**DEPARTMENT OF HEALTH & HUMAN SERVICES** Centers for Medicare & Medicaid Services

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**Ref: S&C-02-33**

**DATE**: **June 6, 2002**

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

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

**TO:** Associate Regional Administrators, DMSO
State Survey Agency Directors

We want to thank the regional office (RO) and State agency staffs participating with central office and its contractor in the development of the ASPEN Complaints/Incidents Tracking System (ACTS). The hard work spent in the development of the automated system and the identification of critical programmatic issues is recognized and greatly appreciated.

To support the implementation of ACTS and other complaint procedure related activities, we have formed two groups. We will be working closely with seven-selected pilot States and the corresponding regional offices to monitor and evaluate the implementation of ACTS from system, policy and workload perspectives. A second workgroup comprised of State agency, regional office, and central office staff will provide expertise and input into the design of program implementation and the development of sound national procedures related to complaints.

The implementation of ACTS is critical to our work in assuring that beneficiaries receive quality care in a safe environment. In addition to States and ROs 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 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.

The new system will be implemented in two phases. The first phase is the ACTS pilot. The second phase is the implementation of ACTS in production. State and CMS representatives have identified guidance that must be provided at the outset to assure

ACTS is used consistently during the pilot phase. Attached is the interim guidance to facilitate successful implementation of the ACTS. This guidance will be reviewed and revised as necessary, and issued in final at the end of the pilot phase.

**Effective Date: June 6, 2002**

/s/
Steven A. Pelovitz

Attachment

Attachment

**Interim Guidance to Support Implementation of the ASPEN Complaint/Incident Tracking System (ACTS)**

## PURPOSE

This interim guidance, used during the pilot phase of ACTS implementation (June 3, through September 30, 2002) includes complaint procedures and data elements identified by State and CMS representatives that must be addressed at the outset to assure consistent data input into ACTS. This guidance includes: specific pilot State responsibilities; and responsibilities of all States and regional offices (ROs), time frames for data input; the scope of ACTS and complaint procedures; the required fields to be completed; and clarification of terms necessary for consistent data input. We will be reviewing this guidance during the pilot phase and revising, as necessary, before October 1, 2002.

## ACTS IMPLEMENTATION RESPONSIBILITIES

The new system will be implemented in two phases. The first phase is the ACTS pilot. The pilot phase of implementation has implications for all States and ROs. During the week of May 20-24, 2002, ACTS was released to all States and ROs.

- Throughout the pilot phase, all States continue to enter data into the OSCAR Complaint System.
- To promote familiarity, all States and ROs are strongly encouraged to enter some live data into ACTS for skilled nursing facilities (SNFs), nursing facilities (NFs), home health agencies (HHAs), end-stage renal disease facilities (ESRDs) and hospitals.
- A select group of States (pilot States) has agreed to assume additional responsibilities.
    - The pilot States are: District of Columbia, North Carolina, South Carolina, Minnesota, Colorado, California and Oregon.
    - The pilot States will enter live data into ACTS and continue to enter data into the OSCAR Complaint System.
    - The selected pilot States will participate in weekly conference calls so that we can monitor and evaluate the implementation of ACTS from system, policy and workload perspectives.
- The CMS ROs for the pilot States will participate in weekly conference calls to monitor and evaluate ACTS during the pilot phase.

The second phase is the implementation of ACTS in production.

- Effective October 1, 2002, the use of ACTS will be <u>mandatory</u> for <u>all</u> States and ROs for the following provider/supplier types: SNFs, NFs, HHAs, ESRDs, and hospitals.
- Additional provider and supplier types will be phased in during future releases of ACTS.

- For SNFs, NFs, HHAs, ESRDs, and hospitals, States and ROs continue to use the OSCAR Complaint System for updates on complaints entered directly in the OSCAR Complaint System prior to October 1, 2002.

## ACTS IMPLEMENTATION TIME FRAMES

| | | | |
|---|---|---|---|
| ACTS released to all States and ROs | 5/20/02 | through | 5/24/02 |
| States & ROs load ACTS | 5/20/02 | through | 6/3/02 |
| *Non-pilot States encouraged to enter data into ACTS | 6/3/02 | through | 9/30/02 |
| *Pilot States enter data into ACTS & OSCAR Complaint System | 6/3/02 | through | 9/30/02 |
| Weekly conference calls with pilot States and corresponding ROs | 6/10/02 | through | 9/30/02 |
| Evaluate pilot phase - system/policy/workload | 6/10/02 | through | 9/30/02 |
| ACTS is mandatory in all States for selected providers/suppliers** | | | 10/1/02 |
| OSCAR Complaint System 'Adds' turned off for selected provider types** | | | 10/1/02 |
| OSCAR Complaint System 'Updates' remain active for selected provider types** | | | 10/1/02 |

** All States and ROs continue to enter data into OSCAR Complaint System - 6/3/02 through 9/30/02*

***Selected provider types are SNFs, NFs, HHAs, ESRDs, and hospitals*

## SYSTEM ASPECTS OF ACTS IMPLEMENTATION

The ACTS automates complaint management operations. It is a window based, client/server application that processes, tracks and reports on complaints against health care facilities. It is designed to manage all operations associated with complaints processing from initial intake and investigation through final disposition. It is fully integrated into the QIES standard system architecture. It is configurable by individual States to accommodate a variety of operational environments. It integrates with ASPEN Central Office (ACO), ASPEN Regional Office (ARO), ASPEN Survey Explorer (ASE), and will integrate with the future enforcement module of QIES.

The features of ACTS include intake capture, allegations tracking, investigation, survey and citation integration and distribution, referrals, and resolution. The system generates required forms (CMS-562, CMS-2567, CMS-2567B, CMS-670, CMS-2802). It can track contacts, witnesses and referrals. The ACTS provides templates for some complaint related form letters. It provides complaint and survey related reports to support our accountability and analysis requirements. For example, States and ROs will be able to generate standardized management reports about volume of complaints, detailed information about a facility, complaint history by allegation type, complaint intervals, and complaint resolution reports.

We encourage all State agencies and CMS ROs to use ACTS to input real data. This ensures all functional areas of the system will be available to States and ROs, especially the important areas in which ACTS and ACO share functionality and data. This provides all States the opportunity to review the system with respect to their own procedures. The production database in each State will be upgraded with the full database patch which implements both ACTS pilot functionality and production level enhancements and fixes to ACO, ARO, and ASE. This implementation will

support upload transactions from both ASPEN (SNF, NF and HHA) and ACTS. The nursing home and HHA certification data from ASPEN will be processed into the ODIE production region as usual. However, during the pilot, complaint transactions will be separated and processed into the OSCAR Complaint System test region, and States will continue to enter CMS-562 and related survey data into the OSCAR Complaint System.

The transition from the ACTS pilot phase to the production phase is scheduled to occur on October 1, 2002. All complaint data gathered during the pilot phase will remain on the State servers.

**PROCEDURE GUIDANCE**

Scope of ACTS and Complaint/Incident Processing Requirements

- State survey agencies (SAs) and Regional Offices (ROs) are required to enter into ACTS all allegations that relate to the violation of Federal conditions of participation, conditions for coverage or long-term care requirements for providers and suppliers whether or not the allegations would result in an on-site complaint survey; **and**
- ACTS includes allegations received by the State survey agency, a separate complaint unit within the State government, or the Federal RO; **and**
- If the allegation requires an on-site survey and the allegation may involve both Federal requirements and State licensure requirements, a Federal on-site complaint investigation is completed and entered into ACTS, at a minimum.

Currently at the 'Intake Type' field in ACTS, the scope of information entered into the system can be categorized. The three selections are: 1) Complaint, 2) Entity Reported Incident and 3) Incident Upgraded to a Complaint. During the pilot phase, to appropriately categorize the scope of information entered into ACTS, the following definitions are applied to the current fields. Incidents and complaints meeting the descriptions below are entered into ACTS:

*1) Complaint*
A complaint generally alleges noncompliance with Federal conditions of participation, conditions for coverage or long-term care requirements. A complaint is generally communicated to the State SA by a third party, such as a beneficiary, family member of a beneficiary, concerned citizen, an organization, other government entity, or an employee of the facility who contacts the State SA without the knowledge or sanction of facility management. During the pilot phase, State licensure only complaints are not entered into ACTS.

*2) Entity Reported Incident*
An entity reported incident is an official self reported notification from a provider or supplier that may result in noncompliance with a Federal condition of participation, condition for coverage or long-term care requirement. Entity reported incidents meeting this definition include: a) those incidents that are currently required by Federal participation requirements to be reported; and, b) incidents required by the State to be reported and these self reported incidents may result in noncompliance with the Federal participation requirements.

*3) Incident upgraded to a complaint*
This field will **not be used** because ACTS accommodates this action. By completing the 'Complaint Priority' field properly, the user is able to document the disposition of the complaint or incident. In other words, we will know that an 'Entity Reported Incident' became an 'Incident Upgraded to a Complaint' by the manner in which the current 'Complaint Priority' field is completed. Checking the appropriate 'Complaint Priority' box using the following definitions provides the necessary information.

If the 'Complaint Priority' of:

- 'Immediately', '2 Working Days', 'Within 5 days of RO approval', 'Within 10 working days', 'Within 45 working days', or 'Next on-site' is selected, the priority selection indicates that further action is necessary.
- 'None' is selected, adequate information has been received about the incident or complaint and no further investigation, analysis, or action is necessary.
- 'Referral' is selected, the complaint or incident is referred at the outset and no further investigation or action on the part of the State SA seems warranted.
- 'Other' is selected, an on-site survey is not necessary but other investigatory action is necessary.

We will use the 'Complaint Priority' fields as described above for the pilot phase; however, for the October release, we may modify the name of the field and choices available to complete the field.

Timeframe for data entry into ACTS
States and ROs are expected to enter data on an ongoing basis from the point of intake of the allegation until the complaint is finalized.

Complaint count
Complaints are be counted by method of intake. The Intake screen of the ACTS contains a field titled "Received by." The choices or drop down options for completing the "Received by" field are walk-in, telephone, written, media, hotline, facsimile, other. Complaints are counted from this field. 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.

Required fields
The ACTS allows both CMS and the States to effectively monitor the investigation of complaints. To perform a more complete assessment of the complaints received, their investigation, and the States' complaint processes, we are requiring that additional data elements (beyond the current Medicare/Medicaid/CLIA complaint form - CMS Form 562) be entered into ACTS. Below is a summary and description of the required fields to be entered into ACTS.

***Intake:*** These fields capture the type of complaint, the complainant(s), and the complainant's narrative details. The date and time of intake are automatically captured as the data is entered into the system. The prioritization level of the complaint may also be set at this time.

***Allegations:*** These fields capture data on the allegation and the categorization of each finding. The categorization of the findings is discussed below under "**Additional Guidance**."

***EMTALA:*** This tab captures information specific to EMTALA complaints regarding the type of emergency, date of RO approval for a survey conducted by the State, and dates for cases referred to the Quality Improvement Organization (QIO). This information is currently being collected and maintained manually by CMS RO and CO staffs.

***Accredited facilities:*** Investigations of complaints against accredited providers are considered validation surveys under the statute. The Regional Office determines whether a survey is to be performed and prepares a CMS-2802, Request for Validation of Accreditation Survey, and forwards it to the State agency. This process is used to authorize the survey and to identify those areas of the provider's operations that are to be investigated. These procedures also apply to allegations of patient dumping under EMTALA by an accredited hospital. With ACTS, the RO enters the appropriate information (or reviews the information entered by the State agency if the State receives the compliant), and the RO authorizes the survey by indicating that a survey is required in the ACTS system. Hence, there is no longer a need for the paper copy of the CMS-2802 to be forwarded to the State agency. The State SA and CMS RO need to coordinate this activity during the pilot phase to assure clear communication involving the CMS-2802 process.

***Investigation:*** This component of ACTS logs the actions and dates of the actions that are taken throughout the complaint process. ACTS records the date the CMS-2567 is issued, the date the Plan of Correction (POC) is approved, the date an Informal dispute Resolution (IDR) is requested, the date the State sends out the complaint packet to the RO/MSA, and the date the provider/supplier is in compliance with Federal requirements. Data from this tab are used to generate Federal survey and workload reports.

***Referrals/Letters/Notices:*** States record in ACTS at least the addressee and date sent for the following types of correspondences:

- ✓ Acknowledgement to the complainant of receipt of the complaint
- ✓ Referrals made to other agencies or organizations
- ✓ Notice of the investigation results to the provider and to the complainant

***Finalization:*** All Federally proposed and imposed actions and dates are recorded in ACTS, along with the reason and date the complaint was closed by the survey agency and the RO.

<u>Optional fields</u>

Although the following fields are available for use, they are not required by CMS at this time:

Ø State-specific fields, including control numbers, State licensure requirements, or State actions
Ø Allegation subtypes
Ø POC Tracking information
Ø Contacts made for requests for information
Ø Witness lists
Ø Text from correspondences sent from the survey agency or CMS ROs
Ø Hot line feature

Some of the tabs and fields related to complainants, affected patients/residents and alleged perpetrators are hidden at this time pending the completion of the development of a System of Records. The Privacy Act of 1974 requires Federal agencies to implement and publish

procedures for the collection, maintenance and storage of personal information. It requires that the information be gathered only for lawful purposes and that the disclosure of personally identifiable records must be limited and safeguarded. In accordance with the Privacy Act, we are developing a System of Records (SOR) for ACTS. The SOR requires approval by the Office of Management and Budget and the Congress, and publication in the Federal Register. The SOR identifies personably identifiable information and the routine uses of records maintained in the system, including entities that may receive disclosure and the purposes of such uses.

**ADDITIONAL GUIDANCE**

Categorization of investigative findings

The State Operations Manual at §3281 currently defines a complaint record as one of four types:

- Substantiated with deficiencies
- Substantiated with no deficiencies
- Unsubstantiated with unrelated deficiencies
- Unsubstantiated with no deficiencies

Findings are entered for each allegation. The ACTS captures more precise information about the categorization of findings. The current ACTS categories are:

- Substantiated: Deficiencies related to the allegation
- Substantiated: No deficiencies
- Unsubstantiated: Allegation did not occur
- Unsubstantiated: Lack of sufficient evidence
- Unsubstantiated: Allegation occurred but it is not a violation of a Federal requirement
- Unsubstantiated: Deficiencies in unrelated areas
- Unsubstantiated: Referred to appropriate agency

We will evaluate the findings categories and their explanations during the pilot phase and revise, as necessary. However, the following explanation for each field will be applied during the pilot phase:

**1. SUBSTANTIATED -** Violation of Federal requirement(s), condition(s) of participation or condition(s) for coverage related to the allegation occurred.

A. Substantiated: Deficiencies Cited Related to the Allegation

The complaint investigation determined that the allegation(s) did occur, and deficiency (ies) related to the allegation is cited. Deficiencies related to the allegation are cited because noncompliance of the entity was determined based: 1) on the finding about the individual named by the complainant in his/her allegation or 2) on the finding about other residents or patients reviewed even if the noncompliance was corrected for the specific individual(s) named by the complainant in the allegation.

For nursing homes only, when Tag F698 is cited on the CMS-2567 for egregious 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. Substantiated: No Deficiencies Cited
The complaint investigation determined that the allegation(s) did occur. However, at the time of the investigation: (1) the facility had taken the actions necessary to correct and prevent the deficient practice, and/or (2) allegation(s) were not serious enough to warrant citing Federal deficiencies. No Federal deficiencies are cited.

**2. UNSUBSTANTIATED -** No Federal deficiencies related to the allegation were substantiated.

A. Unsubstantiated: Allegation did not occur
Evidence indicates that the allegation did not occur.

*Example: An allegation is received that a resident fell from his bed and sustained injuries. The survey agency investigates and finds that there is no documentation that the resident ever fell, the resident has no bruises or other indications of falling, the staff do not recall a fall, and the resident, who is able to communicate, says he never fell out of bed. The survey agency reviews other resident records and observes a sample of other residents at risk for falls. No other instances of falls are recorded or observed. No other deficiencies are cited during the complaint survey.*

B. Unsubstantiated: Lack of sufficient evidence to substantiate the allegation
None of the allegations reported were verified because of insufficient evidence.

C. Unsubstantiated: Allegation occurred, but not a violation of a Federal requirement
A violation of a State licensure only requirement is captured here.

D. Unsubstantiated: Deficiencies in unrelated areas
None of the allegations reported is verified; however, Federal deficiencies were observed and cited in other areas that were not related to the original allegations being investigated.

E. Unsubstantiated: Referred to appropriate agency.
During the evaluation of the complaint a referral to the appropriate agency is made when the allegation is beyond the scope of the Federal requirements and an onsite complaint investigation is not conducted. However, it is possible that after an onsite complaint investigation, it is determined that the complaint allegation must be referred to an appropriate agency, such as, Occupational Safety and Health Administration (OSHA) or Office for Civil Rights (OCR).

Define complaint results: Consistent with the current completion of the CMS-562, if a complaint contains more than one allegation, the overall complaint result in ACTS is classified as one of the following:
1) Substantiated - A complaint result is considered substantiated if at least one allegation has been substantiated because a violation of Federal requirement(s), condition(s) of participation or condition(s) for coverage related to the allegation occurred.

2) Unsubstantiated - A complaint result is considered unsubstantiated when none of the allegations in the complaint record are substantiated and no Federal deficiencies related to the allegation were substantiated.
3) Not Applicable - A complaint result is considered not applicable if only State licensure allegations are logged for the complaint.

**AVAILABLE HELP**

If you have any questions or comments regarding these guidelines, please do not hesitate to e-mail the help line at ASPEN_HELP@IFMC.ORG or call to 1-888-477-7876. The help line will direct any policy questions to the appropriate CMS staff.

Again, your participation and support is paramount during the pilot phase. We hope that this interim guidance is helpful to you as you enter data into the ACTS. Thank you.