DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-35-ALL

DATE: **May 20, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Update of State Operations Manual (SOM) Chapter 5, Triaging Complaints & Referral of Complainants to Accrediting Organizations

Memorandum Summary

Triaging and Referring Complaints:

- A "Non-IJ High" category for prioritizing complaint allegations has been added to Section 5075 of the State Operations Manual (SOM) for non-long term care (non-LTC). It applies to all substantial allegations of noncompliance (except for immediate jeopardy (IJ) allegations), and requires a SA complaint investigation.

- All complainants whose complaints concerning deemed providers/suppliers are prioritized below non-IJ High must be referred to the applicable accrediting organization(s) (AOs).

Revision of intake prioritization categories for non-long term care facilities: We are adding the new intake prioritization category of "non-IJ High" for both deemed and non-deemed non-long term care providers and suppliers. The regulatory standard at 42 CFR 488.7(a)(2) for authorizing a complaint validation survey of a deemed provider/supplier is that the complaint or self-reported incident is a substantial allegation of noncompliance, i.e., it is a complaint, from any of a variety of sources that, if substantiated, would affect the health and safety of patients and raise doubts as to a provider's or supplier's compliance with any Medicare Condition of Participation or Condition for Coverage or Certification. In other words, "substantial allegations" suggest condition-level noncompliance

We believe that the prior triage system, which did not have a "non-IJ high" intake prioritization category for non-long term care providers/suppliers, may have made it harder for SAs to distinguish those cases involving deemed providers or suppliers that warrant an on-site investigation from less serious cases. The amount of time the SA has to begin an investigation of a non-LTC, non-IJ high complaint is 45 calendar days after receipt of the complaint for non-deemed providers and suppliers, or 45 calendar days after authorization of the complaint

investigation by the CMS Regional Office for deemed providers and suppliers. This is the same amount of time as was allowed under the prior triage system for non-IJ medium complaints for non-long term care facilities.

Under the revised set of categories for non-LTC complaint intakes:

- "IJ" Intakes –
    - Non-deemed providers/suppliers: The on-site portion of the survey for these intakes must start within 2 working days of receipt of the complaint/incident.
    - Deemed providers/suppliers: These intakes are to be submitted promptly to the RO with a request for survey authorization; the on-site portion of the survey must start within 2 working days of receipt of RO authorization;
    - EMTALA complaints or reports of deaths associated with use of restraint or seclusion in a hospital or critical access hospital distinct part unit: Surveys are to be completed within 5 working days of receipt of RO authorization.

- "Non-IJ-High" intakes –
    - Non-deemed providers/suppliers: The on-site investigation for these intakes must be started within 45 calendar days of prioritization.
    - Deemed providers/suppliers: These intakes are to be submitted promptly to the RO with a request for survey authorization; the on-site investigation must be started within 45 calendar days of receipt of RO authorization.

- "Non-IJ-Medium" intakes –
    - Non-deemed providers/suppliers: These intakes must be investigated no later than when the next on-site survey (either another complaint or a recertification survey).

    - Deemed providers/suppliers: Complainants are to be advised that the complaint does not meet the criteria for a Federal investigation and they are to be provided information about where to submit a complaint to the applicable AO(s).

- "Non-IJ-Low intakes
    - Non-deemed providers/suppliers: These intakes are to be reviewed, with tracking of possible trends in the nature of complaints, in order to determine if there are common themes that would 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.

    - Deemed providers/suppliers: Complainants are to be advised that the complaint does not meet the criteria for a Federal investigation and they are to be provided information about where to submit a complaint to the applicable AO(s).

For non-IJ-medium and low intakes, the SA (or the RO if the complaint was received by the RO) 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 list of AO complaint contact information, should the individual wish to pursue a

complaint with the AO. The list may be found at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Complaint-Contacts.pdf* .

An advance copy of the revised portions of Chapter 5 is included for your information. It may differ slightly from the final version that will be published at a later date.

Note that until revisions are made to the ACTS system, intakes prioritized as Non-IJ-Medium and Non-IJ-Low, whether for deemed or non-deemed non-long term care facilities, will remain in a pending status, since ACTS currently prevents closing out the intake without an associated survey.

We are also taking this opportunity to clarify the type of information that must be communicated to a provider or supplier that is the subject of a complaint investigation. The Health and Human Services Office of Inspector General (OIG), in its report OEI-01-08-00590, *Adverse Events in Hospitals: Medicare's Response to Alleged Adverse Events*, recommended that we clarify our guidance concerning the investigation of hospital complaints to include a process that would advise hospitals of the general nature of the complaint, while maintaining complainant confidentiality, similar to our existing guidance for nursing homes in Section 5300.2 of the SOM. We concurred with the OIG and, accordingly, we have added a new section 5079 that addresses the disclosure of information regarding the nature of the complaint during the entrance conference. This guidance applies to complaint surveys for all types of non-long term care providers and suppliers.

Questions concerning this memorandum may be addressed to hospitalscg@cms.hhs.gov .

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal **(Advance Copy)** **Date:**

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

I. SUMMARY OF CHANGES: Chapter 5, Sections 5070, 5075, 5080 and 5100 are updated and new Sections 5078 and 5079 are added to reflect current policy

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

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	Chapter 5/Table of Contents
R	Section 5070/Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Section 5075/Priority Definitions for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Section 5075.1/Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Section 5075.2/Non-Immediate Jeopardy – High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Section 5075.3/Non-Immediate Jeopardy - Medium Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Section 5075.4/Non-Immediate Jeopardy – Low Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Section 5075.5/Administrative Review/Offsite Investigation (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers)
R	Section 5075.6/Referral – Immediate (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Section 5075.7/Referral – Other (for Nursing Homes, Deemed and Non-Deemed Providers/Suppliers, and EMTALA)

R	**Section 5075.8/No Action Necessary (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)**
R	**Section 5075.9/Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents**
N	**Section 5078/Pre-Survey Activities**
N	**Section 5079/Entrance Conference - Non-Long Term Care Providers/Suppliers**
R	**Section 5080.2/Survey Exit Conference and Report to the Provider/Supplier**
R	**Section 5100/Investigation of Complaints for Deemed Providers/Suppliers**
R	**Section 5100.1/Basis for Investigation**
R	**Section 5100.2/Initial Response to Complainant**

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2013 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.)

Section 5170 Relates to Hospital Restraint/Seclusion Death Reporting and Investigation

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

Sections 5300 to 5390 relate to nursing homes.

Sections 5500 to 5590 relate CLIA.

5500 - Complaints Involving Unaccredited Laboratories

5500.1 - Control
5500.2 - Acknowledgment
5500.3 - Evaluation
5500.4 - Scheduling Investigations
5500.5 - Conducting Investigations
5500.6 - Conducting Investigations in a Laboratory with a Certificate of Waiver
5500.7 - Conducting Investigations in a Laboratory with a Certificate for PPM Procedures
5500.8 - Post Investigation Actions
5500.9 - Resolution/Closeout

5510 - CLIA-Exempt Laboratory Complaint Investigations - General

5520 - Review of CLIA-Exempt Laboratory Complaints

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

5540 - Complaint Investigations and Surveys of Accredited Laboratories Under CLIA

5550 - RO Direction of Complaint Investigation of an Accredited Laboratory

5560 - Conducting Complaint Survey of an Accredited Laboratory

5570 – Forwarding Investigation Report to RO

5580 - Accredited Laboratory Found in Compliance Following a Complaint Survey

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

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

(Rev.)

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. In situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to *start the on-site* investigat*ion* within two working days of receipt of the *complaint or incident report, or, in the case of a deemed provider or supplier, within two working days of RO authorization for investigation*. *In the case of an EMTALA complaint or a survey related to a report of a hospital or CAH Distinct Part Unit patient death associated with use of restraint or seclusion, the SA's investigation must be completed within five working days of RO authorization for investigation.* For all non-immediate jeopardy situations, the complaint/incident is prioritized within two working days of its receipt, unless there are extenuating circumstances that impede the collection of relevant information.

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, if found to be true and uncorrected, would result in a condition-level deficiency citation) the SA must submit a request for RO approval of a complaint 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 CMS Form 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 CMS Form 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 or critical access hospital (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 triage 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.

5075 - Priority Definitions for Nursing Homes, Deemed and Non-Deemed *Non-Long Term Care* Providers/Suppliers, and EMTALA

(Rev.)

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

(Rev.)

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. All intakes alleging EMTALA noncompliance are also 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.

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*)

(Rev.)

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 a higher level of actual harm may be present, the investigation is to be initiated in accordance with 5075.9. The initiation of these types of investigations is generally defined as the SA beginning an onsite survey.

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

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, 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 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.)

Nursing Homes:

Intakes are assigned *a "medium"* priority if the alleged noncompliance with one or more requirements caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status or function. *The investigation is to be initiated in accordance with 5075.9.*

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 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.)

Nursing Homes

Intakes are assigned *a "low"* priority if the alleged noncompliance with one or more requirements may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage. *The investigation is to be initiated in accordance with 5075.9.*

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.*

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

(Rev.)

Nursing Homes

Intakes are assigned *an "administrative review/offsite investigation"* priority if an onsite investigation is not necessary. However, the SA or RO conducts *and documents in the provider file* an offsite administrative review (e.g., written/verbal communication or documentation) to determine if further action is necessary. *Where an administrative review/offsite investigation is conducted by the SA, the SA may confirm the findings at the next onsite survey.*

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:

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

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

(Rev.)

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**.

*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.)

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

(Rev.)

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 RO, as appropriate.)

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

(Rev.)

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 *a* previous survey investigated the *exact* same *event(s) and either did not find noncompliance, or noncompliance was 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.

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

(Rev.)

	Intake Prioritization			
Provider Type	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium	Non-IJ Low
Nursing homes	SA must initiate an onsite survey within 2 working days of receipt.	SA must initiate an onsite survey within 10 working days of prioritization.	No timeframe specified, but an onsite survey *must* be scheduled.	SA *must* investigate during the next onsite survey.
Non-deemed *non-long term care* providers/suppliers	SA must initiate an onsite survey within 2 working days of receipt.	*SA must initiate an onsite survey within 45 calendar days of prioritization*	*Must be investigated no later than when the next on-site 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 working 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 complete *onsite portion of* investigation within 5 *working* days of receipt of RO authorization.	N/A	N/A	N/A
Death *associated with* restraint/seclusion-Hospitals	SA must complete onsite *portion of* investigation within 5 working days of *RO* authorization.	N/A	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 working days of receipt.	N/A	N/A	N/A

5078 – Pre-Survey Activities
(Issued)

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
(Issued)

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.)

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

(Rev.)

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.*

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

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

The SA/RO 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 RO sends a copy of the written report to the applicable accrediting organization(s), following the procedures specified in Section 5110. At the RO'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.)

5100 - Investigation of Complaints for Deemed Providers/Suppliers

(Rev.)

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.)

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 RO. In accordance with 42 CFR 488.7, the RO 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 RO, 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 RO of all complaints/incidents it receives which, if substantiated, would by their manner and degree suggest condition-level noncompliance. The RO 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 RO does not concur that the allegation rises to this level, either the RO 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 RO instructs the SA to refer the complainant to the applicable accrediting organization, following the procedures in section 5100.2

The RO 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 RO 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 RO completes the Form CMS 2802 in ACTS even if the SA received an initial verbal authorization from the RO to initiate the complaint survey of a deemed provider/supplier. Since ACTS allows the RO to authorize a complaint survey electronically it is not necessary for the RO 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 RO 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 RO authorizes the SA to conduct a complaint investigation or, in a limited number of cases, the RO 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 RO 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

- *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 RO to conduct a survey. If the RO 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 RO 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.*