VI. Survey Process

Introduction:

This category of the guide is the core "how to" for nursing home surveys. Surveyors follow certain protocols to determine the appropriateness of a citation of non-compliance. The survey protocols and guidelines help surveyors in clarifying the intent of the regulations.

What you'll learn:

- Survey team size and composition; survey frequency
- Conflicts of interest for surveyors
- Complaint/incident process and how state agencies manage complaints
- Types of surveys and how they are conducted
- Actions taken when a facility is not in substantial compliance

Presurvey Preparation [SOM §2704]

Prior to conducting a survey, the SA should review documents of record including:

- Licensure records;
- Fire inspection reports;
- Previous survey reports including Life Safety Code and complaints;
- Media reports about the facility; and
- Other publicly available information about the facility (e.g., its own website).

This information is helpful in determining composition of the survey team and the time required for the survey or resurvey.

Team Size, Team Composition, and Survey Length [SOM §7201, see also §2706]

Note: As the language in this section indicates, both the state agencies and CMS Regional Offices are expected to tailor the size and composition of survey teams, as well as the length of surveys, to ensure that they have both the time and the skills necessary to ensure that the needs of the residents in each facility are being met.

Team Size [SOM §7201.1]

Survey team size will vary, depending primarily on the size of the facility being surveyed. The state (or, for federal teams, the RO) determines how many members will be on the team. Survey team size is normally based upon the following factors:

- The bed size of the facility to be surveyed;
- Whether the facility has a historical pattern of serious deficiencies or complaints;
- Whether the facility has special care units; and
- Whether new surveyors are to accompany a team as part of their training.

Team Composition [SOM §7201.2]

The state (or, for federal teams, the RO) decides what the composition of the survey team will be, as long as certain statutory and regulatory requirements are met:

- Standard surveys conducted by a multidisciplinary team of professionals, at least one of whom must be a registered nurse (RN);
- Surveyors free of conflicts of interest (see §7202); and
- Surveyors successfully complete a training and testing program in survey and certification techniques that has been approved by the Secretary.

Surveyors must successfully complete the CMS-approved training and pass the Surveyor Minimum Qualifications Test.

Within these parameters, the states (or, for federal teams, the ROs) are free to choose the composition of each team, and it is the state that determines what constitutes a professional. However, **CMS offers the following guidance**:

- The state or RO should consider using more than one RN on teams that will be surveying a facility known to have a large proportion of residents with complex nursing or restorative needs.
- Because of the strong emphasis on resident rights, the psychosocial model of care, and rehabilitative aspects of care in the regulations and the survey process, the team should include social workers, registered dietitians, pharmacists, activity professionals, or rehabilitation specialists, when possible.

- It is important, to the extent practical, to utilize team members with clinical expertise and knowledge of current best practices that correspond to the resident population's assessed needs, the services rendered in the facility to be surveyed, and the type of facility to be surveyed.
 - Example: If the facility has a known problem in dietary areas, there should be an effort to include a dietitian on the team; if a known problem in quality of life, a

"Because of the strong emphasis on resident rights, the psychosocial model of care, and rehabilitative aspects of care in the regulations and the survey process, the team should include social workers, registered dietitians, pharmacists, activity professionals, or rehabilitation specialists, when possible."

social worker. If the facility specializes in the care of residents with post-trauma head injuries and strokes, a physical therapist may be included on the team.

- In addition to members of individual disciplines routinely included as members of the survey team, consideration should be given to the use of individuals in specialized disciplines who may not routinely participate as team members. These individuals would be available to assist the survey team when specific problems or questions arise.
 - Consultants in these suggested disciplines include, but are not limited to, physicians, physician assistants, nurse practitioners, physical, speech, and occupational therapists, dieticians, sanitarians, engineers, licensed practical nurses, social workers, pharmacists, and gerontologists.
- In order to comply with the requirement that "No individual shall serve as a member of a ... team (surveying a SNF or NF) unless the individual has successfully completed (the CMSapproved) training and testing program," surveyors in training, i.e., those who have not successfully completed the required training, must be accompanied on-site by a surveyor who has successfully completed the required training and testing.

Survey Length [SOM §7201.3]

The length of a standard survey in terms of person hours is expected to vary, based on the size and layout of the facility and the number and complexity of concerns that need to be investigated onsite.

Survey Scheduling [SOM §7205, see also §§2008F, 2700B]

Scheduling and Conducting Surveys [SOM §7205.2]

States must complete standard surveys no later than 15 months after the previous standard survey. Facilities with excellent histories of compliance may be surveyed less frequently to determine compliance, but no less frequently than every 15 months and the state-wide standard survey average must not exceed 12 months.

Changes that may prompt a survey include: a change of ownership, management firm, administrator, or director of nursing. Facilities with poor histories of compliance may be surveyed more frequently to ensure residents are receiving quality care.

The state may conduct surveys as frequently as necessary to determine if a facility complies with the participation requirements as well as to determine if the facility has corrected any previously cited deficiencies.

Unannounced Surveys [SOM §7202.2, see also §2700A]

The state has the responsibility to keep surveys unannounced and their timing unpredictable. This way, surveyors will be more likely to observe conditions and care practices that are typically present. To increase the opportunity for unpredictability in standard surveys, states should incorporate the following procedures when planning facility surveying:

- Facilities, within a given geographical area, should not be surveyed in the same order as was conducted in the previous standard survey [SOM § 7207.2.1]; and
- The time of day, day of the week, and time of month should be varied from the time of the previous standard survey [SOM § 7207.2.2].

Nursing home surveys, including standard surveys, complaint surveys, and onsite revisit surveys, are to be:

- Unannounced;
- Nonsequential; and
- Varied in timing.

CMS Review of State Scheduling [SOM §7207.3]

Regional offices review annually state's procedures for assuring that surveys are not announced through the methods by which they are scheduled or conducted.

Mandatory Sanction Time Frames [SOM §7205.1.1]

These dates should be set based on full months rather than on a number of days.

Example: If a survey ended on January 15, the 3-month effective date for the mandatory denial of payment for new admissions remedy is April 15, and the 6-month mandatory termination date is July 15.

Civil Money Penalties [SOM §7207.4]

If any individual has, in any way, given prior notification to a facility of the date of a *standard survey*, the state or CMS is to contact the regional Office of the Inspector General (OIG) and report the name of the individual and what has occurred. The OIG will further investigate and determine whether to impose a federal civil money penalty of up to \$2,000.

Actions to Ensure SA's Compliance with Standard Survey Interval [SOM §7205.5]

No action is necessary if the standard survey interval for a provider is not greater than 15 months and the state-wide average is not greater than 12 months.

If the standard survey interval for a provider is greater than 15 months and/or the statewide average interval is greater than 12 months, the regional office will notify the state, determine if a problem exists, and take appropriate action. This action is specified in <u>Chapter 8</u> of this manual.

Survey Protocols [SOM §2713]

Accompanying Surveyors [SOM §2713A]

The surveyors may allow, or refuse to allow, facility personnel to accompany them during a survey. Each case is at the SA and surveyor's discretion and is to be addressed with facility management. Facility personnel may be helpful in that they may answer questions or point out certain concerns. Conversely, facility personnel may hinder the surveyor by arguing about observed problems.

Physical Contact with Patients/Residents [SOM §2713B]

The health and dignity of the resident is always of paramount concern and accordingly, a surveyor must respect an individual's right to be observed. A surveyor is not to touch or examine a resident by themselves. However, in certain circumstances when it is permissible and necessary to

determine the physical condition of residents, surveyors must obtain the resident's (or representative's) permission prior to any resident examination..

Example: If the surveyor believes that blankets or clothing are hiding bedsores, bruises, or incontinence, they may remove the coverings and make a determination based on observation.

Interviewing Key Personnel [SOM §2714]

Surveyors will usually meet with the administrator, the director of the facility, or supervisors from other departments to outline the survey plan.

The surveyor interviews the administrator or director of the facility first since they are the key person in the institution. However, even if the administrator feels that they can answer most of the questions, **the surveyor must verify the facts through review of source documents and interviews**.

The surveyor should use a few well-phrased questions to elicit the desired information.

Example: "If you smelled smoke, what would you do?"

Interviewing Residents [SOM §2715]

Surveyors are to interview residents, family members, or legal guardians to evaluate their impressions about the facility's care. However, residents, family members, and legal guardians have the right to refuse interviews. **Surveyors must respect the confidentiality of information provided during these interviews.**

Facility personnel should not accompany the surveyors during resident interviews unless the resident, their family, or their guardian requests the facility personnel's presence. Surveyors should refrain from moving or handling residents during the interviews. Any

The health and dignity of the resident is always of paramount concern.

The SA investigation must be complete enough to document whether **a**) the standards are met, and **b**) the provider is in compliance with all requirements. moving or handling of residents during the interview should be done by a member of the facility staff.

Exit Conference [SOM §2724]

Surveyors conduct an exit conference with the facility's administrator and other invited staff to informally communicate preliminary survey team findings and to provide an opportunity for the interchange of information. The exit conference is conducted as a courtesy to the provider.

It is critical that surveyors establish and maintain control throughout the exit conference.

The surveyor may, however, refuse to continue an exit conference. Below are examples of situations in which a surveyor may refuse:

- If the provider is represented by counsel, surveyors may refuse to continue the exit conference if the provider's attorney attempts to turn it into an evidentiary hearing; or
- Any time the provider creates an environment that is hostile, overly intimidating, or inconsistent with the informal and preliminary nature of an exit conference.

Conflicts of Interest [SOM §§4008, 7202]

Conflicts of interest may arise for nursing home surveyors (inspectors) and their supervisors when their positions as public employees produce potential for private gain or unfair advantages. To protect the integrity of the nursing home certification program, state and federal employees should declare any outside interests and update that declaration as necessary.

SA administrators should require employees to make a declaration of any outside interests and update this declaration periodically. The SA should evaluate the need for preventive measures to protect the integrity of the certification program. In cases where certification work is performed by agencies other than the designated SA, the SA administrators and the subagency administrators have a shared responsibility for such surveillance.

It is not necessary for the SA to inform the RO of all potential and apparent conflict situations. However, if an overt abuse requires corrective action, the SA should inform the RO.

Examples of Potential Conflicts of Interest [SOM §§4008B, 7202.2.2]

The following are examples of situations that may raise a question of possible conflicts of interest, but they do not necessarily constitute conflicts of interest:

- Participation in ownership of a health facility located within the employing state;
- Service as a director or trustee of a health facility;
- Service on a utilization review committee;

- Private acceptance of fees or payments from a health facility or group of health facilities or association of health facility officers for personal appearances, personal services, consultant services, contract services, referral services, or for furnishing supplies to a health facility;
- Participation in a news service disseminating trade information to a segment of the health industry; and
- Having members of one's immediate family engaged in any of the above activities.

Prima Facie [SOM §7202.2.1]

Any of the following circumstances disqualifies a surveyor for surveying a particular facility:

- The surveyor currently works, or, within the last 2 years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed;
- The surveyor has any financial interest or any ownership interest in the facility;
- The surveyor has an immediate family member (defined in <u>42</u> <u>CFR 488.301</u>) who has a relationship with a facility described in SOM §7202; or
- The surveyor has an immediate family member who is a resident in the facility.

Report and Investigation Improper Acts [SOM §7202.3]

Any acts of employees in violation of federal or state laws or regulations regarding conflicts of interest should be handled in accordance with applicable federal or state procedures. In the case of state employees, conflicts of interest violations must be reported to the RO, and the RO must be kept advised of the corrective actions. States should ask for assistance or advice in the case of any impropriety involving a conflict of interest that cannot be handled immediately under an applicable state procedure. The regional office of the Inspector General, along with the CMS RO, will then work in close cooperation with the responsible state officials until the matter is resolved.

Federal and state employees are required to declare any outside interests and update that declaration as necessary.

"CMS and the States must consider all relevant circumstances that may exist... to ensure that the integrity of the survey process is preserved."

Types of Surveys [SOM §7203]

The following protocols are established to provide guidance to surveyors conducting surveys of long-term care facilities participating in the Medicare and Medicaid programs. The protocol consists of survey procedures, worksheets, and interpretive guidelines. Its purpose is to provide suggestions, interpretations, check lists, and other tools for use both in preparation and performance as well as to promote consistency in the survey process.

Initial Certification Surveys [SOM §7203.2, see also §2005 and Appendix P]

The state is responsible for certifying a non-state operated facility's compliance or noncompliance with federal participation requirements. The state conducts the certification survey for state-operated facilities, but the RO is tasked with certifying compliance or noncompliance and determining whether a facility will participate in Medicare and Medicaid programs.

During the initial survey, the focus is on both the residents and the structural requirements that relate to qualification standards and resident rights notification, whether or not problems are identified during the information gathering tasks. (See Appendix P.)

Example: surveyors should verify the qualifications of social workers, dietitians, and activities professionals. (See also <u>SOM §2000</u>.)

Post Survey Revisit (Follow-Up) [SOM §§2732A, 7203.4, 7317.2]

A surveyor may conduct a post survey revisit if, during a previous survey, the surveyor cited deficiencies. The intent is to verify correction of those deficiencies, and if so, the surveyor can determine if the facility now meets the requirements for participation. In some cases, the cited deficiencies may be of a nature that a mail or telephone contact will suffice as long as the SA has no reason to question the validity of the reported corrections. **However, an onsite visit is generally required for deficiencies concerning quality of care.**

If substandard care is identified during a revisit, the surveyor is to complete a partial extended survey if a partial extended or extended survey had not been conducted as the result of the prior standard or abbreviated standard survey.

Abbreviated Standard Survey [SOM §7203.5]

An abbreviated standard survey does not cover all of the aspects covered in a standard survey, but instead focuses on specific area of concern.

- Examples:
 - If review of a complaint allegation concludes that one or more violations of requirements may have occurred, the surveyor should conduct a standard or abbreviated standard survey.

An abbreviated standard survey may be premised on complaints received; a change in ownership, management, or director of nursing; or other indicators of specific concern. If a facility notifies a surveyor of a change in the organization or management, the surveyor should review the change(s) to ensure compliance with the regulations by requesting copies of relevant documents, if not already submitted. If the change(s) raise questions of continued compliance, the surveyor should conduct a survey to determine whether deficiencies are present.

Extended Survey/Partial Extended Survey [SOM §7203.6]

If, as a result of its findings during the standard survey or abbreviated standard survey, the team suspects substandard quality of care, it expands the survey. If the expanded survey verifies substandard quality of care, the state or RO conducts an extended survey or a partial extended survey.

Extended surveys should be conducted within 14 days after completion of the standard survey, and only when substandard quality of care is identified.

State Monitoring Visits [SOM §§7203.7, 7504]

State monitoring visits are visits by the state to oversee a provider's compliance status. These visits may occur:

- During bankruptcy;
- After a change of ownership;
- During or shortly after removal of immediate jeopardy; and
- In other circumstances, as authorized by the CMS RO.

Complaint and Incident Management [SOM §5000]

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.

There are three objectives of the complaint/incident management system:

- **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.
- **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 is designed to identify and correct less serious situations to prevent escalation.
- **Promote efficiency and quality**: Complaints/incidents that are not directly related to federal requirements are forwarded to the appropriate agencies for follow-up and investigation.

Overview [SOM § 5000.2]

All the procedures in this <u>chapter</u> are followed when complaints and reported incidents, including referrals from public entity, are made against a nursing home.

The investigation and resolution of complaints are critical certification activities. The CMS, the state Medicaid agency (SMA), and the state survey agency (SA) are responsible for ensuring that participating providers/suppliers of health care services continually meet federal requirements. This **requires that the SA promptly reviews complaints/incidents, conducts unannounced onsite investigations of reports alleging noncompliance**, and informs the CMS Regional Office (RO) and/or the SMA any time certification requirements are found to be out of compliance.

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

General Intake Process [SOM §5010]

Complaints

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 each complaint. This structure needs to include response timelines and a process to document actions taken by the SA in response to complaints.

The SA response must be designed to protect the health and safety of all residents, patients, and clients.

- 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 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 organizations (QIOs), 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.

Allegations

An allegation is an assertion of improper care or treatment that could result in the citation of a federal deficiency.

- The point of receipt of the allegation is a critical fact-finding and decision-making point.
- 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 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.

Information from Complainant [SOM §5010.1]

The SA should collect comprehensive information necessary to make important decisions about the allegations, such as proper prioritization, including:

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

Information Provided to Complainant [SOM §5010.2]

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

Information regarding the care, treatment, and services provided to beneficiaries can come from a variety of sources, including beneficiaries themselves, family members, and others.

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

CMS RO's Responsibility for Monitoring SA Management of Complaints and Incidents [SOM §5050]

CMS ROs are responsible for monitoring the SAs' management of complaints and incidents to assure that the SAs are complying with the provisions set forth in federal regulations, the SOM [State Operations Manual], and CMS policy memoranda. As part of the monitoring process, the SAs will be evaluated in accordance with the criteria set forth by the State Performance Standard Review. Many states have state laws and regulations that specify how to manage complaints and incidents. Whenever possible, state and federal requirements should be integrated to avoid unnecessary duplication.

Editor's Note: In October 2019, CMS announced that it had begun to implement changes to improve the State Performance Standards System (SPSS) process. This includes plans to significantly enhance oversight of how SAs handle complaints and facility-reported incidents (FRIs), such as how each state prioritizes reports of abuse or neglect, the timeliness of the investigation of reports, and the quality of these investigations. According to CMS, abuse and neglect are never acceptable and CMS included updates in the SPSS guidance that will strengthen its oversight.²

Priority Assignment of Nursing Home Complaints & Incidents [SOM §5070]

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 investigation within two business days of receipt of the complaint or incident report.

Editor's Note: From a consumer perspective, the proper assignment of priority is important since this will determine the type or investigation a state agency will undertake.

² Fiscal Year (FY) 2020 State Performance Standards System (SPSS) Guidance, Memo #20-02-ALL (October 17, 2019). <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-</u> <u>Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-</u> <u>and-Regions-Items/AdminInfo-20-02-ALL</u>.

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. 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.

Immediate Jeopardy [SOM §5075.1]

The regulations 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." <u>Appendix Q</u> 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.

Non-Immediate Jeopardy - High Priority [SOM §5075.2]

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

Non-Immediate Jeopardy – Medium Priority [SOM §5075.3]

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.

Non-Immediate Jeopardy – Low Priority [SOM §5075.4]

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

Administrative Review/Offsite Investigation [SOM §5075.5]

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.

Referral – Immediate [SOM §5075.6]

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 **without delay**. This priority may be assigned **in addition to** one of the priorities in §§5075.1-5075.5. [Bold in original text.]

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.

Referral – Other [SOM §5075.7]

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 §§5075.1-5075.5.

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.

No Action Necessary [SOM §5075.8]

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 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 determines that a complaint investigation is nevertheless warranted.

Maximum Time Frames for Onsite Investigations of Complaints/Incidents [SOM §5075.9]



Report to the Complainant [SOM §5080.1]

The SA/RO 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 the SA's decision-making process including definitions of terms used (i.e., substantiated or validated, unsubstantiated or not validated, etc.);
- Provide a summary of the SA's finding;
- Identify follow-up action, if any, to be taken by the agency (i.e., follow-up visit, plan of correction review, no further action, etc.); and
- Identify appropriate referral information (i.e., other agencies that may be involved).

Complaint Survey Exit Conference and Report to the Provider [SOM §5080.2]

Generally, the SA conducts an exit conference with the provider at the completion of the onsite portion of the complaint investigation survey. The SA informs the provider of the survey findings, including a general description of any deficiencies found. The description should be detailed enough to inform the provider of the types of activities that require the provider's corrective action.

Complaint Investigations [SOM §5300]

Section <u>42 CFR 488.332</u> [of the federal code] provides the federal regulatory basis for the investigation of complaints about nursing homes.

[Note: <u>42 CFR 488.332</u> explicitly states that **the SA "must establish procedures and maintain** adequate staff to investigate complaints" and conduct "on-site monitoring on an as necessary basis when (1) A facility is not in substantial compliance with the requirements and is in the

process of correcting deficiencies; (2) A facility has corrected deficiencies and verification of continued substantial compliance is needed; or (3) The survey agency has reason to question the substantial compliance of the facility with a requirement of participation" (emphases added).]

If necessary, a specialized team may be used to investigate complaints. Team members may include, but are not limited to, an attorney, auditor, and appropriate health professionals.

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

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

The timing, scope, duration, and conduct of a complaint investigation are at the discretion of the SA, *except* when a determination is made that IJ may be present and ongoing, or a higher level of actual harm may be present.

In most cases, the following tasks, or portion of tasks, should be performed during a complaint investigation:

- Offsite survey preparation: Review any information about the facility that would be helpful to know in planning the investigation. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to and substantiated by the ombudsman. Review the related regulatory requirements or standards that pertain to the complaint. [SOM §5300.1]
- Entrance conference/onsite preparatory activities: Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's administrator of the general purpose of the visit. It is important for the surveyor to let the facility know why

they are there but protect the confidentiality of those involved in the complaint. [SOM §5300.2]

- Information gathering: Conduct comprehensive, focused, and/or closed record reviews as appropriate. Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. [SOM §5300.3]
- Information analysis: Review all information collected, and if there are inconsistencies, do additional data collection as needed. Determine whether the allegations are substantiated or unsubstantiated; the facility failed to meet any of the regulatory requirements; and the facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.

To cite past noncompliance, all of the following **three criteria** must be met:

1) The facility was not in compliance with the specific regulatory requirement(s) at the time the situation occurred;

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

3) There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey. [SOM §5300.4]

Action on Complaints of Resident Neglect and Abuse, and Misappropriation of Resident Property [SOM §5310]

- The state must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property. [SOM §5310.1]
- The state reviews all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source of the complaint. [SOM §5310.2]
- If there is reason to believe, either through oral or written evidence, that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the state must investigate the allegation. During the investigation, the SA should evaluate how the facility developed policies and procedures to prevent the abuse, and after the abuse occurred, how the facility took action to report and investigate the allegations while ensuring the safety of the residents. [SOM §5310.3]

Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit [SOM §5330]

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 <u>Medicaid Fraud Control</u> <u>Unit</u>.

RO Oversight of Complaint-Related Processes [SOM §5390]

- 1. The RO considers any complaint data in targeting look-behind surveys or reviews.
- The RO monitors data in summary form either through a log or data system. See <u>§5060</u> [relating to the federal ASPEN Complaints/Incidents Tracking System (ACTS), excerpted in <u>Appendix 7</u>].

These records should include:

- Identification of region or state-wide patterns;
- Pinpointing of problem providers or states;
- Evaluation of SA processing times, workloads, performance, etc.; and
- Identification of overall SA workloads, including unsubstantiated and Medicaid-only complaint volumes.

Limitation on Technical Assistance to a Nursing Home [SOM §2727]

SAs are encouraged to communicate with the nursing home industry and the states are required to "conduct periodic educational programs for staff and residents (and their representatives)... in order to present current regulations, procedures, and policies." However, when a violation of minimum standards is identified, "it is not the surveyor's responsibility to delve into the facility's policies and procedures to determine the root cause of the deficiency or to sift through various alternatives to suggest an acceptable remedy."

Editor's Note: This provision of the SOM is important because it makes clear that the SA is responsible for quality assurance and accountability, not basic training. The requirement that nursing homes have the appropriate supplies and sufficient staff (with the necessary knowledge and skills) to meet the clinical and psycho-social needs of every resident is fundamental to participation in Medicare/Medicaid. Residents, families, and the general public depend on this requirement being met when a resident enters a facility, not taught to a facility after something bad happens.

Nevertheless, substandard care is a serious, widespread, and persistent problem. To circumvent accountability for resident harm when minimum standards are violated, the nursing home industry lobbies for training, aka "technical assistance," to help them learn how to comply with the minimum standards they are already paid to achieve. This provision of the SOM makes clear that the surveyor's role is to assure quality and accountability, not assist poorly performing facilities.

Substandard Quality of Care and Extended and Partial Extended Surveys [SOM §7210]

Editor's Note: "Substandard quality of care" (SQS) has a specific meaning under the federal guidelines. See <u>Appendix 6</u> for more information.

Survey expansion [SOM §7210.2]

When a surveyor suspects substandard quality of care but does not have sufficient information to confirm or refute the substandard quality of care, the survey may be expanded. This expansion does not necessarily constitute an extended or partial extended survey. The only time an extended or partial extended survey is conducted is when substandard care is identified.

Time frames [SOM §7210.5]

An extended or partial extended survey should be conducted immediately, but, if delayed, not later than 14 calendar days after completion of a standard or abbreviated standard survey.

Notices [SOM §7210.6, see also §7320 for more on substandard care]

When substandard quality of care is identified, the state must issue notices to:

- The state board responsible for the licensing of the nursing home administrator; and
- The attending physician of each resident who was identified as having been subject to substandard care.

Nurse Aide Training and Competency Evaluation Program and Competency Evaluation Program [SOM §7210.7]

The nurse aide training and competency evaluation program and competency evaluation program *must be denied or withdrawn* when an extended or partial extended survey is conducted.

Informal Dispute Resolution [SOM §7212]

Regulations require that facilities have the opportunity to dispute cited deficiencies. The informal dispute resolution (IDR) process, as established by the state or CMS RO, must be in writing so that it is available for review upon request.

States should be aware that CMS holds them accountable for the legitimacy of the informal dispute resolution process including the accuracy and reliability of conclusions that are drawn with respect to survey findings. This means that while states may have the option to involve outside persons or entities they believe to be qualified to participate in this process, it is the states, not outside individuals or entities that are responsible for informal dispute resolution decisions. So, when an outside entity conducts the informal dispute resolution process, the results may serve only as a recommendation of noncompliance or compliance to the state. The state will then make the final informal dispute resolution decision and notify the facility of that

decision. CMS will look to the states to assure the viability of these decision- making processes, and holds states accountable for them. (See SOM § 7212.3 for more information on independent informal dispute resolution.)

Certification of Compliance or Noncompliance for SNFs [SOM §7300]

State agencies have the responsibility for certifying a SNF's compliance or noncompliance with federal regulations, *except in the case of state-operated facilities*. **The state's certification is subject to CMS's approval.**

"Certification of compliance" means that a facility's compliance with federal participation requirements is ascertained. If a facility is found to be in compliance, the state certifies and recommends that the RO and/or state Medicaid agency enter into an agreement with the facility. If a facility is not found to be in compliance, the state recommends denial of participation in the Medicare and/or Medicaid programs. In addition to certifying a facility's compliance or noncompliance, the state also recommends appropriate enforcement actions.

Effect of CMS' Validation Authority [SOM §7300.4]

The RO may make independent findings of compliance or noncompliance based on its own validation survey or review of the state's certification. The RO's finding of noncompliance is binding and takes precedence over the state's certification of compliance.

State/Federal Disagreements [SOM §7807]

Only one entity certifies noncompliance and implements enforcement remedies. These procedures are established to provide guidance when the RO's findings do not agree with the state SA's findings. **In the case of state-operated facilities**, the RO's decision always prevails because the state SA does not make the certification of compliance or noncompliance nor does it make any recommendations of enforcement actions. **In the case of SNFs**, the RO's decision always prevails.

Facility Compliance [SOM §7807.2]

If the state SA finds that a facility is not in substantial compliance, but the RO finds that the facility is in substantial compliance, the state SA's finding prevails.

If the state SA finds that a facility is in substantial compliance, but the RO finds that the facility is not in substantial compliance, the RO's finding prevails.

When the RO's finding of noncompliance prevails, it may:

- Impose remedies as specified in §7400;
- Terminate the provider agreement; and/or
- Stop federal financial participation to the state for a nursing facility at the end of six months.

Termination [SOM §7807.3]

When both the state SA and the RO agree that a facility is not in substantial compliance, but disagree as to whether to terminate a facility's provider agreement, the following rules apply:

- If the RO wants to terminate, but the state SA does not, the RO and the SMA impose the alternative remedies and follow the procedures in §7600.
- If the SMA wants to terminate, but the RO does not, the SMA's decision to terminate a nursing facility prevails as long as the termination date is no later than six months after the last day of the standard health survey; and
- If the facility is dually participating, the decision made for the Medicaid portion is applied to the Medicare portion and the RO imposes the decision for both programs.

Remedies [SOM §7807.5]

Either the state or the RO may impose additional or alternative remedies. If the state decides to terminate a provider agreement and the RO chooses to impose a CMP in addition to the termination, both remedies would be imposed. If the state chooses termination and another remedy, the additional remedy would be imposed. However, if both the state and the RO want to impose an additional remedy, only the RO's remedy would be applied.

Notice Requirements [SOM §7305]

No Immediate Jeopardy and an Opportunity to Correct [SOM §7305.1.1]

When no IJ exists and opportunity to correct *will be provided* before remedies are imposed, the surveying entity sends an initial notice to the facility notifying of the following:

- The deficiencies cited;
- The mandatory remedy which must be imposed if the facility fails to achieve substantial compliance at 6 months;
- The approved PoC will establish the outside date by which correction must be made;
- May serve as the formal notice of the imposition of any category 1 remedy;
- The state's proposed remedies will be forwarded to CMS and/or the SMA if correction is not achieved at the first revisit;
- Provides that an acceptable PoC is required in response to the deficiencies;
- Informs the facility of the opportunity for informal dispute resolution (see SOM §7212);
- Specifies that if an acceptable PoC is not timely received, the state will recommend remedies other than category 1 and/or denial of payment for new admissions;
- Provides elements of an acceptable PoC;
- Informs the facility of the disapproval of its nurse aide training program;
- The information the facility must provide when substandard quality of care is determined; and

• When no formal notification of remedies is being provided in this initial notice, language must be inserted to make it clear that the initial notice is not the notice that triggers the imposition of remedies and that any such determination will be provided in a separate notice.

No Immediate Jeopardy and No Opportunity to Correct [SOM §7305.1.2]

When no IJ exists and opportunity to correct *will not be provided* before remedies are imposed, the surveying entity sends an initial notice to the facility notifying of the following:

- Deficiencies cited;
- Provides notice of the provider agreement termination;
- May provide that this notice serves as a formal notice of the imposition of denial of payment for new admissions and/or any category 1 remedy;
- Provides an acceptable PoC is required in response to deficiencies;
- Informs the facility of the opportunity for informal dispute resolution (see SOM §7212);
- Specifies that if an acceptable PoC is not timely received, the state will recommend remedies other than category 1 and/or denial of payment for new admissions;

For more information on notice requirements, including formal notice of remedies, see SOM §7305.2.

- Informs the facility of the disapproval of its nurse aide training program;
- The information the facility must provide when substandard quality of care is determined;
- Provides elements of an acceptable PoC; and
- When no formal notification of remedies is being provided in this initial notice, language must be inserted to make it clear that the initial notice is not the notice that triggers the imposition of remedies and that any such determination will be provided in a separate notice.

Immediate Jeopardy [SOM §7305.1.3]

When an IJ situation exists, the surveying entity sends an initial notice to the facility which must include the following:

- The nature of the IJ;
- Requests an allegation of removal of IJ, including evidence of steps taken to remove IJ;
- Consequences of failure to submit an allegation of removal (e.g., provider agreement termination);
- Remedies recommended with effective dates;
- Opportunity for informal dispute resolution (see SOM §7212);

- Opportunity for independent informal dispute resolution (see SOM §7213) if a CMP subject to being collected and placed in an escrow account is imposed;
- Disapproval of nurse aide training and competency evaluation program and competency evaluation program and appeal rights if the program loss is based on a finding of substandard quality of care;
- When substandard quality of care is determined, the facility must provide the state with a list of physicians of the residents affected; and
- When no formal notification of remedies is being provided in this initial notice, language must be inserted to make it clear that the initial notice is not the notice that triggers the imposition of remedies and that any such determination will be provided in a separate notice; or
- This initial notice can serve as the formal notice of the imposition of any category 1 remedy, which includes directed PoC, state monitoring, and directed in-service training. See SOM §7400.6.1.

Acceptable Plan of Correction [SOM §7317]

Except in cases of past noncompliance, facilities having deficiencies (other than those at scope and severity level A) must submit an acceptable plan of correction. Acceptable plan of correction (PoC), must:

- Address how corrective action will be accomplished for those residents found to have been affected by the deficient practices;
- Address how the facility will identify other residents having the potential to be affected by the same deficient practice;
- Address what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;
- Indicate how the facility plans to monitor its performance to make sure that solutions are sustained; and
- Include dates when corrective action will be completed.

The plan of correction serves as the facility's allegation of compliance and, without it, CMS and/or the state have no basis on which to verify compliance. A plan of correction must be submitted within 10 calendar days from the date the facility receives its Form CMS-2567. If an acceptable plan of correction is not received within this timeframe, the state notifies the facility that it is recommending to the RO and/or the state Medicaid agency that remedies be imposed effective when notice requirements are met. The requirement for a plan of correction is in 42 <u>CFR 488.402(d)</u>. Further, <u>42 CFR 488.456(b)(ii)</u> requires CMS or the state to terminate the provider agreement of a facility that does not submit an acceptable plan of correction.

A facility is not required to provide a plan of correction for a deficiency cited as past noncompliance because that deficiency is corrected at the time it is cited; however, the survey team must document the facility's corrective actions on <u>Form CMS-2567</u>.

Verifying Facility Compliance [SOM §7317.1]

While the plan of correction serves as the facility's allegation of compliance in nonimmediate jeopardy cases, substantial compliance cannot be certified and any remedies imposed cannot be lifted until facility compliance has been verified. The chart in <u>Appendix 8</u> provides a course of action for certifying compliance based on the seriousness of the noncompliance and the number of revisits that have already occurred. It represents a continuum, ranging from accepting the latest correction date on the facility's approved plan of correction as the date of compliance without an onsite revisit, to conducting an onsite revisit to establish that date. The chart also indicates the circumstances under which revisits must occur and remedies must be imposed, as well as provides policy for conducting revisits, lifting remedies, and certifying compliance. It is important to remember that: revisits may be conducted anytime for any level of noncompliance subject to the allowed number of revisits (see §7317.2, below); remedies may be imposed anytime for any level of noncompliance; and revisits are not assured before termination can occur.

Revisits [SOM §7317.2]

When the SA cites deficiencies during the course of a survey, the SA may conduct a revisit to determine if the facility has achieved substantial compliance.

Mandatory onsite revisits are required when a facility's:

- Beginning survey or first onsite revisit finds deficiencies that constitute substandard quality of care, harm, or IJ.
- Second onsite revisit finds any noncompliance.

No guarantee of revisit: A facility is not entitled to any revisits. When conducted, one revisit will normally be conducted after a survey which found noncompliance and another before the expiration of the six-month period by which a facility must be in substantial compliance to avoid termination of its provider agreement.

Number of onsite revisits: Two onsite revisits are permitted without prior approval from the RO.

Timing of revisit: When conducted, onsite revisits occur any time between the last correction date on the PoC and the 60th day from the survey date to confirm that the facility is in substantial compliance and, in certain cases, has the ability to remain in substantial compliance.

Correction of level A, B, and C deficiencies: While facilities are expected to correct deficiencies at levels A, B, and C, deficiencies at these levels are within the substantial compliance range and, therefore, need not be reviewed for correction during subsequent revisits within the same noncompliance cycle.

Revisits to surveys for which substandard quality of care, harm, and IJ are cited: Onsite revisits must continue for these deficiencies even if they lessen to lower levels of noncompliance.

New owner: If a new operator assumes the existing provider agreement, they are responsible for assuring that corrections are made within the revisit policy.

Noncompliance Cycles [SOM §7317.3]

A noncompliance cycle begins with a recertification, complaint, or temporary waiver revisit survey that finds noncompliance and ends when substantial compliance is achieved, or the facility is terminated (or voluntarily terminates) from the Medicare or Medicaid program. The noncompliance cycle cannot exceed six months. Once a remedy is imposed, it continues until the facility is in substantial compliance or is terminated from the programs.

Readmission to Medicare or Medicaid Program After Termination [SOM §7321]

A Medicare provider terminated may not be reinstated into the Medicare program until it has been verified through the "reasonable assurance" process that the provider is capable of achieving **and** maintaining substantial compliance with all applicable participation requirements. (See SOM § 2016B for more information on the reasonable assurance concept.)

Reasonable Assurance Surveys [SOM §7321.3, see also §2016D]

Two surveys are required to verify that the reason for termination no longer exists and that the facility has maintained continued compliance.

- The **first visit** only needs to determine whether the deficiencies that led to the termination have been corrected (i.e., are they now completely removed or at the level of substantial compliance).
- The **second visit** will typically be a full standard survey. However, the RO may instruct the state to conduct the full survey during the first visit and the partial survey at the second.