DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Ref: QSO-19-14-Hospitals, CAHs

DATE: **June 04, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: State Operations Manual (SOM) Emergency Medical Treatment and Labor Act (EMTALA) and Death Associated With Restraint or Seclusion Complaint Investigation Timeline Revisions

Memorandum Summary

- **Complaint Investigation Timelines:** The timeline for investigations in hospitals and critical access hospitals (CAH) for complaints specific to EMTALA and deaths associated with restraint or seclusion is being changed for the Centers for Medicare & Medicaid (CMS) Regional Office (RO) and State Survey Agency (SA) surveyors from completion in five working days to onsite within two business days. This change brings these two categories of complaint investigations in line with other potential immediate jeopardy (IJ) investigations in Medicare-participating non-long term care facilities.

- **Appendix V Revisions:** SOM Appendix V contains the EMTALA regulations, interpretive guidelines and survey process. Part I – Investigative Procedures of Appendix V is being revised to address the change in complaint investigation timelines along with other minor clarifications to the survey process.

Background

The CMS SOM Chapter 5 – Complaint Procedures contains the timelines for onsite complaint investigations in Medicare participating facilities in Section 5075.9. Currently, the timeline for EMTALA complaints and surveys of death in restraint or seclusion in hospitals and CAHs require surveyors to complete their complaint investigation within five working days. To bring these two types of complaint investigations in line with other non-long term care facility complaint investigations prioritized as IJ, the revised timeline will require surveyors to be onsite to initiate their investigation within two business days.

For EMTALA complaints only, the RO is currently able to triage the complaint investigation as IJ but may now triage the complaint as Non-IJ High, based on their review of the allegations. The Non-IJ High prioritization will require survey activity to be initiated within 45 days.

Discussion

Complaints received by the SA or CMS RO are prioritized for investigation based on the details of the allegations. The categories of prioritization include IJ, Non-IJ High, Non-IJ Medium and Non-IJ Low. Although the current timeline for initiation of investigation versus completion of investigation is varied based on type of allegation, the changes addressed in this memorandum and the revisions to SOM Chapter 5 and Appendix V will align complaint investigative timelines in non-long term care facilities for IJ prioritization.

Based on the review of the allegations by the CMS RO, EMTALA complaints against hospitals and CAHs may now be triaged as IJ or Non-IJ High. Complaints specific to death associated with restraint or seclusion in hospitals and CAH Distinct Part Units (DPU) are always prioritized as IJ.

Additionally, SOM Appendix V for EMTALA Part I Investigative Procedures is being revised to address the changes to the complaint triaging prioritization as well as other minor clarifications to the survey process. Any questions regarding the revisions to Chapter 5 or Appendix V should be submitted to HospitalSCG@cms.hhs.gov

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

/s/
Karen Tritz

Attachment –Advanced Copy SOM EMTALA and Death Restraint Seclusion Investigations

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal **Date:**

SUBJECT: Revisions to the State Operations Manual (SOM) Chapter 5 and Appendix V.

I. SUMMARY OF CHANGES: This transmittal includes revisions to SOM Chapter 5 and Appendix V to reflect changes to the complaint investigative process for Emergency Medical Treatment and Labor Act (EMTALA) and surveys related to death in restraint and seclusion complaint investigations.

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

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 5/Section 5070/Priority Assignment for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Chapter 5/Section 5075/Priority Definitions for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA
R	Chapter 5/Section 5075.1/Immediate Jeopardy (for Nursing Homes, Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/Section 5075.2/Non-Immediate Jeopardy - High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers, and EMTALA)
R	Chapter 5/5075.9/Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents
R	Chapter 5/5107.3/Process
R	Chapter 5/5440.2/Scheduling the Investigation
R	Appendix V/Part I Investigative Procedures

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2017 operating budgets.

IV. ATTACHMENTS:

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

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

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

This section does not apply to clinical laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). See Sections 5500 – 5590 for CLIA information.

An assessment of each complaint or incident intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of Federal requirements and his/her knowledge of current clinical standards of practice. In situations where a determination is made that immediate jeopardy may be present and ongoing, the SA is required to start the on-site investigation within two *business* days of receipt of the complaint or incident report, or, in the case of a deemed provider or supplier, within two *business* days of RO authorization for investigation. *The same process applies to* EMTALA complaint*s* or a survey related to a report of a hospital or CAH Distinct Part Unit patient death associated with *the* use of restraint or seclusion. *The* SA's investigation must be *initiated* within *two business* days of RO authorization for investigation.

Generally, an alleged event occurring more than 12 months prior to the intake date would not require a complaint investigation. However, the SA is not precluded from conducting a Federal investigation (with appropriate RO authorization, where required) to determine current compliance status based on the concerns identified in the complaint.

For nursing homes, an onsite survey may not be required if there is sufficient evidence that the facility does not have continuing noncompliance and the alleged event occurred before the last standard survey.

For all intakes concerning deemed status providers or suppliers where the intake involves allegations of substantial noncompliance (in other words, the allegation would result in a condition-level deficiency citation if found to be true and uncorrected), the SA must submit a request for RO approval of a complaint validation survey (i.e., substantial allegation validation survey). The SA must obtain RO approval before conducting a substantial allegation validation survey. The RO will authorize the SA to conduct the survey by issuing electronically via ACTS a Form CMS-2802, which will indicate the specific conditions for which the SA must assess compliance. The RO must authorize assessment of compliance for a whole condition and not just for particular standards within a condition, unless the Form CMS-2802 for the applicable provider/supplier type permits selection of a specific standard, e.g., Life Safety Code.

All allegations of EMTALA violations related to a hospital *(which also includes cancer, children's, long term care, psychiatric, and rehabilitation hospitals)* or CAH, regardless of whether the hospital or CAH is deemed, must be referred to the RO. The RO will determine whether the SA will conduct an EMTALA investigation.

In cases where the SA or RO has noted a pattern of similar complaints about a specific provider or supplier, each of which on its own merits would be triaged at a medium or low level, the SA or RO has the discretion to assign a higher triage level to a current intake based on the noted pattern, in order to ensure timely investigation of the provider's/supplier's compliance with the applicable requirements or Conditions.

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

(*Rev.*)

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

(*Rev.*)

General Provisions

The regulations at 42 CFR 489.3 define immediate jeopardy as, "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." Appendix Q contains the Guidelines for Determining Immediate Jeopardy. Intakes are assigned this priority if the alleged noncompliance indicates there was serious injury, harm, impairment or death of a patient or resident, or the likelihood for such, and there continues to be an immediate risk of serious injury, harm, impairment or death of a patient or resident unless immediate corrective action is taken. *I*ntakes alleging EMTALA noncompliance *may* also *be* assigned this priority. Any hospital self-reported incident of patient death associated with use of restraint or seclusion which the RO determines requires an on-site investigation is also assigned this priority.

When the SA or RO makes the determination that a complaint or incident report suggests an immediate jeopardy may be present, the investigation is to be initiated in accordance with Section 5075.9.

Fires Resulting in Serious Injury or Death

Fires resulting in serious injury or death are prioritized as "immediate jeopardy". The following actions are taken when a report of a fire resulting in serious injury or death in a Medicare/Medicaid certified facility is received from any source:

The SA

- Enters the complaint or self-reported incident into ACTS (Priority = IJ, Allegation Category = Life Safety Code);

- Informs the appropriate RO of fire resulting in serious injury or death no later than one working day after receipt of the intake;

- Compiles information as needed to present a comprehensive picture of the situation surrounding the fire;

- Takes appropriate action necessary to assist the Medicare/Medicaid-certified provider/supplier to protect and/or relocate residents or patients from further harm; and

- Performs the Life Safety Code investigation.

The RO

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

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

- Reports any findings and actions taken by the SA to the CO at the end of the on-site survey; and

- At its discretion, may accompany the SA during the on-site survey.

The CO

- Consults with the RO to determine whether or not issues are present that indicate further investigation to determine the adequacy of current standards and their application; and

- In certain cases CO staff may accompany regional and/or state personnel on the on-site survey.

5075.2 - Non-Immediate Jeopardy - High Priority (for Nursing Homes and Deemed and Non-Deemed Non-Long Term Care Providers/Suppliers*, and EMTALA*)

(*Rev.*)

Nursing Homes:

Intakes are assigned a "high" priority if the alleged noncompliance with one or more requirements may have caused harm that negatively impacts the individual's mental, physical and/or psychosocial status and are of such consequence to the person's well being that a rapid response by the SA is indicated. Usually, specific rather than general information (such as: descriptive identifiers, individual names, date/time/location of occurrence, description of harm, etc.) factors into the assignment of this level of priority.

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

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

Non-Long Term Care Providers/Suppliers

Intakes are assigned this priority if the alleged noncompliance with the applicable Conditions of Participation, Coverage or Certification, *or EMTALA requirements,* if found to be true and uncorrected, would not represent an IJ, but would result in a determination of substantial noncompliance, i.e., at least one condition-level deficiency.

Intakes assigned this priority require an onsite survey to be initiated within 45 calendar days after intake prioritization for non-deemed providers/suppliers, and within 45 calendar days after authorization of the investigation by the RO for deemed status providers/suppliers. The RO has the discretion to request the onsite survey be initiated in less than 45 calendar days.

5075.9 - Maximum Time Frames Related to the Federal Onsite Investigation of Complaints/Incidents (*Rev.*)

	Intake Prioritization			
Provider Type	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium	Non-IJ Low
Nursing homes	SA must initiate an onsite survey within 2 *business* days of receipt.	SA must initiate an onsite survey within 10 *business* days of prioritization.	No timeframe specified, but an onsite survey must be scheduled.	SA must investigate during the next onsite survey.
Non-deemed non-long term care providers/suppliers	SA must initiate an onsite survey within 2 *business* days of receipt.	SA must initiate an onsite survey within 45 calendar days of prioritization	SA must investigate no later than when the next onsite survey occurs	SA must track/trend for potential focus areas during the next onsite survey.
Deemed providers/suppliers	SA must initiate an onsite survey within 2 *business* days of receipt of RO authorization	SA must initiate an onsite survey within 45 days of receipt of RO authorization.	Complainant is referred to the applicable accrediting organization(s)	Complainant is referred to the applicable accrediting organization(s)
EMTALA	SA must *initiate an onsite survey within 2 business days of receipt of RO authorization*	*SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization*	N/A	N/A
Death associated with restraint/seclusion-Hospitals/CAH DPUs	SA must *initiate an onsite survey within 2 business days of receipt of RO authorization*	N/A	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 *business* days of receipt.	N/A	N/A	N/A

5170.3 - Process
(*Rev.*)

The RO evaluates the information required to be reported by the hospital *or CAH DPU* under 42 CFR 482.13(g)(1) to determine whether the situation might involve a violation of 42 CFR 482.13(e) through 42 CFR 482.13(g) and authorizes an on-site investigation if there appears to be a possible violation.

Using the information provided by the hospital *or CAH DPU* in the worksheet, the RO evaluates whether the case warrants an on-site investigation. If the RO determines that the restraint/seclusion death report requires on-site investigation, within *two business* days of receiving the report, the RO enters the reported information into the ACTS restraint/seclusion module and immediately notifies the SA to authorize a complaint survey to investigate the hospital's *or CAH DPU's* compliance with the Patient's Rights requirement at 42 CFR 482.13(e), (f), and (g), including the reported case. The SA accesses the ACTS restraint/seclusion module to see the information reported by the hospital *or CAH DPU* prior to conducting the on-site investigation. The SA is expected to *be onsite to initiate* the investigation within *two business* days of receipt of survey authorization from the RO.

Notice to Protection and Advocacy Organizations

At the same time that the RO notifies the SA that it authorizes the on-site survey, consistent with the ACTS Notice of a Modified or Altered System of Records (SOR) (71 FR 29643, May 23, 2006, SOR 09-70-0565), the RO also provides written notification, by mail or email, to the appropriate Protection and Advocacy Organization (P&A) within the State where the hospital is located, *only* if the P&A has a *current* Data Use Agreement (DUA) with CMS. The RO may contact CMS Central Office for a list of P&A's with current DUAs. The names and addresses for each State's P&A can be located at the following website, at the drop down menu entitled "Get Help in Your State:" www.ndrn.org . **Notification is provided only in those cases for which an on-site survey is authorized.**

The RO provides the following information to the P&A: hospital *or CAH DPU* name, hospital *or CAH DPU* address, name of the deceased, and a copy of the restraint/seclusion death report submitted by the hospital *or CAH DPU*. **An entry must be made on the intake in ACTS indicating the name of the P&A to which the restraint/seclusion death report data was sent and the date it was sent.**

The P&A must have an approved CMS Data Use Agreement (DUA), Form CMS-R-0235, (Exhibit 292) in place before restraint/seclusion death report data may be disclosed to it. In order to get an approved DUA, the P&A must complete and submit a signed CMS DUA, Form CMS-R-0235, including an initialed DUA ACTS SOR- P&A Attachment (Exhibit 293) to the Director, Division of Information Security and Privacy Management (DISPM), Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. DISPM will review the DUA,

assign a unique DUA identifier and expiration date to it, and return a signed copy to the P&A, including an expiration date. CMS Central Office Survey and Certification will maintain and make available to ROs a list of P&As with DUAs.

When completing the Form, P&As must note the following in particular:

- Line 5 of the DUA must state "Restraint/Seclusion Hospital Death Reports." The "Years" and "System of Record" columns should be left blank;

- Line 12 must state "CMS DUA: ACTS SOR Attachment – P&A;"

- The DUA must be signed by the P&A official whom the P&A designates as "Custodian," i.e., the individual who will have actual possession of and responsibility for the data released under the DUA; and

- A P&A may designate more than one Custodian, but if it does so, each individual must complete and sign a Multi-Signature Addendum Form (Exhibit 294).

When approved, the DUA will have an expiration date. DISPM will alert an organization with a DUA of its upcoming expiration date and will give the organization the option of requesting a one-year DUA extension via e-mail, or to close the DUA with a DUA destruction certificate. DISPM has set up a DUA resource email box which accepts all expired DUA resolution requests at DataUseAgreement@cms.hhs.gov.

Custodians may be added or deleted over the life of the primary DUA. To add a new Custodian under an existing DUA, the P&A must submit the following to CMS/DISPM: a letter from the P&A describing the activities planned for the new Custodian and the length of time over which the Custodian will serve, and a Multi-Signature Addendum signed by the appropriate official from the P&A. The Multi-Signature Addendum must show the DUA number of the existing primary P&A DUA. The P&A must assign a case number to all Multi-Signature Addendums beginning with "1" and adding consecutively thereafter. CMS/DISMP will use this number to track the number of Custodians in each P&A. When a P&A seeks to delete an existing Custodian, it must send the CMS/DISPM a letter to this effect. CMS/DISPM will strike out the name of the deleted Custodian from the DUA or Multi-Signature Addendum that added that Custodian, dating and initialing the deletion.

The DUA process described in this section applies to disclosure of hospital *and CAH DPU* restraint/seclusion death reports by CMS to P&As in those cases where the P&A did not first make a request specific to an identified patient; a DUA is not required for other disclosures of information in ACTS to a P&A when permitted in accordance with the ACTS System of Records Notice.

- A P&A may request information about an on-site survey by submitting its request to the SA. The SA will process this request and release information to the P&A in

accordance with standard CMS policy for disclosure of Form CMS 2567, Statement of Deficiencies and Plan of Correction.

If the P&A identifies a particular patient, hospital, and approximate date or dates when the patient was in that hospital *or CAH DPU*, and if the P&A makes a request for additional information, beyond the Form CMS 2567, related to use of restraint or seclusion on that patient, the request is forwarded to the RO. The RO may, in accordance with the ACTS System of Records Notice, release additional information to the P&A.

5440.2 - Scheduling the Investigation
(*Rev.*)

Allegations of EMTALA violation against a non-deemed or deemed hospital *or CAH may* represent a probable immediate jeopardy to the next individual who comes to the hospital requesting examination and treatment for an emergency medical condition. Therefore, *when triaged as IJ by the RO, initiate* the investigation within *two business* days after receipt of the authorization from the RO. The onsite investigation must be conducted on consecutive *business* days. The survey must be completed promptly and is not to be interrupted by other activities. DO NOT ANNOUNCE ANY INVESTIGATIONS.

Based on review of the complaint allegations by the RO, the EMTALA complaint may also be prioritized as Non-IJ High. In these situations, the investigation must be initiated within 45 business days of RO authorization. The onsite investigation must be conducted on consecutive business days. The survey must be completed promptly, should not be interrupted by other activities, and must be unannounced.

State Operations Manual
Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases

(Rev.)

Transmittals for Appendix V

Part I- Investigative Procedures

(Rev.)

I. General Information

Medicare participating hospitals must meet the Emergency Medical Treatment and Labor Act (EMTALA) statute codified at §1867 of the Social Security Act, (the Act) the accompanying regulations in 42 CFR §489.24 and the related requirements at 42 CFR 489.20(l), (m), (q), and (r). EMTALA requires hospitals with emergency departments to provide a medical screening examination to any individual who comes to the emergency department and requests such an examination, and prohibits hospitals with emergency departments from refusing to examine or treat individuals with an emergency medical condition (EMC). *For purposes of this guidance, t*he term "hospital" includes critical access hospitals *(CAHs)*.

The provisions of EMTALA apply to all individuals (not just Medicare beneficiaries) who attempt to gain access to a hospital for emergency care. The regulations define "hospital with an emergency department" to mean a hospital with a dedicated emergency department (ED). In turn, the regulation defines "dedicated emergency department" as any department or facility of the hospital that either (1) is licensed by the state as an emergency department; (2) held out to the public as providing treatment for emergency medical conditions; or (3) on one-third of the visits to the department in the preceding calendar year actually provided treatment for emergency medical conditions on an urgent basis. These three requirements are discussed *below*.

The enforcement of EMTALA is a complaint driven process. The investigation of a hospital's policies/procedures and processes and any subsequent sanctions are initiated by a complaint. If the results of a complaint investigation indicate that a hospital violated one or more of the anti-dumping provisions of §1866 or 1867 (EMTALA), a hospital may be subject to termination of its provider agreement and/or the imposition of civil monetary penalties (CMPs). CMPs may be imposed against hospitals or individual physicians for EMTALA violations.

The RO evaluates and authorizes all complaints and refers cases to the SA that warrant investigation. The first step in determining if the hospital has an EMTALA obligation is for the surveyor to verify whether the hospital in fact has a dedicated emergency department (ED). To do so, the surveyor must check whether the hospital meets one of the criteria that define whether the hospital has a dedicated emergency department.

As discussed above, a dedicated emergency department is defined as meeting one of the following criteria regardless of whether it is located on or off the main hospital campus:

(1) *The hospital department* is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; or

(2) *The hospital department* is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions (EMC) on an urgent basis without requiring a previously scheduled appointment; or

(3) *The hospital department* during the preceding calendar year, (i.e., the year immediately preceding the calendar year in which a determination under this section is being made), based on a representative sample of patient visits that occurred during the calendar year, *provided* at least one-third of all of its visits for the treatment of EMCs on an urgent basis without requiring a previously scheduled appointment. This includes individuals who may present as unscheduled ambulatory patients to units (such as labor and delivery or psychiatric *intake or assessment* units of hospitals) where patients are routinely evaluated and treated for emergency medical conditions.

Hospitals with dedicated emergency departments are required to take the following measures:

- Adopt and enforce policies and procedures to comply with the requirements of 42 CFR §489.24;
- Post signs in the dedicated ED specifying the rights of individuals with emergency medical conditions and women in labor who come to the dedicated ED for health care services, and indicate on the signs whether the hospital participates in the Medicaid program;
- Maintain medical and other records related to individuals transferred to and from the hospital for a period of five years from the date of the transfer;
- Maintain a list of physicians who are on-call to provide further evaluation and or treatment necessary to stabilize an individual with an emergency medical condition;

- Maintain a central log of individuals who come to the dedicated ED seeking treatment and indicate whether these individuals:
    - Refused treatment,
    - Were denied treatment,
    - Were treated, admitted, stabilized, and/or transferred or were discharged;
- Provide for an appropriate medical screening examination;
- Provide necessary stabilizing treatment for emergency medical conditions and labor within the hospital's capability and capacity;
- Provide an appropriate transfer of an unstabilized individual to another medical facility if:
    - The individual (or person acting on his or her behalf) after being informed of the risks and the hospital's obligations requests a transfer,
    - A physician has signed the certification that the benefits of the transfer of the patient to another facility outweigh the risks or
    - A qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed the certification after a physician, in consultation with that qualified medical person, has made the determination that the benefits of the transfer outweigh the risks and the physician countersigns in a timely manner the certification. (This last criterion applies if the responsible physician is not physically present in the emergency department at the time the individual is transferred.
    - Provide treatment to minimize the risks of transfer;
    - Send all pertinent records to the receiving hospital;
    - Obtain the consent of the receiving hospital to accept the transfer,
    - Ensure that the transfer of an unstabilized individual is effected through qualified personnel and transportation

equipment, including the use of medically appropriate life support measures;

- Medical screening examination and/or stabilizing treatment is not to be delayed in order to inquire about payment status;

- Accept appropriate transfer of individuals with an emergency medical condition if the hospital has specialized capabilities or facilities and has the capacity to treat those individuals; and

- Not penalize or take adverse action against a physician or a qualified medical person because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized or against any hospital employee who reports a violation of these requirements.

If the hospital does not have a dedicated emergency department as defined in 42 CFR §489.24(b), apply 42 CFR §482.12(f) which requires the hospital's governing body to assure that the medical staff has written policies and procedures for appraisal of emergencies and the provision of initial treatment and referral (Form CMS-1537, "Medicare/Medicaid Hospital Survey Report").

Hospitals that violate the provisions in 42 CFR §489.24 or the related requirements in 42 CFR §489.20(l), (m), (q), and (r) are subject to civil monetary penalties or termination.

A hospital is required to report to CMS or the State survey agency promptly when it suspects it may have received an improperly transferred individual. Notification should occur within 72 hours of the occurrence. Failure to report improper transfers may subject the receiving hospital to termination of its provider agreement.

To assure that CMS is aware of all instances of improper transfer or potential violations of the other anti-dumping requirements, the State survey agencies must promptly report to the RO all complaints related to violations of 42 CFR §489.24 and the related requirements at 42 CFR §489.20(l), (m), (q), and (r). The RO will decide whether a complaint alleges a violation of these requirements and warrants an investigation.

Quality of care review performed either by the SA or other physicians must not delay processing of a substantiated EMTALA violation. If during the course of the investigation, you identify possible quality of care issues other than those related to the provisions of this regulation, obtain a copy of the patient's medical record and send the case to the RO for referral to the appropriate Quality Improvement Organization (QIO). Contact the RO if the hospital refuses to provide a copy of the medical record.

If you suspect emergency services are being denied based on race, color, national origin, *age, disability, or sex* refer the cases to the RO. The RO will forward the cases to the Office of Civil Rights (OCR) for investigation of discrimination.

A hospital must formally determine who is qualified to perform the initial medical screening examinations, i.e., qualified medical person. While it is permissible for a hospital to designate a non-physician practitioner as the qualified medical person, the designated non-physician practitioners must be set forth in a document that is approved by the governing body of the hospital. Those health practitioners designated to perform medical screening examinations are to be identified in the hospital by-laws or in the rules and regulations governing the medical staff following governing body approval. It is not acceptable for the hospital to allow the medical director of the emergency department to make what may be informal personnel appointments that could frequently change.

If it appears that a hospital with a dedicated ED does not have adequate staff and equipment to meet the needs of patients, consult the RO to determine whether or not to expand the survey for compliance with the requirements of 42 CFR §482.55 ("Condition of Participation: Emergency Services") or 42 CFR §485.618 (CAH Condition of Participation: Emergency Services).

Look for evidence that the procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis.

The hospital should have procedures, which assure integration with other hospital services (e.g., including laboratory, radiology, ICU, and operating room services) to *ensure* continuity of care.

II. Principal Focus of Investigation

Investigate for compliance with the regulations in 42 CFR §489.24 and the related requirements in 42 CFR §489.20(l), (m), (q), and (r). All investigations are to be unannounced. The investigation is based on an allegation of noncompliance. The purpose of the investigation is to ascertain whether a violation took place, to determine whether the violation constitutes an immediate and serious threat to patient health and safety, to identify any patterns of violations at the facility, and to assess whether the facility has policies and procedures to address the provisions of the EMTALA law. The investigation must be *initiated* within *two business* days of the RO authorization.

The focus of the investigation is on the initial allegation of violation and the discovery of additional violations. If the allegation is not confirmed, the surveyors must still be assured that the hospital's policies and procedures, physician certifications of transfers, etc., are in compliance with the requirements of 42 CFR §489.24 and the related requirements at 42 CFR §489.20(l), (m), (q), and (r). If the allegation(s) is confirmed, the investigation would continue, but with an emphasis on the hospital's compliance within the last 6 months.

Ensure that the case(s), if substantiated, is (are) fully documented on Form CMS-2567, Statement of Deficiencies and Plan of Correction. The investigation paperwork should be *submitted to the RO within* ten *business* days following completion of the onsite survey if it appears there may be a violation of §§1866 and 1867 of the Act. If there appears not to be a violation, and the responsibilities of Medicare participating hospitals in emergency cases appear to be met, the time frame to complete the paperwork and *submit* to the RO may be extended to 15 *business* days.

Once the investigation is complete the RO is strongly encouraged to share as much information with the hospital as possible in accordance with the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) regarding the complaint and investigation. The RO may also include any facts about the violation, a copy of any medical reviews (the identity of the reviewer must be deleted), and the identity of the patient involved (not the identity of the complainant or source of the complaint). CMS will determine if the violation constitutes immediate jeopardy to patient health and safety.

The hospital has the opportunity to present evidence to CMS that it believes demonstrates its compliance and the opportunity to comment on evidence CMS believes demonstrates the hospital's noncompliance. CMS' regional offices retain delegated enforcement authority and final enforcement decisions are made there**.**

III. Task 1 - Entrance Conference

A brief entrance conference must be held with the CEO/president of the hospital (or his or her designee) and any other staff the CEO considers appropriate to explain the nature of the allegation, the purpose of the investigation, and the requirements against which the complaint will be investigated. The identity of the complainant and patient must always be kept confidential unless written consent is obtained. Ask the CEO to have the staff provide you with the following information (as appropriate):

- Dedicated ED logs for the past 6-12 months;
- The dedicated ED policy/procedures manual (review triage and assessment of patients presenting to the ED with emergency medical conditions, assessment of labor, transfers of individuals with emergency medical conditions, etc.);
- Consent forms for transfers of unstable individuals;
- Dedicated ED committee meeting minutes for the past 12 months;
- Dedicated ED staffing schedule (physicians *and practitioners* for the past 3 months and nurses for the last 4 weeks) or as appropriate;
- Bylaws/rules and regulations of the medical staff;
- Minutes from medical staff meetings for the past 6-12 months;

- Current medical staff roster;

- Physician on-call lists for the past 6 months;

- Credential files (to be selected by you) include the director of the emergency department and emergency department physicians. Review of credentials files is optional. However, if there has been a turnover in significant personnel (e.g., the ED director) or an unusual turnover of ED physicians, or a problem is identified during record review of a particular physician's screening or treatment in the ER, credentials files should be obtained and reviewed;

- Quality Assessment and Performance Improvement (QAPI) Plan (formally known as Quality Assurance);

- QAPI minutes (request the portion of the quality improvement minutes and plan, which specifically relates to EMTALA regulations. If a problem is identified that would require a more thorough review, additional portions of the quality improvement plan and minutes may be requested for review);

- List of contracted services (request this list if a potential violation of §1866 and 1867 of the Act is noted during the investigation and the use of contracted services is questioned);

- Dedicated ED personnel records (optional);

- In-service training program records, schedules, reports, etc. (optional review if questions arise through interview and record review regarding the staff's knowledge of 42 CFR §489.24);

- Ambulance trip reports and memoranda of transfer, if available (to be selected by you if the cases you are reviewing concern transfers); and

- Ambulance ownership information and applicable State/regional/community EMS protocols.

In addition, if the case you are investigating occurred prior to the time frames mentioned, examine the above records for a three-month period surrounding the date of the alleged violation.

Inform the CEO that you will be selecting a sample of cases (medical records) for review from the ED log and that you will require those records in a timely fashion.

IV. Task 2 - Case Selection Methodology

Even though a single occurrence is considered a violation a sample is done to identify additional violations and/or patterns of violations.

A. **Sample Size**. Select *at least* 20 records to review in depth, using the selection criteria described below. The sample is not intended to be a statistically valid sample and the sample selection should be focused on potential problem areas. The sample size should be expanded as necessary in order to adequately investigate possible violations or patterns of violations.

Note: On revisit surveys, select at least 10 records for review to ensure the hospital is meeting the terms of its Plan of Correction and maintaining compliance with EMTALA requirements. The sample size should be expanded as necessary.

B. **Sample Selection**. The type of records sampled will vary based on the nature of the complaint and the types of patients requesting emergency services. Do not allow the facility staff to select the sample. Use the emergency department log and other appropriate information, such as patient charts, to identify:

- Individuals transferred to other facilities;
- Gaps, return cases, or non-sequential entries in the log;
- Refusals of examination, treatment, or transfer;
- Patients leaving against medical advice *(AMA)* or left without being seen (LWBS); and
- Patients returning to the emergency department within 48 hours.

Sample selection requires that:

1. You identify the *actual* number of emergency cases seen per month for the 6 months preceding the survey*, in each of the hospitals dedicated emergency departments (including labor and delivery departments and psychiatric intake/assessment areas) on or off the main campus*.

2. You *review* transfers of emergency patients to other acute care hospitals *over* the preceding 6 months. Review transfers of patients where it appears that the *sending* hospital could have provided *stabilizing treatment and* continuing medical care.

3. You include the complaint case (s) in the sample, regardless of how long ago it occurred. Select other cases at the time of the complaint in order to identify patterns of hospital behavior and to help protect the identity of the patient.

4. *Focus primarily on the issues specific to the compliant case(s) but also review non-related cases to assess compliance with all EMTALA requirements.*

If you identify additional violations, determine, if possible, whether there *are* pattern*s of discrimination* related to:

- Race;
- Color;
- National *origin*;
- *Age;*
- Disability; or
- *Sex.*

Patterns identified that appear to be related to any of these items must be referred to the Office of Civil Rights (OCR). Select the option "Possible Discrimination – refer to OCR" on the Form CMS-1541B. The RO is responsible for making the referral to OCR.

Representative Sample Size *to determine if a hospital department meets the threshold* for dedicated emergency department, if applicable:

The SA surveyor should consult with the RO prior to conducting the representative sample of patient visits for a hospital department to determine whether the department meets the criteria of being a dedicated emergency department.

To determine if a hospital department is a dedicated emergency department because it meets the "one-third requirement" described above (i.e., the hospital, in the preceding year, had at least one-third of all of its visits for the treatment of EMCs on an urgent basis without requiring a previously scheduled appointment), the surveyor is to select a representative sample of patient visits that occurred the previous calendar year in the area of the hospital to be evaluated for status as a dedicated emergency department. This includes individuals who may present as unscheduled ambulatory patients to units (such as labor and delivery or psychiatric *intake/assessment* units of hospitals) where patients are routinely admitted for evaluation and treatment.

The surveyors will review the facility log, appointment roster and other appropriate information to identify patients seen in the area or facility in question. Surveyors are to review 20 - 50 records of patients with diagnoses or presenting complaints, which may be associated with an emergency medical condition (e.g., cardiac, respiratory, pediatric patients (high fever, lethargy), loss of consciousness, *rupture of membranes, suicidal ideation,* etc.). Surveyors have the discretion (in consultation with the *RO*) to expand the sample size as necessary in order to adequately investigate possible violations or patterns of violations. Do not allow the facility staff to select the sample.

Review the selected cases to determine if patients had an emergency medical condition and received stabilizing treatment. If at least one-third of the sample cases reviewed were for the treatment of EMCs on an urgent basis without requiring a previously scheduled appointment, the area being evaluated is a dedicated emergency department, and therefore, the hospital has an EMTALA obligation. Hospitals that may meet this one-third criterion may be specialty hospitals (such as psychiatric hospitals), hospitals without "traditional" emergency departments, and urgent care centers. In addition, it is not relevant if the entity that meets the definition of a dedicated ED is not located on the campus of the main hospital.

Guidelines to determine if a department of a hospital meets the one-third criteria of being a dedicated emergency department:

For each case, the surveyor should answer three questions.

1. Was the individual an outpatient?

   Y N If not, what was his or her status (e.g., inpatient, visitor or other)?

2. Was the individual a walk-in (unscheduled appointment)?

   Y N

3. Did the individual have an EMC, and received stabilizing treatment?

   Y N

   NOTE- an affirmative yes must be present for both parts of this question for the case to be counted toward the one-third criterion to be met. If **no** is answered for *either* part of this question, the criterion was **not met**, and select no for the overall answer.

All questions must have an answer of yes to confirm that the case is included as part of the percentage (one-third) to determine if the hospital has a dedicated emergency

department. If one-third of the total cases being reviewed receive answers of "yes" to the three questions above, then the hospital has an EMTALA obligation.

Document information concerning your sample selection on a blank sheet of paper or SA worksheet and label it "Summary Listing of Sampled Cases." Include the dates the individuals requested services, any identifier codes used to protect the individual's confidentiality, and the reasons for your decision to include these individuals in your sample.

V. Task 3- Record Review

While surveyors may make preliminary findings during the course of the investigation, a physician must usually determine the appropriateness of the MSE, stabilizing treatment, and transfer. Because expert medical review is usually necessary, obtain copies of the medical and other record(s) of the alleged violation case (both hospitals if an individual sought care at two hospitals or were transferred) and any other violation cases identified in the course of the investigation.

Also, review documents pertaining to QAPI activities in the emergency department and remedial actions taken in response to a violation of these regulations. Document hospital corrective actions taken prior to the survey and take such corrective action into account when developing your recommendation to the RO.

In an accredited hospital, if it appears that CoPs are not met, contact the RO for authorization to extend the investigation. If you are conducting the investigation in a non-accredited hospital, you may expand the investigation to include other conditions without contacting the RO first. When there is insufficient information documented on the emergency record regarding a request for emergency care, it may be helpful to interview hospital staff, physicians, witnesses, ambulance personnel, the individual, or the individual's family. Ask for RO guidance if you are still unable to obtain a consistent and reliable account of what happened.

Any time delivery of a baby occurs during transfer, obtain a copy of all available records and refer the case for review to the QIO physician reviewer.

If you are unsure whether qualified personnel and/or transportation equipment were used to effectuate a transfer, review the hospital's transfer policies, and obtain a copy of the medical record and transfer records.

In cases where treatment is rendered to stabilize an EMC, the medical records should reflect the medically indicated treatment necessary to stabilize it, the medications, treatments, surgeries and services rendered, and the effect of treatment on the individual's emergency condition or on the woman's labor and the unborn child.

The medical records should contain documentation such as: medically indicated screenings, tests, mental status evaluation, impressions, and diagnoses (supported by a history and physical examination, laboratory, and other test results) as appropriate.

For pregnant women, the medical records should show evidence that the screening examination included ongoing evaluation of fetal heart tones, regularity and duration of uterine contractions, fetal position and station, cervical dilation, and status of the membranes, i.e., ruptured, leaking, intact.

For individuals with psychiatric symptoms, the medical records should indicate an assessment of suicide or homicide attempt or risk, orientation, or assaultive behavior that indicates danger to self or others.

In cases where an individual (or person acting on the individual's behalf) withdrew the initial request for a medical screening examination (MSE) and/or treatment for an EMC and demanded his or her transfer, or demanded to leave the hospital, look for a signed informed refusal of examination and treatment form by either the individual or a person acting on the individual's behalf. Hospital personnel must inform the individual (or person acting on his or her behalf) of the risks and benefits associated with the transfer or the patient's refusal to seek further care. If the individual (or person acting on the individual's behalf) refused to sign the consent form, look for documentation by the hospital personnel that states that the individual refused to sign the form. The fact that an individual has not signed the form is not, however, automatically a violation of the screening requirement. Hospitals must, under the regulations, use their best efforts to obtain a signature from an individual refusing further care.

Examine the ambulance trip reports in questionable transfer cases (if available). These records can answer questions concerning the appropriateness of a transfer and the stability of the individual during the transfer.

Appropriate record review should also be conducted at the receiving (or recipient) hospital if the alleged case and any other suspicious transfer cases involve the transfer or movement of the individual to another hospital.

Document all significant record review findings in the complaint investigation narrative.

VI. Task 4- Interviews

To obtain a clear picture of the circumstances surrounding a suspected violation of the special responsibilities of Medicare hospitals in emergency cases, it is necessary to interview facility staff. For example, you may be able to gather a great deal of information from the admitting clerk in the emergency department, the nurses on shift at the time the individual sought treatment, and the Director of Quality Improvement in the hospital to name a few. You may also need to interview witnesses, the patient, *and/or* the patient's family. The physician(s) involved in the incident should be interviewed.

Document each interview you conduct on a blank sheet of paper or SA worksheet and label it "Summary of Interviews." Include the following information, as appropriate, in your notes for each interview:

- The individual's job title and assignment at the time of the incident;

- Relationship to the patient and/or reason for the interview; and

- Summary of the information obtained.

Appropriate interviews should also be conducted at the receiving hospital in cases of transfer or movement of the individual to another hospital.

VII. Task 5-Exit Conference

The purpose of the exit conference is to inform the hospital of the scope of the investigation, including the nature of the complaint, investigation *process*, and requirements investigated, and any hospital CoPs surveyed, *if applicable*. Explain to the hospital staff the consequences of a violation of the requirements in 42 CFR §489.24 or the related requirements in 42 CFR §489.20(l), (m), (q), and (r) and the timeframes that will be followed if a violation is found. *The surveyors may provide preliminary findings but must* not tell the hospital whether or not a violation was identified since it is the responsibility of the RO to make that determination. Inform the CEO (or his or her designee) that the RO will make the determination of compliance based on the information collected during this investigation and any additional information acquired from physician review of the case. Do not leave a draft of the deficiencies of Form CMS-2567 with the hospital. Inform the hospital that the RO will send that information to the hospital once it is complete.

VIII. Task 6- Professional Medical Review

The purpose of a professional medical review (physician review) is to provide peer review using information available to the hospital at the time the alleged violation took place. Physician review is required prior to the imposition of CMPs or the termination of a hospital's provider agreement to determine if:

- The screening examination was appropriate. Under EMTALA, the term "appropriate" does not mean "correct", in the sense that the treating emergency physician is not required to correctly diagnose the individual's medical condition. The fact that a physician may have been negligent in his screening of an individual is not necessarily an EMTALA violation. When used in the context of EMTALA, "appropriate" means that the screening examination was suitable for the symptoms presented and conducted in a non-disparate fashion. Physician review is not necessary when the hospital did not screen the individual;

- The individual had an emergency medical condition. The physician should identify what the condition was and why it was

an emergency (e.g., what could have happened to the patient if the treatment was delayed);

- In the case of a pregnant woman, there was inadequate time to affect a safe transfer to another hospital before delivery, or the transfer posed a threat to the health and safety of the woman or the unborn child;

- The stabilizing treatment was appropriate within a hospital's capability (**NOTE** that the clinical outcome of an individual's medical condition is not the basis for determining whether an appropriate screening was provided or whether the person transferred was stabilized);

- The transfer was effected through qualified personnel and transportation equipment, including the use of medically appropriate life support measures;

- If applicable, the on-call physician's response time was reasonable; and

- The transfer was appropriate for the individual because the individual; requested the transfer or because the medical benefits of the transfer outweighed the risk.

The RO, after receipt and review of the case from the SA, will determine if the case needs to be forwarded to the QIO for a professional medical review.

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

A. **Analysis**. Analyze your findings relative to each provision of the regulations for the frequency *and* dates of occurrence. A single occurrence *of non-compliance with the EMTALA requirements* constitutes a violation and is sufficient for an adverse recommendation. Older cases where the hospital implemented corrective actions with no repeat violations may require consultation with the RO concerning appropriate recommendations. *Separately, any patterns identified related to race, color, national origin, age, disability, or sex should be reported to the RO for possible referral to OCR.*

If a team conducted the investigation, the team should meet to discuss the findings. Consider information provided by the hospital. Ask the hospital for additional information or clarification about particular findings, if necessary.

Review each regulation tag number sequentially in this Appendix, and come to a consensus as to whether or not the hospital complies with each stated requirement. The following outline may be helpful in this review. For each

requirement recommended as not met, record all salient findings on the Form CMS-2567.

Outline of Data Tags Used for Citing Violations of Responsibilities of Medicare Participating Hospitals in Emergency Cases

Deficiency Tags	Requirements
A/*C-2*400	§489.20 Policies and Procedures Which Address Anti-Dumping Provisions
A/*C-2*401	§489.20(m) Receiving Hospitals Must Report Suspected Incidences of Individuals With An Emergency Medical Condition Transferred in Violation of §489.24(e)
A/*C-2*402	§489.20(q) Sign Posting
A/*C-2*403	§489.24(r) Maintain Transfer Records for Five Years
A/*C-2*404	§489.20(r)(2); §489.24(j) On-Call Physicians
A/*C-2*405	§489.20(r)(3) Logs
A/*C-2*406	§489.24(a); §489.24(c) Appropriate Medical Screening Examination
A/*C-2*407	§489.24(d)(3) Stabilizing Treatment
A/*C-2*408	§489.24(d)(4) and (5) No Delay in Examination or Treatment in Order to Inquire About Payment Status
A/*C-2*409	§489.24 (e)(1) and (2) Appropriate Transfer
A/*C-2*410	§489.24(e)(3) Whistleblower Protections
A/*C-2*411	§489.24(f) Recipient Hospital Responsibilities (Nondiscrimination)

B. **Composing the Statement of Deficiencies (Form CMS-2567)**. Support all deficiency citations by documenting evidence obtained from your interviews and record reviews on Form CMS-2567, "Statement of Deficiencies and Plan of Correction." Deficiencies related to the Conditions of Participation should also be documented on Form CMS-2567. Indicate whether your findings show that the deficiency constitutes an immediate jeopardy to patient health and safety, *for example*, a situation that prevents individuals from getting medical screening

examinations and/or a lack of treatment reflecting both the capacity and capability of the hospital's full resources, as guaranteed under §1867 of the Act.

Additional examples *that may rise to the level of immediate jeopardy* include stabilizing treatment not provided when required; failure of an on-call physician to respond appropriately; improper *or inappropriate* transfer; or evidence that there was a denial of medical screening examinations and/or treatment to persons with emergency medical conditions as a direct result of requesting payment information before assessment of the individual's medical condition.

Examples of noncompliance which usually does not pose an immediate jeopardy, include the following scenarios:

1. A transfer which was appropriate, but the physician certification was not signed or dated by the physician;

2. An appropriate, functioning central log that on one particular day is not fully completed; and

3. A written hospital policy that is missing, but nonetheless being implemented.

Do not make a medical judgment, but focus on the processes of the facility "beyond the paper." Identify whether single incidents of patient dumping, which do not represent a hospital's customary practice, are nonetheless serious and capable of being repeated. Immediate jeopardy violations require a 23-day termination track. Non-immediate jeopardy violations require a 90-day termination track.

Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. **Do not prescribe an acceptable remedy**. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings. When it is necessary to use specific examples, use individual identifier codes, not individual names.

The emergency services condition, or any other condition, is not automatically found out of compliance based on a violation of 42 CFR §489.20 and/or 42 CFR §489.24. A determination of noncompliance must be based on the regulatory requirements for the individual condition.

X. Additional Survey Report Documentation

Upon completion of each investigation, the team leader assures that the following additional documentation has been prepared for submission, along with Forms CMS-1541B, CMS-2567, *CMS-670*, and a copy of the medical record(s) to the RO:

A. **Summary Listing of Sample Cases and Description of Sample Selection (See Task 2).** At a minimum, identify:

- The name of each individual chosen to be a part of the sample and the date of their request for emergency services;
- Any individual identifier codes used as a reference to protect the individual's confidentiality;
- The reason for including the individual in the sample (e.g., *inappropriate* transfer, lack of screening, lack of treatment, failure to stabilize, *or if identified as part of a pattern of discrimination*; and
- Include a copy of the medical record(s) for all individuals where the hospital violated the provisions in 42 CFR §489.24.

Also identify:

- How the sample was selected;
- The number of individuals in the sample; and
- Any overall characteristics of the individuals in the sample, such as race, color, nationality, handicap, financial status, and diagnosis.

B. **Summary of Interviews (See Task 4)**. Document interviews conducted with patients, families, staff, physicians, administrators, managers, and others. At a minimum, include the individual's job title and/or assignment at the time of the incident, the relationship to the patient and/or reason for the interview, and a summary of the information obtained in each interview.

C. **Complaint Investigation Narrative (See Task 3)**. Summarize significant findings in the medical records, meeting minutes, hospital policies and procedures, staffing schedules, quality assurance plans, hospital by-laws, rules and regulations, training programs, credential files, personnel files, and contracted services reviewed in the course of the investigation. Briefly summarize your findings in the investigation and the rationale used for the course of action recommended to the RO.