response to ascertain the cause; implementing corrective action; implementing monitoring mechanisms in place to assure continued correction and revision of approaches, as necessary, to eliminate the potential risk of occurrence to other residents and to assure continued compliance.

A citation of past noncompliance must meet all of the criteria described in Task 6 below.

5300.4 - Task 6: Information Analysis
(Rev. 250; Issued: 10-16-26; Effective: 10-16-26; Implementation: 10-16-26)

Review all information collected. If there are inconsistencies, do additional data collection as needed, to resolve the inconsistencies. Determine if there is any other information still needed.

Determine whether:

- *The facility failed to meet any of the regulatory requirements; and*

- *The facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.*

To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

1) *The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;*

2) *The noncompliance occurred after the exit date of the last standard recertification survey and before the survey (standard, complaint, or revisit) currently being conducted; and*

3) *There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.*

A nursing home does not provide a plan of correction for a deficiency cited as past noncompliance as the deficiency is already corrected; however, the survey team documents the facility's corrective actions on Form CMS-2567.

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 - Action on Allegations of Resident Neglect and Abuse, and Misappropriation of Resident Property for Nursing Homes

(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

5310.1 - Written Procedures
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The State must develop and implement written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property, including both complaints and facility-reported incidents. The State's policies and procedures must be consistent with Federal requirements as well as with procedures in the State Operations Manual.

Nursing homes send the following types of incidents to the State Survey Agency:

- All alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property;

- The results of all facility investigations involving alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property; and

- Reasonable suspicions of crimes against nursing home residents.

  NOTE: 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, then the SA forwards the information from the initial report immediately to law enforcement. The SA must follow applicable laws and regulations related to information disclosures, privacy and confidentiality, as it makes referrals. The SA may also contact the CMS Location office for more information.

A. Initial Reporting of Facility-Reported Incidents

The information collected during intake is critical in determining what may be occurring in a facility and the effect(s) that it may have on residents. While States have discretion in how they collect information from facilities (e.g., through electronic submission), at a minimum, the State Survey Agency must provide instructions to the facility and collect sufficient information to determine how the incident should be prioritized. See also Exhibit XX for sample instructions with examples of information and Appendix PP, Tag F609. If the facility has not provided sufficient information, the SA should take this into consideration as it triages the incident.

1. <u>Facility Reported Incidents – Initial Report</u>

The facility must provide in its report sufficient information to describe the alleged violation and indicate how residents are being protected [See

§483.12(c)(3)]. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that state agencies can initiate action necessary to oversee the protection of nursing home residents. See Exhibit XX for a sample form for initial reporting with examples of information and see also Appendix PP, Tag F609.

B. Reporting of Investigation Findings for Facility-Reported Incidents

For alleged violations of abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, the facility is required to submit a report of the results of the investigation within 5 working days to the State Survey Agency (See 42 C.F.R. §483.12(c)(4), Tag F609 of Appendix PP of the State Operations Manual). While States have discretion in how they collect information from facilities (e.g., through electronic submission), at a minimum, the State Survey Agency must provide instructions to the facility and collect sufficient information to determine how the incident should be prioritized.

5-Day Final Report of Suspected Allegation

Within 5 working days of the incident, the facility must provide in its report sufficient information to describe the results of the investigation, and indicate any corrective actions taken, if the allegation was verified. It is important that the facility provide as much information as possible, to the best of its knowledge at the time of submission of the report, so that State agencies can initiate action necessary to oversee the protection of nursing home residents [see §483.12(c)(4)]. See Exhibit XX for a sample form for the investigation report with examples of information, and see also Appendix PP, Tag F609.

5310.2 - Review and Triage of Allegations
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

The State reviews all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source.

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

5310.3 - Investigating Allegations
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If there is reason to believe, either through oral or written evidence, that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation. During the investigation, the SA should evaluate how the facility developed policies and procedures to prevent the abuse, and after the abuse occurred, how the facility took action to report and investigate the allegations while ensuring the safety of the residents.

5310.4 - Factors Beyond the Control of the Individual
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The State must not make a finding that an individual neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

EXAMPLE: A nurse aide could not be found negligent for not providing clean bed and bath linens to a resident if the facility had no clean bed and bath linens available. However, the facility is responsible for providing clean bed and bath linens to residents.

5320 – Reporting Findings of Abuse, Neglect, or Misappropriation of Property to the Nurse Aide Registry

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

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.

5320.2 - Conduct of Hearing for Nurse Aides

1- Time frame to Complete the Hearing

The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.

2 - Hearing Location

The State must hold the hearing in a manner consistent with State practice at a reasonable place and time convenient for the individual.

5320.3 - Reporting Findings

(Rev. 250; Issued: 10-16-26; Effective: 10-16-26; Implementation: 10-16-26)

1 - Reporting to Entities

If the individual waives the right to a hearing or the time to request a hearing has expired, or if the hearing finding is that the individual neglected or abused a resident or misappropriated a resident's property, the findings must be reported in writing within 10 working days to:

a. The individual;

b. Current administrator of the facility in which the incident occurred;

c. The administrator of the facility that currently employs the individual, if it is not the same facility in which the incident occurred;

d. Applicable licensing authorities; and

The nurse aide registry for nurse aides as specified in 42 CFR 483.156(c) and discussed in §4141. Section 4141 discusses the function of the registry, the information contained in the registry, and responsibility for the registry.

2 - Information Submitted to the Nurse Aide Registry

The following information must be included and remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of

law, or the State is notified of the individual's death. See §4141.B.

a. *Documentation of the investigation, including the nature of the allegation and the evidence that led to the conclusion that the allegation was valid;*

b. *The date of the hearing, if the individual chose to have one, and its outcome; and*

c. *A statement by the individual disputing the allegation if the individual chose to make one.*

3 - Information Retained in the Nurse Aide Registry Permanently

The registry must remove entries for individuals who have performed no nursing or nursing-related services for 24 consecutive months, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of property.

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)).

5340 - Post-Survey Certification Actions for Nursing Homes

(Rev. 155, Issued: 06-10-16, Effective: 06-10-16, Implementation: 06-10-16)

Following the investigation, the survey team records any findings on Form CMS-2567, the SA conducts a supervisory review of the CMS-2567 form and sends the provider a copy. The SA requests a POC for any uncorrected deficiencies. See §2728.

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

1. **Noncompliance that Constitutes Immediate Jeopardy to Resident Health and Safety -** The SA initiates procedures in accordance with §§7307 to 7309.

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

3. **In Substantial Compliance** - The SA initiates procedures in accordance with §7319.

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.

5400 - Investigations Involving Alleged Emergency Medical Treatment and Labor Act (EMTALA) Violations
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Section 1866 of the Act, Agreements with Providers of Services, specifies that for a hospital, or any provider of services, to qualify for participation in the Medicare program, it must enter into an agreement with the Secretary of HHS. Effective August 1, 1986, participating hospitals with emergency departments must comply with the requirements of §1867 of the Act as a condition of their provider agreement.

The following Medicare provider agreement requirements, which closely parallel provisions contained in §1866of the Act, must be met by Medicare participating hospitals with emergency departments:

- 42 CFR 489.20(l) requires a hospital to comply with the requirements of 42 CFR 489.24**.** Section **1866(a)(1)(I)** of the Act requires a hospital to have and enforce policies to ensure compliance with the requirements of §1867;

- 42 CFR 489.20(m) requires a hospital to report to CMS or the SA any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition (EMC) from another hospital in violation of the requirements of 42 CFR 489.24(e)**;**

- 42 CFR 489.20(q) requires a hospital to post conspicuously a sign(s) specifying the rights of individuals, under **§1867** of the Act, with respect to examination and treatment for emergency medical conditions and women in labor and to indicate whether or not the hospital participates in the Medicaid program. The letters within the signs must be clearly readable at a distance of at least 20 feet or the expected vantage point of the emergency department clients. The wording of the sign(s) must be clear and in simple terms and language(s) that are understandable by the population served by the hospital;

- 42 CFR 489.20(r)(1) requires a hospital to maintain medical and other records related to individuals transferred, including discharges, to or from the hospital for a period of five years from the date of transfer;

- 42 CFR 489.20(r)(2) requires a hospital to maintain a list of physicians who are on call to provide treatment necessary to stabilize an individual with an emergency medical condition;

- 42 CFR 489.20(r)(3) requires a hospital to maintain a central log on each individual who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, stabilized and transferred, or discharged.

When hospitals do not conform to the requirements of §1867 of the Act, the practice is commonly called "dumping." A hospital with a dedicated emergency department is defined in 42 CFR 489.24(b) as a hospital that offers services for emergency medical conditions within its capacity to do so. The regulations at 42 CFR 489.24 parallel the provisions of §1867 of the Act and contain the following requirements that a hospital with a dedicated emergency department must meet:

- 42 CFR §489.24(a) General. Applicability of provisions of this section.

- 42 CFR §489.24(b) Definitions. As used in this section.

- 42 CFR §489.24(c) Use of dedicated emergency department for non-emergency services.

- 42 CFR §489.24(d) Necessary stabilizing treatment for emergency medical conditions.

- 42 CFR §489.24(d)(1) General. Subject to the provisions of paragraph (d)(2).

- 42 CFR §489.24(d)(2) Exception: Application to inpatients.
- 42 CFR §489.24(d)(3) Refusal to consent to treatment.
- 42 CFR §489.24(d)(4) Delay in examination or treatment.
- 42 CFR §489.24(d)(5) Refusal to consent to transfer.
- 42 CFR §489.24(e) Restricting transfer until the individual is stabilized.
- 42 CFR §489.24(e)(1) General.
- 42 CFR §489.24(e)(2) Appropriate transfer to another medical facility.
- 42 CFR §489.24(e)(3) Provides whistleblower protection to physicians and qualified medical personnel.
- 42 CFR §489.24(f) Recipient hospital responsibilities.
- 42 CFR §489.24(g) Termination of provider agreement.
- 42 CFR §489.24(h) Consultation with Quality Improvement Organization (QIO).
- 42 CFR §489.24(i) Release of QIO Assessment.
- 42 CFR §489.24(j) Availability of on-call physicians.
- 42 CFR §489.24 (j)(1) On-call list.
- 42 CFR §489.24 (j)(2) Hospital on-call policy and procedures.

If a hospital fails to meet these requirements, CMS may terminate the provider agreement in accordance with 42 CFR 489.53. The Office of the Inspector General (OIG) has the responsibility and authority to assess civil monetary penalties (CMPs) or to exclude physicians from the Medicare program when a hospital or physician violates these requirements. Additionally, individuals suffering personal harm and medical facilities suffering financial loss as a result of a violation of these provisions can bring civil action against the offending hospital and physicians. Filing for such civil action is limited to a period of 2 years after the date of the alleged violation. This legislation does not preempt any State or local laws, except to the extent that State or local requirements directly conflict with a requirement of this legislation.

5410 – EMTALA and Born-Alive Infants Protection Act of 2002

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5410.1 - Interaction of the Born-Alive Infant Protection Act and EMTALA

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

With the definition of the terms "person" and "individual" codified at 1 U.S.C. §8, it is clear that there are circumstances where EMTALA protections are applicable to an infant who is born alive, as that term is defined in 1 U.S.C. §8(b).

For example, assume that a hospital's labor and delivery department meets the definition of a "dedicated emergency department." If an infant was born alive in that dedicated emergency department, and a request was made on that infant's behalf for screening for a medical condition, (or if a prudent layperson would conclude, based on the infant's appearance or behavior, that the infant needed examination or treatment for an emergency medical condition and that a request would have been made for screening) the hospital and physician could be liable for violating EMTALA for failure to provide such a screening examination. The born-alive infant is a "person" and an "individual" under 1 U.S.C. § 8(a) and the screening requirement of EMTALA applies to "any individual" who comes to the emergency department.

Another example is a case of an infant born alive elsewhere on the hospital's campus (i.e., not in the hospital's dedicated emergency department) and a prudent layperson observer concluded, based on the born-alive infant's appearance or behavior, that the infant was suffering from an emergency medical condition. In such a circumstance, the hospital and its medical staff are required to perform a medical screening examination on that infant to determine whether or not an emergency medical condition existed. If the hospital or its medical staff determined that the infant was suffering from an emergency medical condition, the hospital has an obligation to admit the infant, or to comply with either the stabilization requirement or the transfer requirement of EMTALA. The born-alive infant is a "person" and an "individual," as described above, and the stabilization and transfer requirements of EMTALA apply to "any individual" who comes to the hospital.

Finally, a third example is when the hospital admits a born-alive infant. EMTALA does not apply to inpatients. If a born–alive infant is admitted to the hospital, EMTALA would not apply to protect the infant in most circumstances. However, the Medicare COPs would apply to the infant once he or she was admitted to the hospital as an inpatient.

5410.2 - Conduct of Investigations

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If a complaint indicates that a born-alive infant has been denied a screening examination, stabilizing treatment, or an appropriate transfer, the complaint is prioritized as an alleged EMTALA violation. It is not necessary to determine that the hospital acted with an improper motive in any failure to provide a screening examination, stabilizing treatment, or an appropriate transfer in order to conclude that an EMTALA violation has occurred.

The Supreme Court of the United States has held that a finding of improper motive is not required to conclude that an EMTALA violation has occurred.

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 - Conducting an Investigation
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5440.1 - Selecting the Team
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA selects surveyors with a background in the profession or area to be investigated. Preferably, the surveyors should have acute care training and experience. All surveyors must be adequately trained in the evaluation of 42 CFR 489.24 cases. Physicians should have experience in peer review.

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.

5440.4 - Conducting the Investigation
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

A complete investigation consists of assessment of the following components:

- Completeness, adequacy and enforcement of policies and procedures which address the provisions of 42 CFR 489.24;

- Prompt reports to the SA or CMS of receipt of an improperly transferred individual by the receiving hospital;

- Presence and completeness of signs posted in emergency departments specifying the rights of individuals under 42 CFR 489.24, and information indicating whether the hospital participates in the Medicaid program;

- Maintenance of medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of transfer, including discharged patients;

- Maintenance of a list of physicians who are on call to provide necessary stabilizing treatment;

- Maintenance of a central log on each individual who comes to the hospital seeking emergency services;

- Provision of an appropriate medical screening examination sufficient to determine the presence of an emergency medical condition;

- Provision of necessary stabilizing treatment;

- Provision of no delay in examination or treatment in order to inquire about insurance status or capability for payment;

- Provision of an appropriate transfer to another medical facility/provider;

- Provision of whistleblower protections; and

- Adequacy of responsibilities of the recipient hospital with specialized capabilities (nondiscrimination).

The survey tasks are listed below for easy reference. See Appendix V for detailed guidance.

- Task 1: Entrance Conference;

- Task 2: Case Selection Methodology;

- Task 3: Record review;

- Task 4: Interviews;

- Task 5: Exit Conference;

- Task 6: Professional Medical Review; and

- Task 7: Assessment of Compliance and Completion of the Deficiency Report.

After the investigation is concluded, complete a Form CMS-1541B (Exhibit 137). If one or more of the provisions of EMTALA are not met, complete Form CMS-2567, using "Principles of Documentation." Describe in detail the facts of each individual case. In addition, specify whether the hospital was aware of the problem and took steps to remedy it prior to the survey. If a SA physician was a member of the investigation team, include the medical review of the case. Use the "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals," (Exhibit 138) for this purpose. In addition, complete Form CMS-562. All the forms must be signed, showing the professional titles of all participating surveyors, and dated.

A hospital may have multiple sites listed under its Medicare provider number. These sites may not be in close proximity of each other and each site may have its own dedicated emergency department (DED). In cases where the alleged EMTALA violation is against a specific site of the hospital, the surveyors should focus their survey investigation at the hospital site mentioned in the complaint intake. However, the surveyors should review all EMTALA related Policies and Procedures of all sites of the hospital. The surveyors need to survey the other sites of the hospital if the survey findings indicate that the potential EMTALA violation maybe widespread.

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 - Termination Procedures for EMTALA Violations
(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

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 - Procedures for QIO Review of Confirmed EMTALA Violation

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Before imposing sanctions under **§1867** of the Act for violations of 42 CFR 489.24, 42 CFR 489.24(h) requires that CMS obtain consultation from the QIO. The OIG holds the authority to assess CMPs against the hospital or physicians or to exclude physicians from the Medicare program for violations of 42 CFR 489.24.

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

5480.2 - EMTALA Case Referral to OIG

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

CMS refers appropriate cases to the OIG for investigation. Periodically, OIG will advise us of the criteria they would prefer CMS to use in referring cases. Examples of the types of cases that may be referred include:

1. **Financial Screening -** The hospital and/or responsible physician refused to examine or treat a person based on the person's insurance status or inability to pay a fee. The financial basis for the decision must be clearly supported by evidence in the file, e.g., documented policy, interview reports.

2. **Patient with Trauma or Acute Emergency Condition -** The hospital and/or responsible physician (including an on-call physician who failed to come to the hospital) failed to screen, stabilize, or appropriately transfer (or, in the case of a hospital with specialized capabilities or facilities, refused to accept an appropriate transfer of) a person with trauma, e.g., a severe head injury, or other acute emergency condition, e.g., heart attack or stroke, requiring immediate and substantial medical intervention.

3. **High Risk Event (such as Birth) Occurs Prior to Arrival at Another Hospital -** The hospital and/or responsible physician discharged or refused to screen/treat a person who gave birth (or is subject to another high risk medical event) prior to arriving at another hospital (especially if transport is by private vehicle).

4. **Death or Serious Harm Results from Dump -** The evidence in the file (including the QIO Review) demonstrates that the dumping violation caused serious medical harm or death to the victim of the violation.

5. **Egregious Violation Prioritized by CMS -** CMS concludes that a CMP is appropriate because of the seriousness of the violation (the person must have had an emergency medical condition) and other relevant factors, e.g., long history of noncompliance, hospital policy resulting in violations, pattern of serious violations, knowing and willful violation. This category is for those cases that CMS determines are very serious and merit a CMP but do not fit within other categories identified by OIG.

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 - Complaint Investigations in Non-Accredited, Non-Exempt Laboratories

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

NOTE: This section applies to complaints against laboratories that hold a CLIA

certificate of compliance (CoC), certificate of waiver (CoW), and certificate for Provider-performed Microscopy (PPM) procedures. See sections 5540-5590 for complaints regarding accredited laboratories, and sections 5510-5530 for State laboratory licensure program (SLLP).

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 by either the State Agency (SA) or CMS. The receiving organization should follow the procedures outlined below.

The SA or CMS should attempt to obtain the following information for every complaint:

- Complainant's name, address, and telephone number, unless the complainant requests anonymity;

- Laboratory's name and address;

- CLIA number; and

- Description of problem, (e.g., personnel, places, and dates of occurrence). The SA or CMS should gather as much information as possible to help focus the complaint survey.

If a laboratory representative refuses to permit a complaint survey, the SA should contact CMS.

There are several entities that may address laboratory complaints including: CMS, SAs, SLLPs, and Accreditation Organizations (AO). Each of these entities share a strong interest ensuring the quality of patient care and the services provided by laboratories. When the complaint involves more than one of these entities, CMS should coordinate communication to ensure an effective and timely resolution of the issue.

NOTE: If a SA surveyor identifies potential fraudulent billing activities on a complaint survey, the surveyor should refer the information to CMS so that the information can be referred to the State OIG with a copy to CMS. CMS can then refer the laboratory to the federal OIG.

5500.1 - Control
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA establishes a file for the complaint and logs the action into the CLIA Data System. The system may be manual or automated but must facilitate tracking and control of all complaints.

NOTE: All complaints alleging noncompliance with CLIA requirements must be entered into the CLIA Data System.

5500.2 - Acknowledgment
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the complainant is known, the SA promptly issues written acknowledgment, e.g., email or letter, that the complaint is being investigated. The SA should not delay acknowledgment pending an investigation unless the investigation takes place within three working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. The SA maintains a copy or record of the notification with the complaint documentation.

5500.3 - Evaluation
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA evaluates any complaint to determine whether it should be investigated by the SA, or whether it should be forwarded to CMS for investigation or referral to the appropriate authority (e.g., OCR, OSHA, CMS). 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 CMS. When the SA does not have jurisdiction, it should forward the complaint to CMS 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 public or media attention, the SA informs CMS immediately.

5500.4 - Scheduling Investigations
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA investigates complaints involving possible immediate jeopardy (IJ) within three working days of receiving the complaint and focuses on the specific problem area. The SA should notify CMS of a possible IJ complaint. Otherwise, the SA follows procedures for prioritizing and investigating certification-related complaints within 45 days. Laboratories with complaints pending are identified and given priority in scheduling of regular certification surveys.

5510 - Conducting Complaint Investigations in Non-Accredited, Non-Exempt Laboratories

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA may contact CMS for guidance on the type of complaint investigation which may include one or more of the following: on-site survey, telephone, electronic communication, letter, or a documentation review depending on the complaint. Complaint investigations are unannounced.

NOTE: The SA should contact CMS when an unannounced complaint survey is problematic, such as when a laboratory will not permit an investigation.

For on-site complaint investigations, the SA performs a full or partial survey based on the allegations. If a complaint alleges generalized inappropriate laboratory practices, the SA evaluates compliance with applicable requirements or conducts a full survey, as needed. If the complaint is of a specific nature, the SA performs a survey focused on areas relevant to the complaint. However, if the SA discovers systemic issues on the focused survey, the survey may be expanded to a full survey.

5510.1 – Conducting Investigations in a Laboratory with a Certificate of Waiver

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SA receives a complaint on a CoW laboratory, CMS authorizes an unannounced complaint survey of a laboratory only if it is based on an 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 493.1775.

As with other laboratories, the SA investigates complaints made against laboratories with a CoW by means of an on-site survey, by telephone, letter, or by a review of documents.

The SA performs the on-site 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 SOM Appendix C.

If a survey determines that a laboratory is performing tests that are not waived, the laboratory should cease testing of the non-waived tests that do not qualify under 42 CFR 493.15(c) and 493.39(a). If the laboratory wants to continue performing non-waived tests, they must submit a CLIA application for the appropriate level of testing and designate a qualified laboratory director. The SA should notify CMS so a cease-and-desist letter and/or notice of other adverse actions for testing outside of the current CLIA certificate can be sent by CMS to the laboratory.

5510.2 - Conducting Investigations in a Laboratory with a Certificate for Provider-performed Microscopy Procedures

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SA receives a complaint on a certificate for PPM laboratory, CMS authorizes an unannounced complaint survey of a laboratory only if based on an allegation of noncompliance. If a survey determines that a laboratory is performing tests that do not qualify under 42 CFR 493.19(c), the laboratory should cease testing. If the laboratory wants to continue performing non-waived tests, they must submit a CLIA application for the appropriate level of testing and designate a qualified laboratory director. The SA should notify CMS so a cease-and-desist letter and/or notice of other adverse actions for testing outside of the current CLIA certificate can be sent by CMS to the laboratory in accordance with 42 CFR 493.47(d).

The survey should not differ from a complaint survey done in any other laboratory performing non-waived testing, as all requirements for moderate complexity testing apply, except the routine survey. Note that there are separate D-tags for PPM personnel (D5980-5995). These specific citations should be used for personnel citations in PPM laboratories. The moderate complexity personnel requirements (D6000-D6075, D6190, D6191) should not be used for PPM laboratories.

If a PPM laboratory's noncompliance with waived testing is found during the survey and the laboratory is not following the manufacturer's instructions when performing the waived tests, cite D1001.

5510.3 – Conducting Investigations in a Laboratory with Certificate of Compliance

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA is responsible for the review and triage of CoC complaints. This does not include federal jurisdictional laboratories within its State.

Note for Transfusion-Related Fatality Investigations: CMS or the SA will conduct the survey within 45 days of the notice from CMS, with notification to CMS when the survey is complete. A copy of the investigation report should be submitted to CMS within 60 days, including the Form CMS-2567, Statement of Deficiencies, if issued.

Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, the SA or CMS conducts an unannounced survey. Summary and information from the FDA are considered confidential and may only be shared within CMS or the SA. It may not be shared with any other party, including

AOs. See SOM Chapter 6 section 6040.

5510.4 – Conducting Investigations in a Laboratory with Certificate of Registration

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Certificates of Registration (CoR), regardless of whether it is a pending CoC or Certificate of Accreditation (CoA), will be investigated by the SA or CMS. The SA enters all complaints received into the CLIA Data System and notifies CMS for approval or denial to perform the survey.

Note for Transfusion-Related Fatality Investigations: CMS or the SA will conduct the survey within 45 days of the notice from CMS, with notification to CMS when the survey is complete. A copy of the investigation report should be submitted to CMS within 60 days, including the Form CMS-2567, if issued.

Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, the SA or CMS conducts an unannounced survey. Transfusion-related fatality investigations must not be referred to an AO for action. However, the AO or multiple AOs, as appropriate, will receive a copy of the Form CMS-2567 and the accompanying notification letter from CMS when the investigation is complete. Summary and information from the FDA are considered confidential and may only be shared within CMS or the SA. It may not be shared with any other party, including AOs. See SOM Chapter 6 section 6040.

5510.5 – Conducting Investigations in a Laboratory with Temporary Testing Sites, Regardless of Certificate Type

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Complaints with No Known CLIA Number:

If the SA receives a complaint on a Temporary Testing Site (TTS) without a known CLIA number, it should be entered into the CLIA Data System as a "No CLIA Number (NOCN)." The TTS location is reviewed and triaged.

The SA performs an on-site complaint survey and gathers evidence about which CLIA number the TTS is operating under, including testing and reporting results. If no CLIA number is identified, the SA notifies CMS.

There may be situations where a complaint crosses multiple states. If the NOCN TTS is operating under a primary site laboratory, the SA contacts CMS. CMS opens an intake in the CLIA Data System and inserts the deficiencies from the referring states. The SA

that performed the complaint survey completes the Form CMS-2567 and the NOCN information in the CLIA Data System and notifies CMS when it is complete. Deficiencies in multiple states are combined on one Form CMS-2567, as applicable. CMS is responsible for collecting and combining the information to issue and release the Form CMS-2567. CMS is responsible for any subsequent enforcement actions.

Complaints with Known CLIA Number Operating Under a Primary Site or Home Base:

If the SA receives a complaint on a TTS, it should be entered into the CLIA Data System under the primary site/home base. The complaint is reviewed and triaged.

If a complaint is received and the primary site/home base is not located in the state that receives the complaint, the information should be forwarded by the SA to CMS. CMS may request that the SA perform a complaint survey on the TTS in its state. In this case the SA enters the complaint into the CLIA Data System as a NOCN. If the TTS is performing tests outside the scope of its CLIA certificate (e.g., CoW performing moderate/high complexity tests), the SA notifies CMS. The SA completes the Form CMS-2567 for the NOCN laboratory and notifies CMS when it is complete.

Deficiencies in multiple states are combined on one Form CMS-2567, as applicable. CMS is responsible for collecting and combining the information to issue and release the Form CMS-2567. CMS is responsible for any subsequent enforcement actions.

5520 - Post Complaint Investigation Actions in Non-Accredited, Non-Exempt Laboratories

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Following the investigation, the SA records any deficiencies on a Form CMS-2567 and provides it to the facility. 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/or principal sanctions. An on-site revisit must be performed before imposing principal sanctions (i.e., limitation, revocation or suspension of the CLIA certificate).

   When IJ is determined, the SA sends the IJ templates, one for each condition-level deficiency, to the laboratory (on-site or off-site). See SOM Appendix Q and SOM Chapter 6 section 6284 for enforcement procedures.
2. **Condition-Level Deficiencies – No Immediate Jeopardy** – If an Allegation of Compliance (AoC) is not submitted or is not credible – Certifies noncompliance and initiates procedures to recommend imposing alternative

and/or principal sanctions. An on-site revisit must be performed before imposing principal sanctions (i.e., limitation, revocation or suspension of the CLIA certificate). See SOM Chapter 6 section 6286 for enforcement procedures.

3. **Standard-Level Deficiencies – Facility Provides an Acceptable Plan of Correction** – Certifies compliance based upon an acceptable Plan of Correction (PoC) and assembles documentation for CMS to review. See SOM Chapter 6 section 6289.

4. **Standard-Level Deficiencies – Facility Unable or Unwilling to Provide Acceptable Plan of Correction –** If a laboratory fails to submit an acceptable PoC, and subsequent requests for an acceptable PoC are unsuccessful, CMS may initiate principal sanctions against the laboratory certificate. See SOM Chapter 6 section 6289.

No Deficiencies - When no deficiencies are identified, no certification action is required.

5530 - Post Complaint Investigation in Non-Accredited, Non-Exempt Laboratories Resolution/Closeout

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA closes out all complaints with a follow-up notice to the complainant noting the complaint was substantiated or unsubstantiated. The SA should send this notice soon after the investigation is completed and retain a copy with the complaint record. Complaints are considered closed when an investigation is complete, and the complainant is notified.

The SA provides follow-up reports, as necessary, to other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must protect the anonymity and privacy of the complainant.

The SA inputs the investigation information into the CLIA Data System within 45 days of the completion of the complaint survey.

1 – Unsubstantiated

The SA indicates “unsubstantiated” in the CLIA Data System. If no deficiencies are found, the SA notifies the complainant via written correspondence that the complaint is unsubstantiated and sends a Form CMS-2567 to the laboratory stating that it is in compliance. If deficiencies are found that are either related or not related to the complaint, the SA sends a Form CMS-2567 to the laboratory with the cited deficiencies along with a request for PoC or AoC.

2 – Substantiated

The SA logs summary information in the CLIA Data System. The SA enters the "substantiated" in the complaint into the CLIA Data System. The laboratory will be charged a fee to cover the cost of the survey if noncompliance is documented.

The SA notifies the complainant via written correspondence (e.g., letter, email) that the complaint is substantiated. The SA reports substantiated complaints using the Form CMS-2567 and retains any appropriate supporting documentation.

The SA provides follow-up reports, as necessary, to any other appropriate parties such as the State Medicaid agency and/or initial referring agencies. The SA must protect the anonymity and privacy of the complainant.

The SA inputs the investigation information into the CLIA Data System within 45 days of the completion of the complaint survey.

5540 - State Laboratory Licensing Program Laboratory (SLLP) Complaint Investigations– General

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

NOTE: State laboratory licensure program is also referred to as exempt state (ES) or CLIA-exempt laboratory.

Complaints may be from any source, including verbal, written, electronic or in the media.

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.

An attempt to maintain the anonymity of the complainant should always be made.

There are a number of entities that address laboratory complaints including: CMS, SAs, SLLPs, and AOs. 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, CMS should be in coordination and communication to ensure an effective and timely resolution of the issue.

5540.1 – Review of State Laboratory Licensing Program Laboratory

Complaints
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Complaints received by CMS:

If CMS receives a complaint against a SLLP laboratory, CMS determines what action is appropriate. CMS may do any of the following:

- Determine the severity of the complaint;
- Send the information to the approved State for their action;
- May 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 IJ concerns.

NOTE: Transfusion-related fatality investigations must be conducted by CMS within 45 days of the notice from CMS, with notification to CMS when the survey is complete. They may not be delegated to the approved SLLP; however, the approved SLLP may accompany CMS on the investigation. In either case, there must be coordination and communication between CMS and the SLLP. Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, CMS conducts an unannounced survey. Where State laws apply to transfusion-related incidents, the approved SLLP should follow its established procedures and coordinate with CMS. The SLLP, as appropriate, will receive a copy of the Form CMS-2567 from CMS when the investigation is complete. See SOM Chapter 6 section 6040.

CMS reviews the approved SLLPs complaint activities as part of the overall annual review. CMS has the discretion to maintain its own complaint tracking system for complaints that have been forwarded to the approved SLLP. However, this information should be an integral part of the SLLPs annual review.

Complaints received by State Laboratory Licensing Program:

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

If the laboratory against which the complaint is alleged is accredited, the SA must also notify the AO.

5540.2 - Conducting Complaint Investigations and Surveys for State Laboratory Licensing Program

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

Complaints Performed by CMS:

CMS will enter a complaint it performs on a SLLP laboratory in the CLIA Data System. When an investigation can be conducted via telephone or electronic communication (e.g., personnel credentials), CMS should do so. CMS attempts to obtain 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;
- CLIA number; and
- Description of problem, involving names, places, and dates.

CMS follows the same procedures for control and acknowledgement indicated in section 5500. Complaints involving potential IJ will be investigated by CMS within three working days of receipt. Complaints not involving potential IJ are investigated within 45 days. All complaint surveys are unannounced.

If a laboratory representative refuses to permit a complaint survey, CMS contacts the SLLP and requests that it contact the laboratory to explain the protocol and, if necessary, suggest that the SLLP take enforcement action against the SLLP laboratory. CMS conducts the complaint survey in accordance with the outcome-oriented survey process (OOSP) found in SOM Chapter 6.

Initially, CMS 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, CMS expands the scope of the survey to include additional standards, conditions, and other CLIA requirements. If the complaint is not substantiated, CMS notifies the laboratory that it is in compliance with the CLIA condition(s). CMS also notifies the approved SLLP of the condition-level compliance.

At the exit conference, CMS informs the laboratory of the deficiencies found. If the deficiencies pose IJ to the health and safety of individuals served by a laboratory or that of the general public, CMS notifies the approved SLLP and the laboratory within three working days by electronic mail and includes a copy of the Form CMS-2567. CMS directs the SLLP to take the appropriate enforcement action. CMS follows-up with the SLLP 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.

5550 - State Laboratory Licensing Program Complaint Post-Investigation Actions

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SLLP fails to take appropriate enforcement action for an IJ case within 23 days of CMS' notification, and the laboratory has not achieved condition-level compliance, CMS may either contact the SLLP or attempt other resolution to eliminate the IJ.

If the deficiencies do not pose IJ to the health and safety of individuals served by a laboratory or that of the general public, CMS prepares a Form CMS-2567 and forwards a letter along with the Form CMS-2567 to the laboratory and to the SLLP within 10 working days of completing the survey. The SLLP is responsible for taking any enforcement action, if necessary, monitoring the correction of the deficiencies, and providing a report to CMS.

CMS completes a Survey Team Composition and Workload Report (Form CMS-670) for all complaint surveys and related activity.

5560 - State Laboratory Licensing Program Complaint Resolution/Closeout

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the SLLP fails to take appropriate enforcement action in non-immediate jeopardy situations, CMS documents its files accordingly. Failure to take and document the necessary enforcement action may subsequently jeopardize the current or future approval of the SLLP.

5570 – Complaint Investigations and Surveys of Accredited Laboratories

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

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 AO requirements are equivalent to CLIA requirements at the condition level, 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.

CMS should evaluate the complaint and take appropriate investigatory action. 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 OOSP. See SOM Chapter 6. If an investigation can be conducted by letter, electronic communication, or telephone, in lieu of an on-site survey, those means should be utilized.

Upon receipt, all complaints are logged and tracked in the same manner as CMS certified laboratories is collected, monitored and maintained. See section 5500.

5570.1 - CMS Direction of Complaint Investigation of an Accredited Laboratory

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

CMS has primary responsibility for the coordination of all activities involving complaints relating to an accredited laboratory when a complaint is received by CMS or SA.

If a laboratory representative refuses to permit a complaint survey, the SA should contact CMS.

Complaints related to an accredited laboratory must be investigated by CMS or SA, as directed by CMS.

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
- Informing and coordinating with all affected parties, including AOs, SAs and CMS when warranted (e.g., in cases potentially involving media coverage, Federal/State Congressional or political interest, legal intervention, etc.).

Although CMS has the lead role in directing the investigation of complaints involving accredited laboratories, all affected entities (i.e., SAs, AOs, CMS) share responsibility in ensuring timely and effective action is taken.

Complaints received by the SA:

If the SA receives an 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 CMS for action. The SA forwards a copy of the acknowledgment letter and the complaint to CMS.

Complaints received by CMS:

If the complaint is received directly by CMS, CMS will promptly send a letter to the complainant acknowledging the complaint and advising the complainant of the intended course of action.

In either case (complaint received by SA or CMS), CMS evaluates the complaint and has the lead in determining the course of action. CMS determines whether CMS, the SA, or the AO, including multiple AOs if circumstances so warrant, will investigate the complaint. If CMS determines that the AO will investigate the complaint, CMS promptly sends a letter to the complainant acknowledging the complaint and informing the complainant to contact the AO with any further questions.

If CMS determines that the SA should investigate the complaint, CMS approves the SA performing the complaint survey in the CLIA Data System and forwards the complaint information electronically, including the approval and notifies the AO when the investigation is complete. If CMS 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 CMS determines that the complaint involves a potential IJ to the individuals served by the laboratory, or to the general public, the SA investigates the complaint within three working days of receiving it from CMS. Otherwise, CMS will direct the SA to investigate non-immediate jeopardy complaints within 45 days and report their findings to CMS and AO at the conclusion of the survey.

Complaints investigated by AOs:

If CMS determines that the AO should carry out its own investigation, it promptly forwards the complaint to the AO for immediate attention. CMS will request to be notified of the results of any investigative action taken. CMS will then notify the SA.

NOTE: Transfusion-related fatality investigations must be conducted by CMS or SA within 45 days of the notice from CMS, with notification to CMS when the survey is complete. Investigations of transfusion-related fatalities are generally announced, since the facility is aware of the possibility of a follow up after the report is made to the FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g.,

media or anonymous complaint, the SA or CMS conducts an unannounced survey. Transfusion-related fatality investigations must not be referred to an AO for action. However, the AO or multiple AOs, as appropriate, will receive a copy of the Form CMS-2567 and the accompanying notification letter from CMS when the investigation is complete. Summary and information from the FDA are considered confidential and may only be shared within CMS or the SA. It may not be shared with any other party, including AOs. See SOM Chapter 6 section 6040.

Complaints received by AOs:

Complaints received directly by AOs will be investigated under each AO's 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., CMS should be promptly alerted by the AO receiving the complaint and consulted concerning appropriate action.

5570.2 - Conducting Complaint Survey of an Accredited Laboratory by CMS or State Agency

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If an on-site survey is warranted, CMS or SA will conduct an unannounced survey of an accredited laboratory based on the allegation of noncompliance. CMS or the SA conducts the complaint survey in accordance with OOSP. See SOM Chapter 6 section 6100-6101.

If the SA is performing the survey, the SA conducts a focused complaint survey, as instructed by CMS. CMS will approve Form CMS-2802A in the CLIA Data System prior to the survey. If the SA finds additional deficiencies during the course of the complaint investigation, it may expand the scope of the survey with CMS approval.

At the exit conference, CMS or the SA informs the laboratory director of the deficiencies found and the procedures to respond to them. If deficiencies are found, a Form CMS-2567 is prepared. The laboratory is informed that the Form CMS-2567 will be made available to the public under the disclosure of survey information provisions. The surveyor should advise the laboratory that the official report of deficiencies is Form CMS-2567.

Standard-level deficiencies: If the deficiencies are at the standard-level, a PoC is requested. However, it is optional for the laboratory to submit a PoC to CMS. For standard only deficiencies, responsibility rests with the AO to follow up and pursue corrective action.

Condition-level deficiencies, non-immediate jeopardy: If the deficiencies are at the condition- level, the laboratory must submit an AoC to CMS. Condition-level

deficiencies **must** be corrected. CMS or the SA indicates to the laboratory that the Form CMS-2567 will be forwarded to the laboratory within 10 working days and that the AoC must be returned to CMS and the SA within 10 calendar days. Upon receipt of the survey information and AoC, CMS, in coordination with the SA, determines whether or not the AoC is credible, and if sanctions will be imposed against the laboratory. CMS notifies the laboratory and AO.

Condition-level deficiencies, immediate jeopardy found: If the deficiencies are at the condition-level and pose IJ to the health and safety of individuals served by a laboratory, or to the general public, an AoC is requested. Condition-level deficiencies must be corrected, so the accredited laboratory must submit an AoC to CMS. CMS or SA indicates to the laboratory that the Form CMS-2567 will be forwarded to the laboratory within three working days of the survey exit date and that the credible AoC and evidence of correction must be submitted to CMS and the SA within 10 calendar days. The IJ template should be given to the laboratory at the time that IJ is determined (see SOM Appendix Q). Upon receipt of the survey AoC and evidence, CMS, in coordination with the SA, determines whether or not the AoC is credible, and if sanctions will be imposed against the laboratory. CMS notifies the laboratory and AO.

If CMS determines that the deficiencies pose IJ, an IJ template must be given to the laboratory at the time IJ is determined (on-site or off-site). See SOM Appendix Q.

5570.3 – Forwarding Investigation Report to CMS by the SA

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If non-immediate jeopardy is found, the SA will submit the appropriate information, including but not limited to, Form CMS-2567, Form CMS-116, Form CMS-209, and surveyor notes to CMS, or through an update to the CLIA Data System within 45 days of completing the survey and notifies CMS of the entry. If the laboratory chooses not to submit a PoC when standard-level deficiencies are found, the SA reports any known information about the laboratory's efforts to correct deficiencies to CMS and AO. If the laboratory does not submit an AoC for condition-level noncompliance, the SA should refer the case to CMS who may begin enforcement actions.

5570.4 - Accredited Laboratory Found in Compliance Following a Complaint Survey

(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If after review of the documentation, CMS 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 AO may contact the laboratory about correcting any deficiencies below condition-level, i.e., standard-level deficiencies only. If no deficiencies are found, a Form CMS-2567 should be issued stating that the accredited laboratory is in compliance with CLIA condition-level requirements.

5570.5 - Accredited Laboratory Found Not in Condition-level Compliance Following a Complaint Survey
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

If the deficiencies found pose an IJ to the health and safety of individuals, the SA prepares the Form CMS-2567, IJ template, and letter notifying the laboratory of the condition-level noncompliance with IJ and requests an AoC. The SA copies CMS when notifying the laboratory and requesting an AoC. The Form CMS-2567 is sent to the laboratory within three working days. CMS will notify the AO and forward the letter and Form CMS-2567 to the AO when the investigation is complete. Based on the laboratory's submitted AoC and evidence of correction, CMS determines if sanctions are to be imposed against the laboratory.

For condition-level noncompliance that is not IJ, the same process is followed except the timeline is 10 working days and no IJ template is required.

5580 - Accredited Laboratories Post Investigation Actions
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

CMS will notify the AO about a potential CMS enforcement action.

The laboratory continues to be accredited by its AO and retains its CLIA Certificate of Accreditation. However, it temporarily comes under the jurisdiction of CMS and becomes subject to the same CLIA requirements, survey, and enforcement procedures as applied to non-accredited laboratories found out of compliance. The laboratory remains under the jurisdiction of CMS until either it comes into condition-level compliance, or the certificate is revoked.

Should the condition-level deficiencies, including an IJ situation, be corrected before the adverse action is taken or completed, CMS or the SA will advise the laboratory that it will perform an on-site revisit it to ensure it is in condition-level compliance, and that IJ has been removed. In all cases of condition-level noncompliance, an on-site revisit will be performed before the principal sanctions of revocation or suspension are imposed. This includes, but is not limited to, a credible AoC is not received, or the laboratory does not submit an AoC. CMS will notify the AO.

5590 - Accredited Laboratories Resolution/Closeout
(Rev. 234; Issued: 09-12-25; Effective: 09-12-25; Implementation: 09-12-25)

The SA will submit the appropriate information to CMS, or through an update to the CLIA Data System within 45 days of completing the survey and notifies CMS of the entry. If the laboratory chooses not to submit an AoC when condition-level deficiencies are found, CMS will notify the AO that the laboratory is out of compliance, and CMS

will move forward with an enforcement action. A copy of all correspondence, as well as the Form CMS-2567 and AoC, is provided to the AO by CMS. Complaints are considered closed when referred to an AO by CMS.

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 Location 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. 250; Issued: 10-16-26)

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

Rev #	Issue Date	Subject	Impl Date	CR#
R250SOMA	10/16/2026	Revisions to State Operations Manual (SOM), Chapter 5	10/16/2026	N/A
R234SOMA	09/12/2025	Revisions to State Operations Manual (SOM) Chapter 5 - Complaint Procedures, Sections 5500-5590	09/12/2025	N/A
R212SOMA	02/10/2023	Revisions to State Operations Manual (SOM) Chapter 5.	10/24/2022	N/A
R212SOM	02/10/2023	Revisions to State Operations Manual (SOM) Chapter 5	10/24/2022	N/A
R208SOM	10/21/2022	Revisions to State Operation Manual (SOM), Appendix PP Guidance to Surveyors for Long Term Care Facilities	10/24/2022	N/A
R191SOM	07/19/2019	Revisions to the State Operations Manual (SOM) Chapter 5 and Appendix V	07/19/2019	N/A
R155SOM	06/10/2016	Revisions to State Operations Manual (SOM) Chapter 5	06/10/2016	N/A
R120SOM	09/19/2014	Revisions to State Operations Manual (SOM) Chapter 5	09/19/2014	N/A
R88SOM	08/27/2013	Revisions to State Operations Manual (SOM) Chapter 5	07/19/2013	N/A
R86SOM	07/19/2013	Revisions to State Operations Manual (SOM) Chapter 5 – Rescinded and replaced by Transmittal 88	07/19/2013	N/A
R50SOMA	07/10/2009	Revisions to Chapter 5, "Complaint Procedures"	07/10/2009	N/A
R18SOMA	03/17/2006	Revisions to Chapter 5, "Complaint Procedures"	03/17/2006	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A