

Center for Medicaid and State Operations

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DATE: November 14, 2002

FROM: Director
Survey and Certification Group
Center for Medicaid and State Operations

SUBJECT: Interim Guidance to Support National Pilot of the
ASPEN Complaints/Incidents Tracking System (ACTS)

TO: Associate Regional Administrators, DMSO
State Survey Agency Directors

The implementation of ACTS is critical to our work in assuring that beneficiaries receive quality care in a safe environment. It is necessary that we collect information in a standard format that is accurate, timely and describes concerns associated with the care of Medicare and Medicaid beneficiaries. In addition to States and Regional Offices recommending an automated tracking system, several reports in recent years have highlighted this need. The ACTS is a component of the Quality Improvement and Evaluation System (QIES) and responds to some of the problems found by the GAO and the OIG. The ability to capture data that are useful, analyze this data in a meaningful way, and use the products of the analysis to make refinements and improvements is critical to quality improvement. ACTS provides a mechanism for: better management of complaints, improved oversight of States' processes, tracking responsiveness to the public, and addressing GAO and OIG concerns about inadequate reporting systems for complaints.

On October 15, 2002 we issued a brief memorandum, delaying the implementation of ACTS in production and promising more information. Now, we would like to share with you the reasons for delaying the implementation of ACTS in production, provide you with an implementation plan for a National Pilot of ACTS 6.0, and supply guidance regarding the scope of data entry and definitions for key fields currently in ACTS 6.0.

We delayed the full implementation of ACTS in production because we had learned a great deal during the last several months from States and CMS Regional Offices (ROs)

participating in the pilot, a related policy and procedure workgroup, or both. Based on participant feedback and much discussion, we made revisions to the ACTS 5.5 software and issued ACTS 6.0 to all States in October. In addition, we know that:

- Some States are ready to use ACTS in October;
- Some States want to retain their State systems as it meets their needs, but the burden of dual data entry into ACTS is prohibitive;
- In many States there is a backlog of intakes entered into State systems that have not been investigated, completed, or entered into OSCAR Complaint System and this redundant entry of information in ACTS will impose the burden of recreating intakes to complete the upload process;
- Some States have organizational structures that separate complaint and incident intake information; and
- Variation among States exists regarding what is reported to the State survey agency, what is entered in the system, how a complaint or incident is prioritized, and how the findings are categorized. These differences could impact the reliability of data entered in ACTS, as well as disrupt business operations within States.

On November 15, we begin a National Pilot of ACTS 6.0 for nursing homes (SNFs and NFs), home health agencies (HHAs), end-stage renal disease facilities (ESRDs), and hospitals. The goals of the National Pilot include:

- Promoting a common understanding and building consensus regarding complaint and incident procedures and application of policy;
- Providing States the time necessary to develop internal procedures that support changes to national policies; and
- Identifying further system refinements necessary.

The information provided in the attachments will be used during the National Pilot of ACTS. This information replaces S&C-02-33 issued on June 6, 2002. The attachments are:

- ✓ *Attachment 1* outlines implementation responsibilities.
- ✓ *Attachment 2* provides management procedures to support implementation.
- ✓ *Attachment 3* contains contact information to assist State agencies.

We rely on the continuous participation of all States and Regional Offices during the National Pilot to achieve our goals. Thank you for your support and feedback, as it is paramount to the implementation of ACTS in production.

Effective Date: November 15, 2002

Training: This information should be shared with all survey and certification staff, their managers, QIES coordinators, and State/Regional Office training coordinators.

/s/
Steven A. Pelovitz

Attachments

Interim Guidance to Support Implementation of a National Pilot of the
ASPEN Complaints/Incidents Tracking System (ACTS)
Responsibilities

PURPOSE

Hands-on experience using ACTS will increase proficiency with the software and identify refinements and clarification needed. To facilitate this, specific responsibilities and expectations of all States and CMS regional offices (ROs) as part of the National Pilot of ACTS are described below. (If a State finds the data entry expectation is unreasonable, it should contact the CMS Regional Office.)

ACTS NATIONAL PILOT RESPONSIBILITIES

During the National Pilot of ACTS –

- All States continue to enter data into the OSCAR Complaint System; and
- All States will be required to enter at least 15% of their specified intake, with a minimum of ten intakes per month into ACTS. More specifically, States would have to enter at least 15% of complaints that allege Federal noncompliance and 15% of incidents that are required to be reported by Federal regulations. Complaints and incidents are defined in Attachment 2.

If any of the above intakes leads to an onsite survey, the State uses ACTS to upload the data to the special test area of ODIE for validation purposes, in addition to entering the data into the OSCAR Complaint System.

We recognize that the OSCAR Complaint System captures only a subset of ACTS data. When CASPER, the national reporting component of QIES is operational, we will be able to report on ACTS data nationally.

During the National Pilot each State should indicate to its RO whether complete intake data entered into ACTS should be used for review of the State Performance Standards.

ACTS NATIONAL PILOT TIME FRAMES

November 15, 2002 to February 28, 2003	States enter all complaint surveys into the OSCAR Complaint System.	ACTS National Pilot – All States will enter into ACTS for SNFs, NFs, HHAs, ESRDs, and HOSPITALS at least 15% of their specified intake, with a minimum of ten intakes per month. More specifically, States are asked to enter at least 15% of complaints that allege Federal noncompliance and 15% of incidents that are required to be reported by Federal regulations. Attachment 2 defines complaints and incidents.
March 1, 2003 to May 4, 2003	The OSCAR Complaint System will be turned off for SNFs, NFs, HHAs, ESRDs, and HOSPITALS and all complaint surveys for these provider types will be uploaded to the production OSCAR Complaint System via ACTS. For surveys of SNFs, NFs, HHAs, ESRDs, and HOSPITALS resulting from intakes not captured in ACTS, States will use the “Quick Entry 562” feature of ACTS to capture and upload the required information (CMS-562, CMS-670, CMS-2567) to the production OSCAR Complaint System.	
May 5, 2003 to Future	The “Quick Entry 562” feature will be used for surveys that include intakes received before May 5, 2003.	ACTS must be used for all intakes received after May 5, 2003 for SNFs, NFs, HHAs, ESRDs, and HOSPITALS.

Additional Guidance Regarding Coordination of Complaint Related Responsibilities for Providers/Suppliers Other Than Nursing Homes

When a complaint is received concerning a provider or supplier other than a nursing home, State agencies determine if there is a substantial allegation of noncompliance with a Condition of Participation (CoP) (provider) or Condition for Coverage (CfC) (supplier), and, if so, perform a complaint survey for any Condition(s) which is/are allegedly noncompliant. If the complaint involves a provider or supplier that CMS has deemed to meet the Conditions because of accreditation by an accrediting body that CMS has recognized, the regional office must approve and request a survey of the accredited provider or supplier by the State agency.

The regional office's request for a survey may be a verbal request to initiate the survey followed by a written and/or electronic (through ACTS) request (Form CMS 2802). The State may initiate a complaint survey based on the receipt of the verbal request. The authority to request a survey may be delegated by the regional office manager to a non-manager. Whether the survey is of one or all CoP or CfC, it will be treated as a complaint survey under the ACTS system rather than a recertification survey, because the complaint is the basis for the survey. If, as a result of the complaint survey, the State determines that one or more conditions of a deemed provider or supplier are noncompliant, it may discuss the situation with the RO to determine when to perform a full survey of the facility.

If the State agency determines as a result of the complaint survey that the provider or supplier, other than a nursing home, has one or more noncompliant CoP or CfC, it will conduct a survey of all COP regardless of whether the provider/supplier is accredited by a CMS recognized accrediting body. Before a full survey is conducted, the RO must remove the provider's or supplier's deemed status. (In an HHA a partial extended or an extended survey is conducted.) If a complaint survey covering all CoP or CfC is conducted within 3 months of a scheduled recertification survey it may be used in lieu of the recertification survey.

The RO notifies all providers and suppliers of all enforcement action that arise from complaint surveys that result in the facility being determined to have one or more noncompliant CoP/CfC, and/or there is a finding of immediate jeopardy.

Continue to follow the existing SOM rules and protocols for handling cases of immediate and serious threat to patient health and safety (SOM 3010-3012), survey and certification guidance (SOM 2724-2778), investigation of complaints against accredited providers/suppliers (SOM 3260-3276) and investigation of complaints against non-accredited providers/suppliers (SOM 3280-3298) among others.

Interim Guidance to Support Implementation of a National Pilot of the
ASPEN Complaints/Incidents Tracking System (ACTS)
Procedures

PURPOSE

The following information provides interim instructions and procedures, along with definitions for the key fields in ACTS 6.0 System to be used by States and CMS Regional Offices during the National Pilot phase for SNFs, NFs, HHAs, ESRDs, and hospitals. Based on workgroup participation, some fields in ACTS 5.5 have been revised; ACTS 6.0 reflects the changes. All States and CMS Regional Offices should continue to evaluate this guidance during the National Pilot. The guidance may be revised, if necessary. The guidance will be issued as a Survey and Certification numbered policy letter prior to full implementation of ACTS in production.

PROCEDURE GUIDANCE

Scope of ACTS and Complaint/Incident Processing Requirements for SNFs, NFs, HHAs, ESRDs, and HOSPITALS

- Complaints, as defined below, that relate to the violation of Federal conditions of participation, conditions for coverage or requirements for participation for providers and suppliers are entered into ACTS. During the National Pilot, at least 15% of these complaints should be entered into ACTS.
- Incidents, as defined below, mandated by Federal requirements to be self-reported are entered into ACTS. During the National Pilot, at least 15% of these incidents should be entered into ACTS.
- ACTS includes complaints and incidents received by the State survey agency, a separate complaint unit within the State government, or the Federal Regional Office (RO); and
- If the intake information received requires an onsite survey and the allegation may involve both Federal requirements and State licensure requirements, a Federal onsite survey is completed and entered into ACTS, at a minimum.

Definitions for Key Fields in ACTS

Key fields in ACTS 6.0 are described below to facilitate a better understanding of the expectation for information entered into ACTS and how that information is categorized.

Intake Type and Intake Subtype

The 'Intake Type' field in ACTS 6.0 offers two choices: 1) *Complaint* and 2) *Incident*. To appropriately categorize the scope of information entered into ACTS and to provide States with a system that may be used to capture State specific information, there are

several intake subtypes under each intake type. Intake information meeting the definition of certain Intake Subtypes is required while other Intake Subtypes remain optional. The following definitions are used to guide data input at the Intake Type and Intake Subtype fields of ACTS 6.0:

1) *Complaint*

A *complaint* is a report made to the State survey agency or CMS Regional Office 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. Complaints are further categorized into the following three subtypes:

- A) *Federal COPs, CFCs, RFPs, EMTALA*: The complaint alleges 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 complaints that allege noncompliance with Federal requirements only or both Federal and State requirements. **(States and ROs are required to enter these cases into ACTS.)**
- B) *State-only, licensure*: The complaint alleges noncompliance with State licensure requirements only. **(States have the option to enter these cases into ACTS during the National Pilot.)**
- C) *No State or Federal provider compliance issue involved*: The complaint does not appear to allege a provider's or supplier's noncompliance with Federal or State requirements. **(States have the option to enter these cases into ACTS during the National Pilot.)**

2) *Incident*

An *incident* is an official notification to the State survey agency or CMS Regional Office 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. Incidents are further categorized into the following five subtypes:

- 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. **(States are required to enter these cases into ACTS.)**
 - 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). **(States are required to enter these cases into ACTS.)**

- 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 State survey agency. 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 State survey agency must follow its complaint policies and procedures to investigate incidents of this type. **(States have the option to enter these cases into ACTS during the National Pilot.)**
- 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 State survey agency. This type of incident does not imply noncompliance with Federal conditions or requirements. **(States have the option to enter these cases into ACTS during the National Pilot.)**
- 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 State survey agency. Example: An investigative report from an outside agency. (States have the option to enter these cases into ACTS during the National Pilot.)
- 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. **(States have the option to enter these cases into ACTS during the National Pilot.)**

Received Date

At the intake tab in ACTS 6.0 the *Received* date and time is completed using the following guidance:

Start Date: _____ *Time:* _____ The start date is the date of the telephone call or electronic correspondence; or, the date stamped by the State agency or CMS Regional Office receiving office of the written correspondence.

End Date: _____ *Time:* _____ The end date is the date the SA or RO has sufficient information to prioritize the complaint or incident. It is used for those infrequent situations, in which more information is needed before the complaint or incident priority can be assigned. By default, the End Date and Time is equal to the Start Date and Time. However, in ACTS 6.0 the Received End Date must not be greater than 7 days from the Received Start Date.

Linking an Intake with a Previously Conducted Survey

ACTS 6.0 permits a complaint or incident to be linked to a previous survey if the complaint/incident was received within 30 days of the survey date. We expect that this would happen infrequently and only after careful and professional review of the nature and timing of the complaint and incident information received. However, when considering substantiating an intake with a previously completed survey, the following factors must be thoroughly evaluated:

- Were the same events investigated?
- Did the previously completed survey evaluate the appropriate individuals?

If the response to both questions is “Yes”, the complaint or incident intake could be linked to a previous survey.

Priorities

ACTS 6.0 provides the following choices for prioritizing a complaint or an incident. Priorities: IJ (Immediate Jeopardy); Non-IJ- High; Non-IJ- Medium; Non-IJ- Low; Non-IJ-Administrative Review/Offsite Investigation; Referral-Immediately; Referral-Other; and No Action Necessary. All complaints and incidents are prioritized. The priority choices in ACTS accommodate the ability to distinguish incidents needing further action or an onsite survey from those incidents requiring no further action.

These choices are defined as follows:

- A. *Immediate Jeopardy* – Complaints/incidents assigned this priority indicate that 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. The Appendix Q of the State Operations Manual contains further guidelines. In situations where a determination is made that immediate jeopardy may be present and ongoing, the State is required to investigate within two working days of receipt of the information. For hospital EMTALA complaints, the investigation is completed within five working days after receipt of the authorization from the Regional Office.
- B. *Non-Immediate Jeopardy - High*: Complaints/incidents assigned this priority indicate that the provider’s or supplier’s noncompliance with one or more conditions or requirements may have caused, or is likely to cause a significant problem in care and treatment. (For nursing homes, if the State agency makes the determination that a higher level of actual harm may be present, the onsite survey is to be initiated within 10 working days of its receipt.)
- C. *Non-Immediate Jeopardy - Medium*: Complaints/incidents assigned this priority indicate that the provider’s or supplier’s noncompliance with one or more conditions or requirements, although not causing actual harm, may impact the care and treatment of residents and patients. Non-EMTALA hospital and non-immediate jeopardy complaints for providers with deemed status require an onsite survey within 45 working days after approval by the RO.
- D. *Non-Immediate Jeopardy - Low*: Complaints/incidents are assigned this priority for situations that allege no substantive impact to the health or safety of the residents, patients, or clients and an onsite survey would be conducted within 120 days.
- 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 State agency or CMS regional office to the provider may be needed to ensure compliance with the Federal requirements.
- F. *Referral – Immediately*: Complaints/incidents are assigned this priority if the seriousness of a complaint/incident and/or State procedures requires referral or reporting to another agency or board immediately for investigation. Regardless, the State Agency has the responsibility to assess the facility’s compliance with Federal requirements.

- G. *Referral - Other*: Complaints/incidents assigned this priority indicate referral to another agency or board for investigation or for informational purposes. Regardless, the State Agency has the responsibility to assess the facility's compliance with Federal requirements.
- H. *No action necessary*: Adequate information has been received about the incident/complaint and no further investigation, analysis, or action is deemed necessary.

Investigate within ____ days: A numerical time frame is entered to support the priority selected above for conducting an onsite survey or further investigative action.

Investigation Due By: A corresponding calendar date is entered. The system will not accept a date later than 120 calendar days from the 'End Received Date.'

Complaint count

Received by: Intakes are counted from this field. The choices are E-mail, In-person, Telephone, Written, Media, Hotline, Fax and Other. For example, if one person calls with ten allegations about one provider, this is counted as one complaint. If six persons call with the same allegation, there are six telephone calls and ACTS counts this as six complaints. If one letter is received with one or many allegations and signed by 20 persons, it is counted as one complaint.

Allegation Findings:

Findings are entered for each allegation. The choices in ACTS 6.0 for findings are 1) *Substantiated* and 2) *Unsubstantiated*. The Types and Subtypes for *Substantiated* and *Unsubstantiated* are defined as follows:

1. 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 State survey agency 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.

2. 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 State survey agency 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.

Overall Findings

The *Overall Findings* field in ACTS 6.0 is automatically calculated. The Overall Findings are either 1) Substantiated; 2) Unsubstantiated; or 3) Not Applicable (Incident).

Investigation Completed

The *Investigation Completed* date is the date that the result of the investigation is issued to the provider or supplier.

The ACTS 6.0 tracks the closure of complaint and incident files at the Actions/Close Tab. *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 State or CMS Regional Office 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 is the date associated with the latest above action.

Personal Identifiable Fields

In response to requests from the States, we have included personal identifiable fields in ACTS. Each State must adhere to its State laws as it collects and maintains data 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/aspdownload.html.

POINT OF CONTACT IN EACH CMS REGIONAL OFFICE

All State agency comments and concerns 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 during the National Pilot 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
IX	Richard Shirasawa	415-744-3712 RShirasawa@cms.hhs.gov
X	Demetra Kossligk	206-615-2314 DKossligk@cms.hhs.gov