DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations / Survey & Certification Group

Admin Info: 07-06

DATE: **January 12, 2007**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Release of Federal Documents by the State Survey Agency (SA)

Letter Summary

This memorandum provides guidance to States on the disclosure of Federal documents that are:

(1) Maintained by the SA on Medicare or dually-certified providers (both long-term care and non long-term care) as a result of implementation of its Agreement with the Secretary, Health and Human Services under §1864 of the Social Security Act (§ 1864 Agreement), and

(2) Accessible to SAs through the Automated Survey Processing Environment System (ASPEN), ASPEN Enforcement Manager System (AEM), Complaints/Incident Tracking System (ACTS), and Online Survey Certification & Reporting System (OSCAR)/ Online Data Input & Edit System (ODIE).[1]

Federal Documents Maintained by the SA

[1]The contractual and policy framework for this guidance is as follows:

- Articles III and XIII of the §1864 Agreement. These articles provide the overall framework within which SA disclosure decisions are governed. Specifically, Article III provides that States "shall comply with regulations and general instructions as the Secretary may prescribe for the administration of this Agreement." Article XIII, titled "Confidential Nature and Limitations on Use of Information and Records," further provides that the "State shall adopt policies and procedures to ensure that information contained in its records and obtained from the Secretary or from any provider or supplier of services will be disclosed only as provided in the [Social Security] Act or regulations." Article I of the § 1864 Agreement defines "Act" to be Title XVIII of the Social Security Act. Article XIII, therefore, incorporates Title XVIII of the Social Security Act and the regulations that implement Title XVIII.

- Sections 3300–3320 and 7900–7907 of the State Operations Manual (SOM). These instructions apply to the handling and disclosure of Federal documents.

- NOTE: Certain Federal and State records may be subject to 45 CFR Parts 160–164 (HHS' Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule). This letter does not address the specific requirements of the HIPAA Privacy Rule.

Section 3304 of the State Operations Manual (SOM) states that the SA should distinguish between information and documents obtained as an agent of the Centers for Medicare & Medicaid Services (CMS) and those documents the State independently acquires through a State program.

Information and documents that the State independently acquires through a State program must be handled under State law because the documents are State, not Federal, records. For example, requests for survey or certification documents for **Medicaid**-only providers would fall under applicable State open records laws because such records are State, not Federal, records.

However, information and documents the SA acquires solely in its role as an agent of CMS are subject to CMS disclosure rules. This means that the SA must comply with 42 CFR Part 401, 45 CFR Part 5, SOM §§ 3300 through 3320 and SOM §§ 7900 through 7907 in responding to requests for such documents. The SA, if it has not already done so, must adopt policies and procedures for the handling and disclosure of Federal records that comport with the cited regulations and instructions. Such policies and procedures should be developed in partnership with the Regional Office (RO) and include the involvement of the RO Freedom of Information Act (FOIA) Coordinator.

Documents the SA May Release

***Form CMS-2567 for Surveyed Providers and Suppliers (Other than SNFs or NFs)*:** The SA may release the Form CMS-2567 consistent with the provisions contained within this paragraph. Disclosure of any Form CMS-2567 that the State generates on a provider or supplier must comply specifically with 42 CFR 401.126(b)(1), 42 CFR 401.133(a), SOM § 3308A and SOM § 3314. This means that, when requested:

1. Prior to release, the provider must have had an opportunity to review the report (not exceeding 60 days) and offer comments within the overall time frames cited below.
2. Prior to release, the report must have been provided to CMS (through ASPEN), and the disclosure made within 30 days of CMS's receipt of the report.
3. The disclosure must be made within 90 days following completion of the survey by the SA.
4. Pertinent written comments, if received from the surveyed provider within the time frames above, must be disclosed with the report.
5. Individual identifiers within the report (of patients, health care practitioners, or others) must be deleted (this does not include alphanumeric patient/resident or staff identifiers).

Releasable Information on SNFs and NFs: Per 42 CFR 488.325 and SOM §§ 7900 and 7903A disclosure of SNF and NF results is made within 14 calendar days after such information is made available to those facilities. Plans of corrections are made available when approved (42 CFR 488.325(a)(3)). Additional releasable information/records are set forth at §7900.

Other Releasable Records on Surveyed Providers and Suppliers (including SNFs and NFs): SOM §§ 3308 and 3308A describe additional information that States may disclose directly to the public, upon request, including:

1. Whether a facility does or does not participate in the Medicare/Medicaid/CLIA program;

2. The Official Medicare/Medicaid/CLIA report of a survey **except** to the extent that it contains:

- The name of any patient;
- Medical information about any identifiable patient;
- The identity of a complainant;
- The address of anyone other than an owner of the facility; or
- Information which could be defamatory toward any identifiable person.

NOTE: The SA reviews the report of survey (CMS Form-2567), and if it contains any of the above elements, it deletes the information from the report by blocking it out fully prior to release of the report. (See 42 CFR 401.118)

3. Citations of deficiencies that have been conveyed to the provider following a survey, except to the extent the report contains any of the identifiable information listed above. The SA blocks this information out prior to release of the statement of deficiencies;

4. Plan of Correction (PoC) and pertinent comments submitted by the provider relating to Medicare/Medicaid/CLIA deficiencies cited following a survey, except to the extent the PoC or comments contain any of the identifiable information listed above. The SA blocks this information out prior to release of the PoC;

5. Official notices of involuntary provider termination (including alternative remedies);

6. Reports and information about a laboratory's performance in proficiency testing programs (Note: information about any individual person's performance may <u>not</u> be released);

7. Information contained within the CMS manuals distributed to the SAs, intermediaries, carriers, providers, or suppliers; and

8. Statistical data on provider characteristics that do not identify any specific provider or individual.

9. CMS-116, CLIA Application for Certification; however, the name of the laboratory director must be blocked prior to the release of the application. CMS-209, Laboratory Personnel Report (CLIA), <u>may not be released.</u>

Paper or electronic copies of these Federal electronic documents may be released by the SA. Again, any individual identifiers (other than patient/resident or staff alphanumeric identifiers) must be deleted from the information prior to release.

***Releasable By Agreement*:** SOM § 3318 states that confidential certification information may be released by the SA to another State component, or to a county or other local entity which performs survey functions for the SA. However, the SA must first obtain an agreement by the component or other entity to use the information for certification or licensure purposes with the understanding that such information may not be released to another party.

***Information Releasable to Original Source*:** SOM § 3316 states any party is entitled to information which that party originally supplied. For example, copies of medical records obtained during a survey can be released to the facility during the informal dispute resolution process.

Disclosure Requests Requiring Consultation With and Possible Submission to Regional Office

Section 3320 of the SOM directs the SA to obtain advice from the RO when a request is received for confidential Medicare information under circumstances other than as permitted by § 3308. CMS considers surveyor notes, worksheets, internal working papers, and other informal survey memoranda by the SA as covered by Article XIII of the § 1864 Agreement because these records embody information obtained from providers. Thus, the SA should consult the CMS RO with respect to the disclosure of these and other applicable documents. During this consultation, it should be clarified whether the records were generated and gathered solely for Federal purposes to comply with the § 1864 Agreement. If they were, the requested records are Federal records that are under the control of CMS. Under § 3314 of the SOM, in this situation, the SA is to decline to disclose the requested records, and direct the requester to contact the RO for those records. If the documents were not solely gathered for Federal purposes, see the paragraph below on *Documents Maintained by the SA for Joint Federal/State Use*.

The SA is to immediately forward to the RO any legal request for records, including subpoenas duces tecum and State court orders that are in the nature of a protective order, if the SA is not authorized to release the records under SOM §§ 3308, 3308A, 3314, 7900 and 7903A, which are discussed above in this letter.

Documents Maintained by the SA For Joint Federal/State Use

SOM §3304 states that when the SA obtains a record that is not in the public domain and is held for joint use by CMS and other State or Federal programs, the SA must apply the most restrictive confidentiality policies of all the programs to which the information relates.

> **Example**: A given Form CMS-2567 on a hospital is held for joint use by CMS and the State. Under State disclosure law, survey findings are releasable before a plan of correction is received. Under Federal law, the surveyed provider must be given a reasonable opportunity (not exceeding 60 days) to review the report and offer comments which may be incorporated into the report; and the report must be furnished to CMS. In this situation, the SA's disclosure must be based upon Federal law.

Under other circumstances, it is permissible for a SA to apply State law that is more stringent than Federal law.

> **Example**: Federal law requires the SA to delete the identity of individuals from the Form CMS-2567 prior to release. However, State law requires the deletion of additional information to ensure that the individual's identity is protected. In this situation, because the State's disclosure law is more stringent than Federal law, the SA's disclosure must be based upon State law.

In each State, the staff designated to release documents should be aware of: 1) Federal documents that are maintained by the SA; 2) Federal documents the State is authorized to release; and 3) the identity of the RO individual for consultation purposes.

Documents Accessible to the SA through Electronic Systems

Federal survey and certification systems, including ASPEN, AEM, ASPEN Central Office (ACO), ACTS, and OSCAR/ODIE originate from the Federal government. Generally speaking, when the SA enters individual files into these systems, it is as an agent of CMS. Therefore, any Federal electronic documents retrieved from these databases and the databases themselves may not be released by the State unless authorized to do so by CMS.

If you have any additional questions regarding this matter, please contact Melodye Hardy, Freedom of Information Officer, CMS, at (410) 786-5358.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this announcement should be shared with all State agency staff and supervisors designated to release documents.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management