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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-09

DATE: **November 13, 2003**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Guidelines to Support Management of Complaints and Incidents and the National Implementation of the ASPEN Complaints/Incidents Tracking System (ACTS)

Letter Summary

- **ACTS Effective Jan. 1, 2004:** The national ACTS implementation date is January 1, 2004. State survey agencies (SA) may fully implement ACTS now or at any time prior to January.
- **Thanks**: We thank the many state staff who labored with us to create and pilot-test this national electronic complaint tracking and management system.
- **Pilot Successfully Concluded:** The pilot phase of ACTS is now ended. States may fully implement ACTS now, may phase up gradually to 100% on January 1, 2004, or may cease the current 15% sampling in favor of a "transition-rest" until the 100% reporting in January.
- **OSCAR Reporting**: Any SA that has not fully implemented ACTS must continue to upload data to the Online Survey, Certification and Reporting (OSCAR) Complaint System. Use the Quick Entry 562 feature in ACTS or enter all intake and investigation information in ACTS.
- **Extension Period for Exceptional State Systems**: We may approve an extended transition period for a very limited number of states that have exceptionally capable and fully implemented legacy systems and for whom immediate implementation of ACTS will cause both undue hardship and loss of critical business function. Such states must agree to provide data equivalent to ACTS data via electronic means during the transition period, produce periodic reports, and ensure that CMS has full information on ACTS-covered complaints for the period beginning January 1, 2004. Contact your CMS Regional Office (RO) ACTS coordinator (see attachment 4) by December 1, 2003 for an application to request extended transition. All applications must be submitted to the RO by December 15, 2003.
- **Attachments 1-4** offer guidance on ACTS definitions, tools, and complaint management.

In this memorandum we provide direction and guidance in the management of complaints and reported incidents for nursing homes, home health agencies, end-stage renal disease facilities, hospitals, suppliers of portable X-ray services, providers of outpatient physical therapy or speech pathology services, rural health clinics, and comprehensive outpatient rehabilitation facilities.

The management of complaints and reported incidents is supported by the national implementation of the ASPEN Complaints/Incidents Tracking System (ACTS), effective on January 1, 2004. However, a State survey agency (SA) may fully implement ACTS at any time prior to January 1, 2004. The pilot phase of ACTS ends effective immediately.

Even if a State chooses not to implement ACTS until January 1, SAs must continue to upload data to the Online Survey, Certification and Reporting (OSCAR) Complaint System either by using the Quick Entry 562 feature in ACTS or by entering all intake and investigation information in ACTS.

We recognize that the national implementation of ACTS affects the data entry workload or system integration challenges for some States that have established business processes with supporting legacy systems for tracking activities. We may approve a limited extension of the transition period for a very small number of states that have exceptionally capable and fully implemented legacy systems and for whom immediate implementation of ACTS will cause both undue hardship and loss of critical business function. Such states must agree to provide data equivalent to ACTS data via electronic means during the extended transition period, produce periodic reports specified by CMS, and ensure that CMS receives full information on ACTS-covered complaints for the period beginning January 1, 2004. We believe that the ACTS download capability (expected in mid-2004) will remove the need for any extension except in the most rare of circumstances. Please convey such requests, together with necessary system description and documentation, to the CMS Regional Office contact by December 1, 2003.

This memorandum replaces the interim guidance issued November 8, 2002 (S&C 03-04). For nursing homes, this memorandum replaces the October 1999 memorandum, *Guiding Principles for Complaint Investigations,* as well.

Improving the management and oversight of complaints and reported incidents is essential to ensuring protection and quality of service for the citizens we serve. We believe ACTS will improve our collective capability to track, investigate, and respond to complaints and incidents. We also believe it will conserve public dollars by virtue of a single national system rather than the creation of many state systems. We therefore appreciate wholeheartedly the diligent work of participating state and regional staff as together we address policy and procedural challenges related to ACTS and to the effective management of complaints and incidents. Thank you.

Contacts: Questions about this memorandum may be addressed to Kathy Lochary at Klochary@cms.hhs.gov and Elaine Lew at Elew@cms.hhs.gov.

Effective Date: January 1, 2004

Dissemination: This policy should be shared with all appropriate survey and certification staff, their managers, QIES coordinators, and the state/regional office training coordinators.

/s/
Thomas E. Hamilton

CC: Survey and Certification Regional Office Management (G-5)

Attachment 1 – Guidance to Support Management of Complaints and Incidents
Attachment 2 - Guidance to Distinguish Between the Priorities of Immediate Jeopardy and Non-Immediate Jeopardy-High in Nursing Home Allegations
Attachment 3 - ACTS Required Fields
Attachment 4 – ACTS RO Contacts

GUIDANCE TO SUPPORT MANAGEMENT OF COMPLAINTS AND INCIDENTS

INTAKE PROCESS

An allegation is an assertion of improper care or treatment against a Medicare, Medicaid or CLIA participating program 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 and in a number of formats. Allegations may come directly from beneficiaries themselves, beneficiaries' family members, health care providers, concerned citizens, public agencies, or in published or broadcast media reports. Report sources may be verbal or written. In some instances, the complainant may request anonymity.

Information To Collect From Complainant

To the extent possible, the SA captures complete information necessary to make important decisions about the allegations. In instances where written allegations are received, either subsequent verbal and/or written communication may be necessary to obtain comprehensive information. In the case of allegations received verbally (telephone or face-to-face meetings), an important opportunity exists to obtain complete information to assist with the decision-making and investigative processes.

Comprehensive information should be collected during the intake process to allow for proper triage to occur. This information includes the following:

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

Information To Provide To Complainant

An effective complaint intake process provides information to assist the complainant in resolving his/her conflicts. The information provided to the complainant may be communicated verbally during initial or subsequent telephone discussions or through written correspondence when acknowledging receipt of the allegation. In either case, the following elements, at a minimum, are provided as part of the intake:

- The SA's 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.

TRIAGE and PRIORITY ASSIGNMENT

A complaint is a report made to the SA or RO by anyone other than the administrator or authorized official for a provider or supplier that alleges noncompliance with Federal and/or State laws and regulations. If, based on the intake information received, the SA determines that the allegation(s) falls within the authority of the SA, the SA triages the intake to determine 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 time lines and an orderly process to document actions taken by the SA in responding to every allegation. If a State's triage 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 time frames. The SA is expected to be able to share the logic and rationale that was utilized in triage and prioritization of the allegation for investigation. The SA response must be designed to protect the health and safety of all residents, patients and clients.

An assessment of each intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of current clinical standards of practice and Federal requirements. In situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to investigate within two working days of receipt of the information. For all non-immediate jeopardy situations, the complaint/incident is to be prioritized within two working days of its receipt, unless there are extenuating circumstances that impede the collection of relevant information. There are circumstances when a provider/supplier is required to report information to the SA. This is defined as an incident - an official notification to the SA or RO from a self-reporting provider or supplier (i.e., the administrator or authorized official for the provider or supplier), or from a separate agency that is providing information about a provider or supplier. The reported incident intake is prioritized after sufficient information is gathered and evaluated. The SA response is expected to protect the health and safety of all residents, patients and clients.

An investigation is a review to determine if a deficient practice is or was present, and to assess the degree of harm to any resident(s), patient(s) or client(s). To assist in planning the investigation, the SA reviews any information about the provider that would be helpful to know. This may include the provider's compliance history, the provider's quality indicators, 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. For non-deemed providers and suppliers, CMS expects the SA to investigate allegations of violations of the Federal participation requirements.

For deemed providers and suppliers, if the SA receives a substantial allegation of noncompliance, an appropriate investigation is initiated, if one is warranted, once RO approval has been obtained. (In 1997 CMS, then HCFA, issued "Guidelines for Complaint Investigation." These guidelines continue to serve as a generic, supplementary document to assist SAs with investigative protocols.)

Generally, allegations about nonrecurring events that occurred more than twelve months prior to the intake date will not require the SA to conduct an investigation. However, the SA is not precluded from conducting an investigation to determine current compliance status based on concerns identified during the intake or triage process. More specifically for nursing homes, if there is sufficient evidence that the facility does not have continuing noncompliance, as evidenced by a systemic problem, and the intake reported relates to an event that occurred before the last standard survey, an onsite survey may not be required.

PRIORITY DEFINITIONS

Immediate Jeopardy - Section 42 CFR 489.3 defines 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." Intakes are assigned this priority if the intake information indicates immediate corrective action is necessary because a provider's or supplier's alleged noncompliance with one or more conditions or requirements may have caused, or is likely to cause, serious injury, harm, impairment or death to a resident, patient or client. Immediate jeopardy, immediate and serious threat, and serious and immediate threat are interchangeable terms.

In situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to investigate within two working days of receipt of the information except: 1) For all Medicare deemed providers/suppliers complaint and incident intakes, the SA investigates a complaint within two working days of receipt of the Form CMS-2802, Request for Validation of Accreditation Survey, from the RO if the RO determines that the complaint involves potential immediate jeopardy to patient health and safety; 2) For hospital EMTALA complaints, the investigation is completed within five working days after receipt of the authorization from the RO; 3) For restraint/seclusion death reports, the SA completes the investigation within five working days of receipt of telephone authorization from the RO. (Appendix Q of the State Operations Manual (SOM) contains the Guidelines for Determining Immediate Jeopardy.)

Non-Immediate Jeopardy - High – *(harm that impairs mental, physical and/or psychosocial status)* Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused harm that negatively impacts the individual's mental, physical and/or psychosocial status and is 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.

Regarding allegations pertaining to residents in nursing homes, if the SA makes the determination that a higher level of actual harm may be present, the investigation is to be initiated within 10 working days of its receipt. The initiation of these types of investigations is generally defined as the SA beginning an onsite survey. It is often difficult to distinguish between those allegations that would require an investigation within two working days (immediate jeopardy) from those that would require an investigation within 10 working days (higher level of actual harm). The following are some examples of allegations that indicate that a higher level of actual harm may be present:

- Resident is intimidated/threatened;
- Resident is physically abused - spitting/slapping/sticking with sharp object/pushing/pinching;
- Unexplained/unexpected death, with circumstances indicating that there was abuse or neglect;
- Sexual assault/sexual harassment/coercion;
- Falls resulting in fracture (e.g., handrails not secured);
- Inappropriate use of restraints resulting in injury;
- Inadequate staffing which negatively impacts on resident health and safety; and
- Failure to obtain appropriate care or medical intervention, i.e., failure to respond to a significant change in the resident's condition.

Attachment 2 describes examples to assist the SAs in distinguishing between the priorities of Immediate Jeopardy and Non-Immediate Jeopardy - High.

Non-Immediate Jeopardy - Medium – *(harm or potential of more than minimal harm that does not significantly impair mental, physical and/or psychosocial status)* Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions has caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status to function. An onsite survey should be scheduled to review these intakes.

Non-EMTALA, and non-immediate jeopardy complaints for providers/suppliers with deemed status require an onsite survey within 45 calendar days after approval by the RO.

Non-Immediate Jeopardy – Low *(discomfort)* Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage. An onsite investigation may not be scheduled, but the allegation would be reviewed at the next onsite survey.

Administrative Review/Offsite Investigation - This priority is used for complaint and incident intakes triaged as not needing an onsite investigation. However, further investigative action (written/verbal communication or documentation) initiated by the SA or RO to the provider is gathered and the additional information is adequate in scope and depth to determine that an onsite investigation is not necessary; however, the SA has the discretion to review the information at the next onsite survey.

Referral – Immediate - Complaints/incidents are assigned this priority if the seriousness of a complaint/incident and/or State procedures requires referral or reporting to another agency, board, or network without delay for investigation.

Referral – Other - Complaints/incidents assigned this priority indicate referral to another agency, board, or network for investigation or for informational purposes.

When the SA refers the complaint 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. Regardless of who conducts the investigation, the SA has the responsibility to assess the provider's or supplier's compliance with Federal conditions or requirements and the time frames for investigation are not altered by the referral to another agency. (Expressed requests by law enforcement that the SA defer an onsite investigation would be discussed with the CMS RO, as appropriate.)

No action necessary - Adequate information has been received about the complaint or incident intake such that the SA can determine with certainty that no further investigation, analysis, or action is necessary.

For all cases except EMTALA, that do not allege immediate jeopardy, and at the SAs discretion an intake may not require a new onsite investigation if, at a previously completed survey, the same events were investigated; the previously completed survey evaluated the appropriate individuals, including those identified in the intake; and the situation did not worsen.

INVESTIGATION FINDINGS AND REPORTS

Each SA establishes reporting policies, procedures and formats including report language targeted to specific audiences. The SA/RO provides the complainant and the investigated provider a written report of the investigation findings as a summary record of the investigation. The following principles guide preparation of the report to the complainant:

- Acknowledge the complainant's concern(s);
- Identify the SA's regulatory authority to investigate the complaint/incident and any statutory or regulatory limits that may bear on the authority to conduct an investigation;
- Provide a summary of investigation methods (e.g., on-site visit, written correspondence, telephone inquiries, etc.);
- Provide date(s) of investigation;
- Provide an explanation of your SA's decision-making process including definitions of terms used (i.e., substantiated or validated, unsubstantiated or not validated, etc.);
- Provide a summary of your SA's finding. (Note: To the extent possible the summary should not compromise the anonymity of individuals, or include specific situations that may be used to identify individuals, when anonymity has been requested or is appropriate in the judgment of the SA);
- Identify follow-up action, if any, to be taken by your 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).

ADDITIONAL INSTRUCTIONS

For Deemed Providers and Suppliers

Before the SA conducts a complaint investigation survey against an accredited hospital or deemed provider/supplier, it must receive authorization from the RO. It is the RO's responsibility to determine whether the complaint alleges one or more Condition-levels of non-compliance. If the complaint identifies one or more Condition-levels of non-compliance, the RO must authorize the complaint investigation by completing the applicable CMS-2802. If the RO does not authorize the complaint investigation, the SA may conduct a complaint investigation should it determine that the accredited hospital or deemed provider/supplier is non-compliant with its State regulations (i.e., State licensure laws). RO authorization is not required when the SA's basis for conducting the complaint investigation is related to a State regulation.

The RO must forward a completed CMS-2802 to the SA via ACTS even when the SA received an initial verbal authorization from the RO to initiate the complaint validation survey of a deemed provider/supplier. Since ACTS allows the RO to authorize a complaint validation survey electronically by completing the RO Signature box on the deemed tab, it is not required to send a signed hard copy of the CMS-2802 to the SA via fax or US Postal Mail. Once the SA receives the authorization through ACTS it may begin its complaint investigation of an accredited hospital or 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 is the basis for the survey.

CMS Regional Office Responsibility

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 State Operations Manual (SOM), and CMS policy memoranda. As part of the monitoring process, the SAs will be evaluated in accordance with the criteria set forth by the State Performance Standard Review. Many States have State laws and regulations that specify how to manage complaints and incidents. Whenever possible, State and Federal requirements should be integrated to avoid unnecessary duplication. CMS ROs should accept State requirements that meet or exceed the intent of the Federal requirements. However, at a minimum, it is expected that noncompliance with Federal requirements resulting from a complaint or reported incident will receive follow-up and be documented in ACTS.

State Operations Manual References

This guidance supports data entry into ACTS and supplements existing procedures contained in the SOM in Chapter 3 and in Chapter 7 and Appendix P for nursing homes. There are different procedures for conducting complaint investigations for deemed and non-deemed facilities. The SAs and ROs follow the procedures outlined in the SOM at §§3280-3298 for non-deemed providers/suppliers, at §§3260-3276 for deemed provider/suppliers and at §§3400-3413 for EMTALA.

Data Entry
From the effective date of this memorandum to the effective date for full implementation of ACTS, SAs must continue to upload data to the OSCAR Complaint System either by using the Quick Entry 562 feature in ACTS or by entering all intake and investigation information in ACTS.

ACTS must be used for the intake of all allegations received on or after **January 1, 2004** for skilled nursing facilities, nursing facilities, home health agencies, end stage renal disease facilities, hospitals, suppliers of portable X-ray services, providers of outpatient physical therapy or speech pathology services, rural health clinics, and comprehensive outpatient rehabilitation facilities. ACTS is a Federal system and data entered into ACTS is subject to Federal laws governing disclosure and the protection of an individual's right to privacy.

SAs and ROs are required to enter into ACTS:

- All complaint information gathered as part of the SA survey and certification responsibilities as set forth in the 1864 Agreement, regardless if an onsite survey is conducted; ***and***
- All reported incident information gathered as part of the SA survey and certification responsibilities as set forth in the 1864 Agreement and requires an onsite survey.

The information is entered into ACTS regardless of the entity within a State carrying out this function. The information recorded in ACTS reflects the facts furnished by the complainant at the time of the intake. If the intake information requires an onsite survey and the allegation may involve both Federal and State licensure requirements, a Federal onsite survey is completed and entered into ACTS, at a minimum.

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

Attachment 3 defines the required fields in ACTS.

AVAILABLE HELP

- For assistance with ACTS systems related issues do not hesitate to e-mail the help line at ASPEN_HELP@IFMC.ORG or call to 1-888-477-7876.
- The ACTS Training Manual and the ACTS Procedures Guide are accessible electronically at: www.qtso.com/aspendownload.html.
- Attachment 4 lists the CMS Regional Office contacts.

Attachment 2

GUIDANCE TO DISTINGUISH BETWEEN THE PRIORITIES OF IMMEDIATE JEOPARDY AND NON-IMMEDIATE JEOPARDY-HIGH IN NURSING HOME ALLEGATIONS

(The following scenarios are intended only to assist in the triage of certain allegations of noncompliance in a nursing home. Each situation is unique, and the following examples should be considered as guidance only. An additional resource is Appendix Q (Guidelines for Determining Immediate Jeopardy) of the State Operations Manual.)

1. Allegations of abuse

- **Unexplained, unexpected death, with circumstances indicating that there was abuse or neglect** - A report of abuse/neglect resulting in an unexplained or unexpected death would not be triaged as immediate jeopardy if it is clear that the abuse/neglect is not present and ongoing. Whether or not an alleged perpetrator is still present in the facility and has unsupervised interaction with residents would be a consideration in assessing the urgency for an onsite visit. Unless the intake information is sufficient to determine the conditions are not present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

- **Resident is physically abused – spitting/slapping/sticking with sharp object, pushing, pinching** - A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. The extent of the injuries, whether or not the alleged perpetrator is still present in the facility and has unsupervised interaction with the residents, the frequency and duration of the behavior as well as the facility history, recent complaint reports, deficiencies cited, and other available information should also be reviewed in making a decision regarding the triage of complaints alleging physical abuse. Unless the intake information is sufficient to determine the conditions are not present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

- **Sexual assault, sexual harassment and sexual coercion** - A report of sexual assault, sexual harassment or sexual coercion would not be triaged as immediate jeopardy if it is clear that the threat of sexual abuse is not present and ongoing. A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Whether or not an alleged perpetrator is still present and has unsupervised interaction with the residents in the facility would be a consideration in assessing the urgency for an onsite visit. Unless the intake information is sufficient to determine the conditions are not present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

- **Verbal Abuse - Resident is intimidated/threatened** – A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Possible indicators of a higher level of actual harm could include: the resident crying, fleeing, not want to leave their room, fearful, not participating in activities, communicating, etc.). The frequency and duration of the behavior, as well as the facility history, recent complaint reports, deficiencies cited, and other available information should also be reviewed in making a decision regarding the triage of intakes alleging verbal abuse. Whether or not an alleged perpetrator is still present in the facility and has unsupervised interaction with the residents would be a consideration in assessing the urgency for an onsite visit. Unless the intake information is sufficient to determine whether or not the conditions are present and ongoing, the complaint should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

2. Falls resulting in fracture or serious injury - A report of falls resulting in fracture would not be triaged as immediate jeopardy if it is clear that the conditions causing and/or contributing to the falls are not present and ongoing. If the intake information is not sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within 2 working days. A higher level of actual harm would exist if the situation has caused harm that negatively impacts on the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Factors to consider would be whether or not falls are preventable (the cause of the fall was the result of something the facility did or failed to do) or non-preventable (the cause of the fall was not the result of something the facility did or failed to do). Unless the intake information is sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

3. Inappropriate use of physical or chemical restraints resulting in serious injury - A report of inappropriate use of restraints resulting in injury would not be triaged as immediate jeopardy if it is clear that the inappropriate use of restraints is not present and ongoing. If the intake information is not sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days. A higher level of actual harm would exist if the situation has caused harm that negatively impacts the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. Unless the intake information is sufficient to determine whether or not the conditions are present and ongoing, the intake should be triaged as immediate jeopardy and an onsite visit should be conducted within two working days.

4. Inadequate staffing that negatively impacts resident health and safety - A higher level of actual harm would exist if the situation has caused harm negatively impacting on the resident's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. The intake would need to provide information about the nature and frequency of the problems created for residents by the inadequate staffing. Other information that could be used to triage the allegation of inadequate staff would be facility history, recent complaint reports, deficiencies cited, MDS data (falls, weight loss, etc). Allegations of inadequate staff should also be analyzed to assess whether or not the lack of staff poses a life safety code violation that places residents at risk. The source or sources of the allegations may impact on the classification of the complaint. Numerous complaints from multiple sources could elevate the priority for an investigation.

Attachment 3

ACTS REQUIRED FIELDS

TAB	*FIELD(s)*	*DEFINITION*
Intake	**Intake Type**	1) *Complaint* - A *complaint* is a report made to the SA or RO by anyone other than the administrator or authorized official for a provider or supplier that alleges noncompliance with Federal and/or State laws and regulations. 2) *Incident* - An *incident* is an official notification to the SA or RO from a self-reporting provider or supplier (i.e., the administrator or authorized official for the provider or supplier), or from a separate agency that is providing information about a provider or supplier
	Intake Subtype (for Complaints)	A) *Federal COPs, CFCs, RFPs, EMTALA*: The allegation relates to noncompliance with the Federal condition(s) of participation (COPs), condition(s) for coverage (CFCs), requirement(s) for participation (RFPs), or EMTALA requirement(s). This would include allegations of noncompliance with Federal requirements only or both Federal and State requirements. **(SAs and ROs are required to enter these cases into ACTS.)** B) *State-only, licensure*: The allegation is related to noncompliance with State licensure requirements only. **(SAs have the option to enter these cases into ACTS.)** C) *No State or Federal provider compliance issue involved*: The allegation does not relate to noncompliance with Federal or State survey and certification requirements. **(SAs have the option to enter these cases into ACTS.)**

TAB	*FIELD(s)*	*DEFINITION*
	Intake Subtype (for Incidents)	A) *Federally required, entity-reported*: A provider or supplier is required by Federal law, regulation, or policy to report this type of incident, which includes the following: a. 42 C.F.R. §482.13(f)- *Standard: Seclusion and restraint for behavior management.* The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)** b. 42 C.F.R. §483.13- For skilled nursing facilities (SNFs) and nursing facilities (NFs), the facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported …to other officials in accordance with State law through established procedures (including to the State survey and certification agency). **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions**.) B) *State-required, may result in Federal noncompliance, entity-reported*: A provider or supplier is required by State law, regulation, or policy to report this type of incident to the SA. This type of incident may result in noncompliance with a Federal condition(s) of participation, condition(s) for coverage, requirement(s) for participation, or EMTALA requirement(s). Therefore, the SA must follow its complaint policies and procedures to investigate incidents of this type. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)** C) *State-required, all other, entity-reported*: A provider or supplier is required by State law, regulation, or policy to report this type of incident to the SA. This type of incident does not imply noncompliance with Federal conditions or requirements. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)** D) *Reported by other agencies*: A separate agency or entity is required by State law, regulation, or policy to officially report this type of incident to the SA. Example: An investigative report from an outside agency. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)** E) *None of the above*: A provider or supplier is not required by Federal or State laws, regulations, or policies to report this type of incident. **(SAs and ROs are required to enter into ACTS all incidents that lead to an onsite survey of Federal requirements or conditions.)**
	Complainant's Name	For an incident the name of the official reporting the information is entered.
	Source	*A selection is made from a predefined list. The user cannot select more than 3.*
	Received Dates: Start/End	*Start Date:* The date of the telephone call or electronic correspondence; or, the date stamped by the SA or RO receiving office of the written correspondence. *End Date:* The date the SA or RO has sufficient information to prioritize the complaint or incident. This is the date in which the SA or RO determines 1) whether an onsite survey to assess Federal compliance or further action is necessary and 2) the appropriate time frame for investigation.

TAB	*FIELD(s)*	*DEFINITION*
	Priority	*At least one priority must be selected for each intake. Some combinations are not permitted.* A) *Immediate Jeopardy*: Intakes assigned this priority indicate immediate corrective action is necessary because a provider's or supplier's noncompliance with one or more conditions or requirements may have caused, or is likely to cause, serious injury, harm, impairment or death to a resident, patient or client. B) *Non-Immediate Jeopardy - High*: Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused harm negatively impacting on the individual's mental, physical and/or psychosocial status and is of such consequence to the person's well being that a rapid response by the SA is indicated. This level of complaint is represented by specific rather than general information, such as, descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc. C) *Non-Immediate Jeopardy - Medium*: Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions has caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status to function. D) *Non-Immediate Jeopardy - Low*: Intakes are assigned this priority if a provider's or supplier's alleged noncompliance with one or more requirements or conditions may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage. An onsite investigation may not be scheduled but the allegation would be reviewed at the next scheduled onsite survey, at the latest. E) *Administrative Review/Offsite Investigation*: This priority is used for complaints/incidents that are triaged as not needing an onsite investigation. However, further investigative action (written/verbal communication or documentation) initiated by the SA or RO to the provider may be needed to ensure compliance with the Federal requirements. The additional information is adequate in scope and depth to determine that an onsite investigation is not necessary; however, a SA has the discretion to review the information at the next onsite survey. F) *Referral – Immediate*: Complaints/incidents are assigned this priority if the seriousness of a complaint/incident and/or State procedures requires referral or reporting to another agency, board or network immediately for investigation. G) *Referral - Other*: Complaints/incidents assigned this priority indicate referral to another agency, board, or network for investigation or for informational purposes. H) *No action necessary*: Adequate information has been received about the complaint/incident such that the SA can determine with certainty that no further investigation, analysis, or action is necessary. For all cases except EMTALA, that do not allege immediate jeopardy, and at the SAs discretion an intake may not require a new onsite investigation if, at a previously completed survey, the same events were investigated; the previously completed survey evaluated the appropriate individuals, including those identified in the intake; and the situation did not worsen. These types of intakes should be linked to the appropriate survey that has already reviewed the issue.
	Investigate Within X Days	*Completion is required if the Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D).* *A numerical time frame in calendar days is entered to support the Priority selected. The calendar date of the intake is counted as day zero.*

TAB	*FIELD(s)*	*DEFINITION*
	Investigation Due By	*Completion is required if the Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D).* *A corresponding calendar date is entered.*
Allegations	**Allegation Category**	*At least one allegation category from a predefined list per intake is required unless Priority H - No Action Necessary is selected.*
	Findings (Substantiated)	A *substantiated* allegation is an allegation that did occur and is verified by evidence. An allegation is considered substantiated based on the finding about the individual or specific situation named by the complainant in his or her allegation; or, other residents or patients reviewed or similar situations, even if the noncompliance was corrected for the specific individual(s) named by the complainant in the allegation. A. *Federal deficiencies related to the allegation are cited* For nursing homes only, when Tag F698 is cited on the CMS-2567 for egregious past noncompliance between two periods of compliance for which a civil money penalty was imposed, ACTS automatically generates a check in the PNC (past noncompliance) box located at the Actions/Close tab. B. *State deficiencies related to the allegation are cited* C. *No deficiencies related to the allegation are cited* The SA determined that the allegation did occur. However, at the time of the investigation, the provider had taken action necessary to prevent the deficient practice, and/or the allegation was not serious enough to warrant citing deficiencies. (This is not applicable for EMTALA, for EMTALA see the State Operations Manual at §3410.) D. *Referral to appropriate agency* After investigation, the complaint/incident was forwarded to the appropriate agency.
	Findings (Unsubstantiated)	An *unsubstantiated* allegation is an allegation where evidence cannot support that the allegation did occur. A. *Allegation did not occur* Evidence indicates that the allegation did not occur. *B. Lack of sufficient evidence* The SA is unable to verify that the allegation did occur because of insufficient evidence. The evidence is inconclusive. C. *Referral to appropriate agency* After investigation, the complaint/incident was referred to the appropriate agency.
	Priority	*This field is shared with Intake page and Deemed page (when applicable).*
	Investigate Within X Days	*This field is shared with Intake page and Deemed page (when applicable).*
	Investigation Due By	*This field is shared with Intake page and Deemed page (when applicable).*

TAB	*FIELD(s)*	*DEFINITION*
	Death Associated with Restraint/ Seclusion [Grid]	*For Hospitals: When allegation type = Death Associated with Restraint/Seclusion (05), at least one row must be completed, except for Urban/Rural field.*
EMTALA (Fields required only if 'Create EMTALA Allegation' box is checked)	**EMTALA RO Response**	
	EMTALA RO Response Date	
	Type of Emergency	
	RO EMTALA Determination	
	Resolution	
	RO Confirmed Violation Date *or* **RO Confirmed No Violation Date**	*One of these fields should always be completed*
	Type of Allegation	
Deemed and Accredited (Fields enabled if 'Deemed for Medicare Participation' or 'Accredited' box is checked).	**Priority**	*This field is shared with Intake and Allegation pages.*
	RO Response	*There are no edits on these fields at this time.*
	Regional Representative	
	Region	
	Date	
Investigation	**Investigated By**	*Required when Complaint Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D)*
	Investigation Completed	*Required when Complaint Priority is Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D)* The date that the result of the investigation is communicated to the provider or supplier.

TAB	*FIELD(s)*	*DEFINITION*
Actions/Close	**Forwarded to RO/MSA**	If the intake originates from the CMS RO, the SA should check the "Forwarded to CMS/MSA" box in all complaint/incident scenarios. If the intake originates from the SA, SAs <u>should not</u> check the box or enter a date for all <u>nursing home</u> intakes. For non-long-term care intakes, the SA should check the "Forwarded to RO/MSA" box on the complaint/incident record in the three following scenarios: i. If the complaint/incident survey is on an accredited/deemed provider/supplier. ii. If the complaint results in an EMTALA investigation. iii. If the complaint/incident survey is on an "other than accredited/deemed provider or supplier" and the SA is recommending termination.
	Proposed Action	*At least one proposed action per complaint/incident record if a survey is present.*
	Proposed Action Date	Date of the notice sent to the provider/supplier informing the provider/supplier of actions that may be taken as a result of the investigation findings. If the provider/supplier is in compliance, the proposed action date is the date the provider/supplier is notified that it is in compliance. *At least one proposed action date per complaint/incident record if a survey is present.*
	Overall Findings	*Supplied by ACTS (For complaints, uses same rule as Findings: Required when Complaint Priority = Immediate Jeopardy or Non-immediate Jeopardy (Priorities A – D); for incidents, defaults on-screen to Not Applicable).*
	Reason Closed	Field is completed by selecting one or more of the following: A. *Paperwork complete* – All information and documentation, including notification to the complainant, if applicable, related to this complaint or incident has been completed in the SA or RO file. B. *Withdrawn* – The complainant contacted the entity receiving the allegation and asked that the allegation be removed. C. *Referred* - At the intake, during administrative review, or after the onsite complaint survey, it is determined that the issues involved must be directed to another agency or organization for resolution. D. *No jurisdiction* – The issues identified at intake, during an administrative review or after a survey do not involve Medicare/Medicaid participation requirements. E. *Provider/Supplier Termination* – The provider or supplier has been terminated from participation in the Medicare and/or Medicaid programs.
	Date Closed	*Date associated with the latest reason closed action selected.*

TAB	*FIELD(s)*	*DEFINITION*
NOTIFICATION: Notices Button (every tab) and the Acknowledgement and Parties Notified section on the Investigation Properties tab		*At least one notification is required, except when Priority is No Action Necessary.*

Attachment 4

POINT OF CONTACT IN EACH CMS REGIONAL OFFICE

All State agency questions related to the attached guidance are to be directed first to the CMS regional office point of contact. To assure consistency, CMS central and regional offices will work closely to jointly address concerns and questions.

REGION	NAME	CONTACT INFORMATION	
I	Ray Porter	617-565-1260	RPorter@cms.hhs.gov
II	Richard Minkoff	212-264-8531	Rminkoff@cms.hhs.gov
III	Paul Velez	215-861-4302	PVelez@cms.hhs.gov
IV	Brenda Nimmons	404-562-7405	Bnimmons@cms.hhs.gov
V	Maria Neff	312-886-5203	Mneff@cms.hhs.gov
VI	Sergio Mora	214-767-6301	SMora@cms.hhs.gov
VII	Paul Shumate	816-426-2408	PShumate@cms.hhs.gov
VIII	Nancy Walker	303-844-7037	NWalker@cms.hhs.gov
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X	Demetra Kossligk	206-615-2314	DKossligk@cms.hhs.gov