CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 212 **Date: February 10, 2023**

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

I. SUMMARY OF CHANGES:
Technical corrections to multiple sections in the State Operations Manual found in Chapter 5. These technical corrections include correct implementation dates.

NEW/REVISED MATERIAL-EFFECTIVE DATE: October 21, 2022
IMPLEMENTATION DATE: October 24, 2022
except for 5060 –October 1, 2024 and 5075.9 – October 1, 2023

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Table of Contents
R	Chapter 5/5000 - Management of Complaints and Incidents
R	Chapter 5/5000.1/ Purpose of the Complaint/Incident Process
R	Chapter 5/5010/ General Intake Process
R	Chapter 5/5060/ASPEN Complaints/Incidents Tracking System (ACTS)
R	Chapter 5/ 5060.1/Data Entry
R	Chapter 5/5060.2/Reports
R	Chapter 5/5070/ Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Chapter 5/5075/ Priority Definitions for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Chapter 5/5075.1/Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)

R	Chapter 5/5075.2/ Non-Immediate Jeopardy - High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.3/ Non-Immediate Jeopardy - Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Chapter 5/5075.4/ Non-Immediate Jeopardy – Low Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Chapter 5/5075.6 /Referral -Immediate (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.8/No Action Necessary (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.9/ Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents
R	Chapter 5/5080.1/ Report to the Complainant
R	Chapter 5/5300.5/ Task 7: Exit Conference
R	Chapter 5/5310/Action on Allegations of Resident Neglect and Abuse, and Misappropriation of Resident Property for Nursing Homes
R	Chapter 5/ 5310.1/ Written Procedures
R	Chapter 5/5310.2/ Review and Triage of Allegations
R	Chapter 5/5310.2A/ Review and Triage of Allegations/ Immediate Jeopardy Priority
R	Chapter 5/5330/ Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit for Nursing Homes

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

State Operations Manual
Chapter 5 - Complaint Procedures

Table of Contents
(Rev. 212; 02-10-23)

Transmittals for Chapter 5

Sections 5000 to 5080.1 relate to all Medicare/Medicaid-certified provider/supplier types.

Sections 5300 to 5390 relate to nursing homes.

5000 - Management of Complaints and Incidents

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

NOTE: "CMS Regional Office (RO)" is used interchangeably with "CMS location" throughout this Chapter of the SOM.

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.

5010 - General Intake Process

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

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 RO 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 RO if State regulations conflict directly with any part of these complaint procedures.

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

5060 – ASPEN Complaints/Incidents Tracking System (ACTS)
(Rev. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

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

The SAs and ROs are required to enter into ACTS:

- All complaint*s* 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.

Revisions related to the entry of self-reported incidents into ACTS will be implemented no later than October 1, 2024, in order to provide time for the SAs to prepare given the resource constraints in the SAs.

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

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. Revisions related to the timeframes for investigating nursing home complaints and facility-reported incidents will be implemented no later than October 1, 2023, to provide time for the SAs to prepare given the resource constraints in the SAs.

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 RO 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 RO 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 RO 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 RO approval of a complaint validation survey (i.e., substantial allegation validation survey). The SA must obtain RO approval before conducting a

substantial allegation validation survey. The RO will authorize the SA to conduct the survey by issuing electronically via ACTS a Form CMS-2802, which will indicate the specific conditions for which the SA must assess compliance. The RO 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 RO. The RO will determine whether the SA will conduct an EMTALA investigation.

In cases where the SA or RO 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 RO 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 (Note: Revisions related to the timeframes for investigating nursing home complaints and facility-reported incidents will be implemented no later than October 1, 2023, to provide time for the SAs to prepare given the resource constraints in the SAs); 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. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

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 and it is uncertain that they are adequately protected.*
- *For nursing homes, all intakes alleging eviction of a resident to an unsafe location.*
- 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 RO determines requires an on-site investigation is also assigned this priority.

When the SA or RO 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: Revisions related to the timeframes for investigating nursing home complaints and facility-reported incidents will be implemented no later than October 1, 2023, to provide time for the SAs to prepare given the resource constraints in the SAs.)

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 ACTS (Priority = IJ, Allegation Category = Life Safety Code);
- Informs the appropriate RO 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 RO

- Informs CMS Central Office (CO) of the fire and planned actions, sending a copy of the alert to the Life Safety Code specialist;

- Consults with the CO to determine whether there is an indication for CO participation in the survey for program evaluation purposes;

- Reports any findings and actions taken by the SA to the CO 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 RO 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 staff may accompany regional 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. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

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.

When the SA makes the determination that *the alleged noncompliance may have caused actual physical and/or psychosocial harm to the resident(s), the 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. Investigating nursing home complaints and facility-reported incidents according to these timeframes will be implemented no later than October 1, 2023, to provide time for the SAs to prepare given the resource constraints in the SAs.*

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 RO for deemed status providers/suppliers. The RO 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. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

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. For complaints and facility-reported incidents that are assigned a "medium" priority, the SA must initiate an onsite survey within 45 calendar days of receipt of the initial report. Investigating nursing home complaints and facility-reported incidents according to this timeframe will be implemented no later than October 1, 2023, to provide time for the SAs to prepare given the resource constraints in the SAs.

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 RO, if the RO 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. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

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)*. The investigation is to be initiated in accordance with section 5075.9. *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.*

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 RO, if the RO 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.

5075.6 - Referral – Immediate (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)

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 ACTS 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 RO, as appropriate.)

5075.8 - No Action Necessary (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)

Intakes are assigned a "No Action Necessary" priority if the SA or RO 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 RO, 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/RO:

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

2) *Facility-reported incidents involving injuries where the resident was able to explain or describe how he/she received the injury as long as there is no other indication of abuse or neglect;*

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

4) *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. 212; Issued; 02-10-23; Effective: 10-21-22; Implementation: 10-24-22)

	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 RO authorization	SA must initiate an onsite survey within 45 calendar days of receipt of RO 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 RO authorization.	SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization	N/A	N/A
Death associated with restraint/seclusion-Hospitals	SA must initiate an onsite survey within 2 business days of receipt of RO 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.

5080.1 - Report to the Complainant

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

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).

5300.5 - Task 7: Exit Conference

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

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 the complaint was substantiated 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 the complaint is unsubstantiated, (i.e., the surveyor(s) cannot determine that it occurred and there is no indication of deficient practice), 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. Facility Reported Incidents – Initial Report

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

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 ACTS: 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 ACTS: 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.

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

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

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

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

If the SA receives information that a suspected crime may have occurred in a facility and there is indication that it has <u>not</u> 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 RO substantiates a finding of abuse, the SA or RO must report the substantiated findings 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)).