

MEMORANDUM
Texas Department of Human Services

TO: Long Term Care-Regulatory
Regional Directors and State Office Managers

FROM: Susan Syler, Acting Unit Director
Long Term Care-Regulatory Policy
State Office MC: W-519

SUBJECT: Regional Survey & Certification Letter #03-01

DATE: March 14, 2003

The attached RS&C Letter is being provided to you for information purposes and should be shared with all professional staff.

- RS&C Letter No. 03-01 - Validation Surveys of Accredited Ambulatory Surgery Centers (ASC), Home Health Agencies (HHA), and Hospices.

If you have questions about this subject, please contact Dodjie B. Guioa with Centers for Medicare and Medicaid Services at (214) 767-6179 or e-mail him at Dguioa@cms.hhs.gov.

[signature on file]

Susan Syler

SS:cos

[Attachment](#)

c: Evelyn Delgado, E-340
Paul Leche, W-615
Merrie Duflot, W-404
Regional Administrators



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Division of Survey and Certification, Region VI

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January 2, 2003

REGIONAL SURVEY AND CERTIFICATION LETTER NO. 03-01

TO: All State Survey Agencies (Action)
All title XIX Single State Agencies (Information)

SUBJECT: Validation Surveys of Accredited Ambulatory Surgery Centers (ASC), Home Health Agencies (HHA), and Hospices.

This letter delineates the responsibilities in the validation survey process. It provides guidance to State Survey Agencies (SSA) in performing validation surveys on accredited providers.

BACKGROUND AND AUTHORITIES

Sections 1865(e) of the Social Security Act (the Act) calls for validation surveys of all provider types that may be deemed for Medicare participation under Section 1865(b) of the Act. These entities covered under Section 1865(b) include: Ambulatory Surgical Centers (ASCs), Home Health Agencies (HHAs) Critical Access Hospitals (CAHs), Hospices, and other provider/supplier entities. Regulations authorizing such surveys are found in 42 CFR 488.7. As stated in the regulatory procedures at 42 CFR 488.7, the Centers for Medicare and Medicaid Services (CMS) may require a survey of an accredited provider or supplier to validate its organization's accreditation process. These surveys are conducted on a representative sample basis or in response to substantial allegations of non-compliance. **A provider or supplier selected for a validation survey must authorize the validation survey to take place and must authorize the validation survey agency to monitor the correction of any deficiencies found through the validation survey.**

If a provider or supplier selected for a validation survey fails to comply with the requirements, it will no longer be deemed to meet the Medicare conditions. The provider or supplier will be subject to full review by the State agency in accordance with 488.11 and may be subject to termination of its provider agreement under 489.53.

VALIDATION PROCEDURES

OBJECTIVE OF VALIDATION SURVEYS



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Validation surveys are intended to provide a reasonable estimate of an accreditation organization's performance and to assess the ongoing acceptability of accreditation as an alternative to routine survey and certification activities. In order to assure a fair basis for comparing the effectiveness of accreditation programs, survey agencies will conduct validation surveys in accordance with the survey protocol for the specific facility type being surveyed. If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. The provider or supplier will be subject to the participation and enforcement requirements found under 488.24. A full review by a State survey agency in accordance with 488.11 is indicated and consequently may be subject to termination of the provider agreement under 439.53. An accredited provider or supplier will again be deemed to meet the Medicare conditions if:

- (1) CMS finds that the provider or supplier meets all the applicable Medicare conditions,
- (2) It withdraws any prior refusal to allow a validation survey,
- (3) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider's or supplier's current accreditation survey.

ACCREDITATION ORGANIZATION RESPONSIBILITIES:

- A. Designates primary contact person for validation issues.
- B. Provides survey schedule dates with the names and addresses for each deemed provider/supplier type deemed to CMS CO on a quarterly basis.
- C. Provides written notification of cancelled surveys.
- D. Provides written notification of provider/supplier withdrawals from the accreditation organization's deemed program.
- E. Submits survey findings to CO regarding providers/suppliers having condition level non-compliance with Medicare conditions.

CMS CENTRAL OFFICE (CO) RESPONSIBILITIES:

- A. Randomly selects all validation surveys using accreditation or re-accreditation survey schedules and information obtained from the AO's.
- B. Forwards the validation sample listing to the Regional Office's (RO).
- C. Analyzes the validation survey findings.

REGIONAL OFFICE (RO) RESPONSIBILITIES:

- A. Notifies the SA of the provider/supplier selected for validation by preparing and sending the appropriate form CMS-2802 to the SA. The RO must complete Item 6 of the 2802 to indicate the provider's/supplier's last AO survey date.
- B. Forwards the appropriate Model Facility Letter to the SA.
- C. Analyzes the survey findings within **30 days** after receiving the SA's validation survey findings.
- D. Issues the final decision within **30 days** after receiving the SA's validation survey findings.
- E. Sends a copy of the final decision letter to the CMS CO and AO.

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- F. Inputs the validation survey information into OSCAR within **60 days** of the final decision.
- G. Sends a monthly report on all validation activity to CO.

STATE AGENCY (SA) RESPONSIBILITIES:

- A. Schedules the validation survey between **60 days to 6** months following the AO survey end date
- B. Reports the validation survey dates to the RO.
- C. Completes the Model Facility Letter prior to conducting the survey and will hand carry the letter to the facility on the survey begin date.
- D. Conducts an **unannounced** validation survey in accordance with the survey protocol for the facility being surveyed.
- E. Uses the appropriate survey forms (see attached exhibit 63) and interpretive guidelines when conducting the validation survey.
- F. Forwards all completed validation survey documents to the RO within 30 days of the validation survey end date.

FACILITY NOTIFICATION LETTER FOR UNANNOUNCED VALIDATION SURVEYS

1. Three versions of this letter exist for various provider/supplier entities: ASCs (Attachment A), HHAs (Attachment B), and Hospices (Attachment C). Until validation surveys become unannounced for hospitals, continue to follow the instructions for hospital surveys in Section 3240-3257 of the SOM. Please select the appropriate letter for the type of provider/supplier being surveyed.
2. The State Agency prepares these letters on State Agency (SA) letterhead before the validation survey's begin date. The SA must insert specific information into the letter, as indicated by the bolded type.
3. The SA survey team must provide the signed original letter to the provider's/supplier's Administrator upon its arrival. In addition, the SA must provide copies of the signed letter to the Centers for Medicare and Medicaid Services (CMS) Central office (CO) and the Regional Office (RO) contact person.
4. The SA must allow the provider/supplier time to contact its staff members to invite them to the Opening Conference.
5. The SA must conduct the validation surveys following the protocols and procedures for a Medicare certification survey in a non-accredited provider/supplier.
6. The SA must report all validation survey findings to CMS CO through its RO contact person.

Contact Dodjie B. Guioa by telephone at 214-767- 6179 or through e-mail at Dguioa@cms.hhs.gov if you have any questions regarding the foregoing matter.

Sincerely,

Molly Crawshaw, Chief
Survey and Certification Operations Branch

Attachment A
Sample Notification Letter for ASC

Provider/supplier Name:

Provider number:

Address:

Dear **Mr./Mrs. (last name of provider/supplier Administrator):**

On behalf of the Centers for Medicare and Medicaid Services (CMS), the **(insert State Agency (SA) name)** will conduct a random unannounced validation survey at **(insert provider/supplier name)** on **(insert survey begin date)**.

BACKGROUND

Section 1865(e) of the Social Security Act (the Act) authorizes validation surveys of all provider/supplier entities deemed for Medicare or Medicaid participation under section 1865(b) of the Act. These provider/supplier entities covered under Section 1865 (b) include Ambulatory Surgical Centers (ASCs), Home Health Agencies (HHAs) and Hospices. Furthermore, Section 1864(c) authorizes the Secretary to enter into an agreement with any State or local agency performing the Medicare certification functions to conduct validation surveys.

Through Federal regulations, CMS permits the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care, Inc. (AAAHHC), and the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) to deem ASCs for participation in the Medicare program.

The above referenced accreditation organizations (AOs) received this recognition based on CMS' review of each AO's survey and accreditation processes. In addition, CMS reviewed each AO's health and safety standards and determined that the AO's programs met or exceeded the Medicare conditions of coverage for ASCs. **(insert provider/supplier name)**, a deemed status ASC through accreditation by **(insert AO name)**, has been selected by CMS for a random, unannounced validation survey.

SELECTION PROCESS

CMS draws a representative random sample of all ASCs on a quarterly basis from AOs' accreditation/re-accreditation survey schedules. All ASCs, deemed by the AO, have an equal probability of being selected for a random unannounced validation survey.

SURVEY PROCESS

The SA may conduct a validation survey within 60 days from the AO survey end date or up to 6 months after the AO survey end date. The **(insert AO name)** conducted an accreditation/re-accreditation survey of the **(insert provider/supplier name)** on **(insert survey end date)**.

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The SA will conduct this validation survey following the protocols of a Medicare certification survey and report all survey findings to CMS. The SA will conduct this validation survey in accordance with 42 CFR 488.7, and the SOM Sections 3240-3257. The (insert provider/supplier name) will have an opportunity to review findings of the validation survey; present comments to CMS; and submit a plan of correction for any deficiencies found.

Section 1865 of the Act requires a provider/supplier selected for a sample validation survey to authorize the AO to release its most current accreditation survey to the Secretary (or an Agency designated by him), upon request. The SA will ask the providers/suppliers administrator to sign a HCFA-1514 which authorizes the AO to release its survey findings to CMS.

We appreciate your full cooperation in working with the (insert SA name) survey team as they complete this unannounced validation survey.

If you have any questions regarding this process, please call (insert RO Staff contact person's name) at (insert contact person's telephone number).

Sincerely,

Attachment B
Sample Notification Letter for HHA

Provider/supplier Name:

Provider number:

Address:

Dear **Mr./Mrs. (last name of provider/supplier Administrator):**

On behalf of the Centers for Medicare and Medicaid Services (CMS), the **(insert State Agency (SA) name)** will conduct a random unannounced validation survey at **(insert provider/supplier name)** on **(insert survey begin date)**.

BACKGROUND

Section 1865(e) of the Social Security Act (the Act) authorizes validation surveys of all provider/supplier entities deemed for Medicare or Medicaid participation under section 1865(b) of the Act. These provider/supplier entities covered under Section 1865 (b) include Ambulatory Surgical Centers (ASCs), Home Health Agencies (HHAs) and Hospices. Furthermore, Section 1864(c) authorizes the Secretary to enter into an agreement with any State or local agency performing the Medicare certification functions to conduct validation surveys.

Through Federal regulations, CMS permits the Community Health Accreditation Program (CHAP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), to deem HHAs for participation in the Medicare program.

The above referenced accreditation organizations (AOs) received this recognition based on CMS' review of each AO's survey and accreditation processes. In addition, CMS reviewed each AO's health and safety standards and determined that the AO's programs met or exceeded the Medicare conditions of coverage for HHAs. **(insert provider/supplier name)**, a deemed status HHA through accreditation by **(insert AO name)**, has been selected by CMS for a random, unannounced validation survey.

SELECTION PROCESS

CMS draws a representative random sample of all HHAs on a quarterly basis from AOs' accreditation/re-accreditation survey schedules. All HHAs, deemed by the AO, have an equal probability of being selected for a random unannounced validation survey.

SURVEY PROCESS

The SA may conduct a validation survey within 60 days from the AO survey end date or up to 6 months after the AO survey end date. The **(insert AO name)** conducted an accreditation/re-accreditation survey of the **(insert provider/supplier name)** on **(insert survey end date)**.

The SA will conduct this validation survey following the protocols of a Medicare certification survey and report all survey findings to CMS. The SA will conduct this validation survey in accordance with

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42 CFR 488.7, and the SOM Sections 3240-3257. The (insert provider/supplier name) will have an opportunity to review findings of the validation survey; present comments to CMS; and submit a plan of correction for any deficiencies found.

Section 1865 of the Act requires a provider/supplier selected for a sample validation survey to authorize the AO to release its most current accreditation survey to the Secretary (or an Agency designated by him), upon request. The SA will ask the providers/suppliers administrator to sign a HCFA-1514 which authorizes the AO to release its survey findings to CMS.

We appreciate your full cooperation in working with the **(insert SA name)** survey team as they complete this unannounced validation survey.

If you have any questions regarding this process, please call **(insert RO Staff contact person's name)** at **(insert contact person's telephone number)**.

Sincerely,

Attachment C
Sample Notification Letter for Hospice

Provider/supplier Name:

Provider number:

Address:

Dear **Mr./Mrs. (last name of provider/supplier Administrator):**

On behalf of the Centers for Medicare and Medicaid Services (CMS), the **(insert State Agency (SA) name)** will conduct a random unannounced validation survey at **(insert provider/supplier name)** on **(insert survey begin date)**.

BACKGROUND

Section 1865(e) of the Social Security Act (the Act) authorizes validation surveys of all provider/supplier entities deemed for Medicare or Medicaid participation under section 1865(b) of the Act. These provider/supplier entities covered under Section 1865 (b) include Ambulatory Surgical Centers (ASCs), Home Health Agencies (HHAs) and Hospices. Furthermore, Section 1864(c) authorizes the Secretary to enter into an agreement with any State or local agency performing the Medicare certification functions to conduct validation surveys.

Through Federal regulations, CMS permits the Community Health Accreditation Program (CHAP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), to deem Hospices for participation in the Medicare program.

The above referenced accreditation organizations (AOs) received this recognition based on CMS' review of each AO's survey and accreditation processes. In addition, CMS reviewed each AO's health and safety standards and determined that the AO's programs met or exceeded the Medicare conditions of coverage for hospices. **(insert provider/supplier name)**, a deemed status Hospice through accreditation by **(insert AO name)**, has been selected by CMS for a random, unannounced validation survey.

SELECTION PROCESS

CMS draws a representative random sample of all hospices on a quarterly basis from AOs' accreditation/re-accreditation survey schedules. All hospices, deemed by the AO, have an equal probability of being selected for a random unannounced validation survey.

SURVEY PROCESS

The SA may conduct a validation survey within 60 days from the AO survey end date or up to 6 months after the AO survey end date. The **(insert AO name)** conducted an accreditation/re-accreditation survey of the **(insert provider/supplier name)** on **(insert survey end date)**.

The SA will conduct this validation survey following the protocols of a Medicare certification survey and report all survey findings to CMS. The SA will conduct this validation survey in accordance with

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42 CFR 488.7, and the SOM Sections 3240-3257. The (insert provider/supplier name) will have an opportunity to review findings of the validation survey; present comments to CMS; and submit a plan of correction for any deficiencies found.

Section 1865 of the Act requires a provider/supplier selected for a sample validation survey to authorize the AO to release its most current accreditation survey to the Secretary (or an Agency designated by him), upon request. The SA will ask the providers/suppliers administrator to sign a HCFA-1514 which authorizes the AO to release its survey findings to CMS.

We appreciate your full cooperation in working with the **(insert SA name)** survey team as they complete this unannounced validation survey.

If you have any questions regarding this process, please call **(insert RO Staff contact person's name)** at **(insert contact person's telephone number)**.

Sincerely,