
CMS Manual System

Pub. 100-07 State Operations

Provider Certification

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

Transmittal 38

Date: NOVEMBER 28, 2008

SUBJECT: Revisions to Exhibits 37, 196, and 287.

I. SUMMARY OF CHANGES: The following exhibits are revised to conform to current policy:

- Exhibit 37, “Model Letter Announcing Validation Survey of Accredited, Deemed Provider/Supplier;”
- Exhibit 196, “Model Letter Announcing to Accredited Provider/Supplier After a Sample Validation Survey that It Does Not Comply with All Conditions of Participation/Conditions for Coverage;” and
- Exhibit 287, “Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey.”

NEW/REVISED MATERIAL - EFFECTIVE DATE*: November 28, 2008
IMPLEMENTATION DATE: November 28, 2008

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	Exhibit 37/ Model Letter Announcing Validation Survey Of Accredited, Deemed Provider/Supplier
R	Exhibit 196/ Model Letter Announcing To Deemed, Accredited Provider/Supplier After A Sample Validation Survey That It Does Not Comply With All Conditions Of Participation/Conditions For Coverage
R	Exhibit 287/ Authorization By Deemed Provider/Supplier Selected For Accreditation Organization Validation Survey

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2009 operating budgets.

IV. ATTACHMENTS:

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

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

EXHIBIT 37

(Rev. 38, 11-28-08)

MODEL LETTER ANNOUNCING VALIDATION SURVEY OF
ACCREDITED, **DEEMED PROVIDER/SUPPLIER**

PLEASE NOTE: Per Section 2700A, all surveys are unannounced; this letter is to be provided to the facility administrator as part of the survey entrance conference.

(Date)

Facility Administrator Name

Facility Name

Address

City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear (Administrator Name):

Section 1865 of the Social Security Act (the Act) provides *that entities* accredited by CMS-*recognized national accreditation organizations may be* deemed to meet the Medicare *health and safety* Conditions.

Section 1864 of the Act authorizes the Secretary to *enter into an agreement with State health or other appropriate agencies to* conduct, on a selective sampling basis, surveys of accredited *deemed facilities subject to Medicare certification requirements. CMS uses such surveys* as a means of validating the accrediting organization's survey *and accreditation process*. In (Name of State), Medicare validation surveys of accredited *deemed providers and suppliers* are conducted by the (State agency). This agency, under agreement with the Centers for Medicare & Medicaid Services (CMS), surveys *institutional providers and suppliers* of Medicare services to determine compliance with the Medicare *health and safety conditions*.

The last accreditation survey of [**Facility Name**], conducted by [AO], was completed on [date].

Your facility has been selected for a sample validation survey. This is an unannounced survey following procedures established by CMS.

Section 1865 of the Act requires *facilities* deemed to meet the *Medicare conditions* to authorize the accrediting body to release to the Secretary (or to a State agency designated by him), upon his request, a copy of the accreditation survey information of such institution.

(Name)

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(Date)

You may also be requested to provide or verify *additional* information *required by CMS for general certification purposes* by a member of the survey team.

During the *validation* survey, the State agency will determine compliance with all *Medicare health and safety requirements applicable to your type of facility*. The survey team will request facility documents to review, require access to all areas of the *facility*, and observe patient services or procedures to assist them in their compliance determination.

If the validation survey results in a finding by the CMS Regional Office that a provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet Medicare conditions and may be subject to termination of its provider or supplier agreement, in accordance with 42 CFR 488.7(d). Additionally, in accordance with 42 CFR 401.133, a copy of the Medicare sample validation survey findings will be subject to public disclosure after the facility has been given an opportunity to review the findings, present comments to CMS, and submit a plan of correction for any deficiencies cited.

If you have any questions regarding this letter, please telephone [Name] at [Telephone number].

Sincerely yours,

State Agency Director

Enclosures:

*Authorization by Deemed Provider/Supplier Selected for Accreditation Organization
Validation Survey*

cc:

CMS, DSC, Regional Office

CMS, CMSO, Division of Acute Care Services

EXHIBIT 196

(Rev. 38, 11-28-08)

**MODEL LETTER ANNOUNCING TO *DEEMED*, ACCREDITED
PROVIDER/SUPPLIER AFTER A SAMPLE VALIDATION
SURVEY THAT *IT* DOES NOT COMPLY WITH
ALL CONDITIONS OF PARTICIPATION/
CONDITIONS FOR COVERAGE**

(90-Day Termination Track): Do Not Use When Immediate and Serious Threat to Patient Health
or Safety Deficiencies Exist)

(Date)

Administrator Name
Hospital Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear **(Administrator)**

Section 1865 of the Social Security Act (the Act) and pursuant regulations provide that a *provider or supplier accredited by (name of accreditation organization)* will be “deemed” to meet all of the Medicare Conditions (of Participation (CoPs *or for Coverage (CfCs, as applicable)*) for **(type of provider/supplier)**, *(add for hospitals: with the exception of those relating to utilization review, the special medical record and staffing requirements for psychiatric hospitals, and special requirements for hospital providers of long-term care services (“swing beds”)).* Section 1864 of the Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to conduct, on a selective sampling basis, surveys of accredited *providers/suppliers* participating in Medicare as a means of validating reliance on the accreditation process.

When a (type of provider/supplier), regardless of its accreditation status, is found to be out of compliance with the (CoPs or CfCs), a determination must be made that the facility no longer meets the requirements for participation as a provider or supplier of services in the Medicare program. Such a determination has been made in the case of (facility name) and accordingly, the Medicare agreement between (facility name) and the Secretary is being terminated.

A validation survey conducted by the (State agency) at (name of facility) on (date) found that the facility was not in compliance with all the (CoPs or CfCs) for (type of facility). A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction.). These deficiencies have been determined to be of such a serious nature as to substantially limit the facility's capacity to provide adequate care. The date on which the agreement terminates is (date). (Add, in the case of a hospital or CAH: The Medicare program will not make payment for services furnished to patients who are admitted on or after (date of termination). For inpatients admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days of inpatient services furnished on or after (date of termination). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your facility on (date of termination) to the (name and address of the RO involved) to facilitate payment for these individuals.)

We will publish a public notice in the (local newspaper). You will be advised of the publication date for the notice. If you feel that these findings are incorrect, you have 15 days from the date of this notice to request an informal review of the findings by this office as provided by 42 CFR 488.456(c)(2). Include in the request any evidence and arguments which you may wish to bring to the attention of the Centers for Medicare & Medicaid Services (CMS). [Public notice language is optional]

Termination can only be averted by correction of the deficiencies within 45 days of your receipt of this letter. Your plan of correction (written on the enclosed statement of Deficiency and Plan of Correction forms) should be returned to us as soon as possible.

An acceptable plan of correction must contain the following elements:

- 1. The plan for correcting each specific deficiency cited;*
- 2. The plan should address improving the processes that led to the deficiency cited;*
- 3. The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;*
- 4. A completion date for correction of each deficiency cited must be included;*
- 5. All plans of correction must demonstrate how the provider/supplier has incorporated its improvement actions into its applicable Quality Assessment and Performance Improvement (QAPI) program, addressing improvements in its systems in order to prevent the likelihood of the deficient practice reoccurring. The plan must include the monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements; and*
- 6. The plan must include the title of the person responsible for implementing the acceptable plan of correction.*

After termination, if you wish to be readmitted to the program, you must demonstrate to the (State agency) and CMS that you are able to maintain compliance. Readmission to the program will not be approved until CMS is reasonably assured that you are able to sustain compliance.

If you do not believe this termination decision is correct, you may request a hearing before an Administrative Law Judge (ALJ) of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 CFR 498.40 et. seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to the Consortium Survey and Certification Officer, (address). We will forward your request to the Chief Administrative Law Judge in the Office of Hearing and Appeals.

At your option you may instead submit a hearing request directly (accompanied by a copy of this letter) to the following address. Send a copy of your request to this office also.

*Departmental Appeals Board, Civil Remedies Division
Room G-644-Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: Director, Departmental Appeals Board*

A request for a hearing should identify the specific issues, and the findings of fact, and conclusions that you consider to be incorrect. You may be represented by counsel at a hearing at your own expense.

Sincerely yours,

*Consortium Survey and Certification Officer
(or its equivalent)*

cc: (Accreditation Organization)

EXHIBIT 287

(Rev. 38, 11-28-08)

**AUTHORIZATION BY DEEMED PROVIDER/SUPPLIER SELECTED FOR
ACCREDITATION ORGANIZATION VALIDATION SURVEY**

To Whom it May Concern:

Certain types of providers and suppliers may be deemed in compliance with the appropriate Medicare Conditions of Participation or Conditions for Coverage program by submitting evidence of accreditation *from a Centers for Medicare & Medicaid Services (CMS)*-authorized accreditation organization. CMS may subsequently require a survey of an accredited provider or supplier to validate the accreditation organization's process.

In signing this form, I acknowledge that I have been advised that **(name of provider/supplier)** has been selected for a validation survey. Furthermore, I acknowledge that, in accordance with the provisions of 42 CFR 488.7(b), I must authorize:

- 1) The validation survey by the State Survey Agency to take place; and
- 2) The State Survey Agency to monitor the correction of any deficiencies found through the validation survey.

Signature of Authorizing Individual

Printed/Typed Name of Individual

Name of Provider/Supplier

Date