CMS Manual System
Pub. 100-07 State Operations Provider Certification

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

Transmittal 117 **Date: June 6, 2014**

SUBJECT: Revision to Medicare State Operations Manual (SOM), Chapter 9 - Exhibits

I. SUMMARY OF CHANGES: Various Exhibits are being revised concerning deemed status providers and suppliers; Rural Health Clinics (RHC) and swing bed hospitals; and hospital reports of deaths associated with restraint or seclusion. Exhibit 25, Model Letter to RHC Regarding Scheduling a Survey, is being deleted since all surveys must be announced. The updates accurately reflect current survey and certification policy established in the State Operations Manual.

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 6, 2014
IMPLEMENTATION DATE: June 6, 2014

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	9/Table of Contents
D	9/Exhibit 25 Model Letter to Rural Health Clinic Regarding Scheduling a Survey
R	9/Exhibit 37 Model Letter Announcing Validation Survey of Deemed Status Provider/Supplier
R	9/Exhibit 162 Model Letter: Request for a Plan of Correction Following an Initial Survey for Swing-bed Approval in a Hospital
R	9/Exhibit 196 Model Letter Announcing to Deemed Status Provider/Supplier after a Validation Survey that it does not Comply with all Medicare Conditions
R	9/Exhibit 199 Model Letter Announcing to Deemed Status Provider/Supplier after a Substantial Allegation Survey that it will Undergo a Full Survey
R	9/Exhibit 287 Authorization by Deemed Provider/Supplier Selected for Validation Survey
R	9/Exhibit 353 Report of a Hospital Death Associated with Restraint or Seclusion (Form CMS-10455)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2014 operating budgets.

IV. ATTACHMENTS:

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

Medicare State Operations Manual
Chapter 9 - Exhibits

Exhibits
(Rev.117, Issued: 06-06-14)

Exhibit	Description	Download
25	Model Letter to Rural Health Clinic Regarding Scheduling a Survey	*Deleted*
37	Model Letter Announcing Validation Survey Of Deemed *Status* Provider/Supplier	http://www.cms.gov/manuals/downloads/som107_exhibit_037.pdf
196	Model Letter Announcing to Deemed *Status* Provider/Supplier after a Validation Survey that it does not Comply with all *Medicare* Conditions	http://www.cms.gov/manuals/downloads/som107_exhibit_196.pdf
199	Model Letter Announcing to *Deemed Status Provider/Supplier after a Substantial Allegation Survey that it will Undergo a Full Survey*	http://www.cms.gov/manuals/downloads/som107_exhibit_199.pdf
287	Authorization by Deemed Provider/Supplier Selected for *Validation Survey*	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_287.pdf
353	*Report of a* Hospital Death *Associated with Restraint or Seclusion (Form CMS-10455)*	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_353.pdf

EXHIBIT 37
(Rev. 117, Issued: 06-06-14)

MODEL LETTER ANNOUNCING VALIDATION SURVEY OF DEEMED *STATUS* 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 *Centers for Medicare & Medicaid (*CMS*)*-recognized national *accrediting* organizations may be deemed to meet the *applicable* Medicare Conditions *of Participation, Conditions for Coverage, or Conditions for Certification*.

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 *or in response to a substantial allegation of noncompliance*, surveys of deemed *status providers or suppliers* 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 CMS, surveys providers and suppliers *subject to certification* to determine compliance with the *applicable* Medicare conditions.

[Choose one of the following, whichever is applicable] Your facility ***(has been selected for a sample validation survey) (is the subject of a substantial allegation of noncompliance)***. This is an unannounced survey following procedures established by CMS.

In accordance with the provisions of 42 CFR §488.7(b), your facility 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 substantial noncompliance found through the validation survey.*

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 Medicare health and safety requirements applicable to your type of facility. The survey team will *require access to all areas of the facility, observe patient services or procedures to assist them in their compliance determination, ask questions of facility staff and may also request facility documents to review.*

If the validation survey results in a finding by the CMS Regional Office that a *deemed status* provider or supplier is *not in substantial* 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 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 deficiencies cited. *In those cases where the deemed status provider or supplier is not required to submit an acceptable plan of correction, the provider or supplier may voluntarily submit one. In the latter case the plan of correction will not be reviewed for acceptability but may be released along with the validation survey findings.*

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 *for* Validation Survey

cc:
CMS, DSC, Regional Office
(For sample validation surveys only) CMS, CCSQ, SCG, Division of Acute Care Services

EXHIBIT 162
(Rev. 117, Issued: 06-06-14)

Model Letter: Request for a Plan of Correction Following an Initial Survey for Swing-bed Approval in a Hospital

Name/Title of Hospital Administrator, CEO, or Responsible Individual
Name of Hospital
Street Address
City, State, Zip Code

Re: CMS Certification Number (CCN)

Dear _____:

You will find enclosed the Form CMS-2567 "Statement of Deficiencies and Plan of Correction," which enumerates deficiencies found as a result of the initial Medicare *swing bed* certification survey completed at your facility on (date).

Your plan of correction must be returned to this office, signed and dated, with an anticipated completion date for each corrective action, within ten (10) days of receipt of this letter.

An acceptable plan of correction must contain the following *elements*:

1. The plan for correcting each specific deficiency cited;

2. The plan for improving the processes that led to the deficiency cited, including how the hospital is addressing improvements in its systems in order to prevent the likelihood of recurrence of the deficient practice;

3. The procedure for implementing the plan of correction, if found acceptable, for each deficiency cited;

4. A completion date for correction of each deficiency cited;

5. The monitoring and tracking procedures that will be implemented to ensure that the plan of correction is effective and that the specific deficienc(ies) cited remain corrected and in compliance with the regulatory requirements; and

6. The title of the person(s) responsible for implementing the acceptable plan of correction.

A complete copy of the Form CMS-2567 is subject to public disclosure. All responses must be shown on this form. Attachments may be submitted as supporting documentation.

The State agency will review the plan to determine if it is acceptable. If acceptable and the State determines that a revisit is not necessary, the State will recommend certification as a hospital

with swing-bed approval to the *Centers for Medicare & Medicaid Services (*CMS*)* regional office *(RO)*. If a revisit is deemed necessary, and the State determines by the revisit survey that the facility is in compliance, the State will recommend certification as a hospital with swing-bed approval. The CMS-RO will *make the determination whether the hospital will be certified for swing bed services, as well as* the effective date of the swing bed certification.

Sincerely,
(State Agency)

Enclosure: Form CMS-2567

EXHIBIT 196
(Rev. 117, Issued: 06-06-14)

MODEL LETTER ANNOUNCING TO DEEMED *STATUS* PROVIDER/SUPPLIER AFTER A VALIDATION SURVEY THAT IT DOES NOT COMPLY WITH ALL *MEDICARE* CONDITIONS
90-Day Termination Track:

Use after the following types of surveys when there are findings of condition-level noncompliance:

- *Sample Validation Survey;*
- *Substantial Allegation (Complaint) Validation Survey when the RO does not require a subsequent full survey*
- *Full Survey After a Substantial Allegation Validation Survey*

Do Not Use:

- When *an i*mmediate *jeopardy exists and was not removed before the survey team exited the facility (See Exhibit 195); or*
- *In the case of a Substantial Allegation Validation Survey when the RO requires a subsequent full survey (See Exhibit 199*)

(**Date**)
Name/*Title of Hospital Administrator, CEO, or Responsible Individual*
Facility Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear _____:

Section 1865 of the Social Security Act (the Act) and *Centers for Medicare & Medicaid Services (CMS)* regulations provide that a provider or supplier accredited by *a CMS-approved Medicare accreditation program of* **(name of *accrediting* organization)** will be "deemed" to meet all of the Medicare ***(*Conditions of Participation (CoPs) or for Coverage or for Certification (CfCs), as applicable)** for **(type of provider/supplier**. *In accordance with* Section 1864 of the Act *State Survey Agencies may* conduct *at CMS's direction surveys of deemed status providers/suppliers* on a selective sampling basis*, in response to a substantial allegation of noncompliance, or when CMS determines a full survey is required after a substantial allegation survey identifies substantial noncompliance. CMS uses such surveys as a means of validating the accrediting organization's survey and accreditation process.*

***(In the case of a full survey after a complaint survey, add the following:** Your deemed status was removed on **(date)** as a result of findings of substantial noncompliance resulting from a substantial allegation validation survey.)* A ***(for full survey after a complaint, insert:** follow-up full)* survey conducted by the **(State agency)** at (**name of facility**) on (**date**) found that the

facility was not in *substantial* compliance with the *following* (**CoPs or CfCs**) for **(type of facility)**.

(List CoPs or CfCs with condition-level deficiencies)

(Except in the case of a full survey which was conducted after a complaint validation survey, add the following: *As a result, effective* ***(date)*** *your deemed status has been removed and survey jurisdiction has been transferred to the* ***(State agency).)***

A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction.).

When a **(type of provider/supplier)**, regardless of *whether it has deemed* 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 *CMS* is being terminated. The date on which the *Medicare* 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 *services to* these individuals.**)**

We will publish a public notice in the (**local newspaper**) *at least fifteen days prior to the termination date*. **[Public notice language is optional]**

Termination can only be averted by correction of the deficiencies*, through submission of an acceptable plan of correction (PoC) and subsequent verification of compliance by (* ***State Agency)****. The Form CMS 2567 with your POC and dated and signed by your facility's authorized representative must be submitted to* ***(State Agency)*** *no later than* ***(enter date that is 10 calendar days after the date of this notice)****. Please indicate your corrective actions on the right side of the Form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date".*

An acceptable PoC must contain the following elements:

1. The plan for correcting each specific deficiency cited;

2. The plan *for* improving the processes that led to the deficiency cited*, including how the hospital is addressing improvements in its systems in order to prevent the likelihood of recurrence of the deficient practice;*

3. The procedure for implementing the PoC*, if found acceptable,* for each deficiency cited;

4. A completion date for correction of each deficiency cited;

5. The monitoring and tracking procedures *that will be implemented* to ensure *that* the PoC is effective and that *the* specific deficien*(*cies*)* cited remain corrected and in compliance with the regulatory requirements; and

6. The title of the person*(s)* responsible for implementing the acceptable PoC.

Copies of the Form CMS-2567, including copies containing the facility's PoC, are releasable to the public in accordance with the provisions of Section 1864(a) of the Act and 42 CFR 401.133(a). As such, the PoC should not contain personal identifiers, such as patient names, and you may wish to avoid the use of staff names. It must, however, be specific as to what corrective action the hospital will take to achieve compliance, as indicated above.

Your facility will be revisited to verify necessary corrections. If CMS determines that the reasons for termination remain, you will be so informed in writing, including the effective date of termination. If corrections have been made and your facility is in substantial compliance, the termination procedures will be halted, and you will be notified in writing.

If your Medicare agreement is terminated and 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 *your Medicare agreement is terminated and* 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 *the final notice of termination*. Such a request may be made to (***name, title,*** **address** ***of RO ARA***). 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.

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

Send a copy of your request to this office also.

A request for a hearing should identify the specific issues, the findings of fact, and conclusions *of law, if applicable, with which you disagree*. You may be represented by counsel at a hearing at your own expense.

Sincerely yours,

Regional Office DSC

Enclosure:
CMS Form-2567 Statement of Deficiencies

cc: *State Survey Agency*
Accrediting Organization

EXHIBIT 199
(Rev. 117, Issued: 06-06-14)

MODEL LETTER ANNOUNCING TO *DEEMED STATUS PROVIDER/SUPPLIER* AFTER A SUBSTANTIAL ALLEGATION SURVEY THAT *IT WILL UNDERGO A FULL SURVEY*

Do Not Use:

- When *an* immediate *jeopardy* exist*s and was not removed before the survey team exited the facility (See Exhibit 195); or*
- *In the case of a substantial allegation survey finding substantial noncompliance, when the RO does **not** require a subsequent full survey before proceeding with enforcement action (See Exhibit 196)*

(**Date**)

Name/Title of Provider/Supplier Administrator*, CEO, or Responsible Individual*
Provider/Supplier Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear (**Administrator**)

Section 1865 of the Social Security Act (the Act) and *Centers for Medicare & Medicaid Services (CMS)* regulations provide that a *provider or supplier* accredited by *a CMS-approved Medicare accreditation program of **(name of accrediting organization)** will be "deemed" to meet all Medicare **(Conditions of Participation (CoPs) or for Coverage or for Certification (CfCs), as applicable)** for **(type of provider/supplier).** In accordance with Section 1864 of the Act a State Survey Agency may conduct, at CMS's direction and in response to a substantial allegation of noncompliance, surveys of deemed status providers/suppliers. CMS uses such surveys as a means of validating the accrediting organization's survey and accreditation process.*

A validation survey conducted by the **(State agency)** at (**name of facility**) on (**date**) found that the facility was not in *substantial* compliance with *the following* (**CoPs or CfCs**) for **(type of facility)**.

(List CoPs or CfCs with condition-level deficiencies)

*As a result, effective **(date)** your facility's deemed status is being removed and survey jurisdiction has been transferred to the (State agency SA).*

A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction). *You are not required to submit a plan of correction (PoC) for these*

deficiencies, but you may do so voluntarily. The PoC will ***not*** *be reviewed to determine if it is acceptable. Copies of the Form CMS-2567, including copies containing a facility's PoC, are releasable to the public in accordance with the provisions of Section 1864(a) of the Act and 42 CFR 401.133(a). As such, if you choose to submit a PoC, it should not contain personal identifiers, such as patient names, and you may wish to avoid the use of staff names.*

The (**State agency**) will conduct a*n unannounced* full survey of your *facility* to assess compliance with all the *applicable* Medicare *conditions*. *If that survey indicates your facility is in substantial compliance with all of the applicable conditions, CMS will restore your deemed status and notify you in writing of this. If that survey indicates your facility is not in substantial compliance with one or more of the applicable conditions, then CMS will initiate action to terminate your Medicare agreement and will notify you in writing of this, including your opportunity to make timely correction of deficiencies identified.*

In accordance with 42 CFR §498.3(d), this notice of findings is an administrative action, not an initial determination, and therefore formal reconsideration and hearing procedures do not apply.

Sincerely yours,

Regional Office DSC

Enclosure:
CMS Form-2567 Statement of Deficiencies

cc: *State Survey Agency*
Accrediting Organization

Exhibit 287
(Rev. 117, Issued: 06-06-14)

AUTHORIZATION BY DEEMED PROVIDER/SUPPLIER SELECTED FOR VALIDATION SURVEY

(date)

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 *or Conditions for Certification* program by submitting evidence of accreditation *from a Centers for Medicare & Medicaid Services (*CMS*)-approved Medicare* accreditation *program*. CMS may subsequently*, in accordance with Section 1864 of the Act, conduct, either on a selective sampling basis or in response to a substantial allegation of noncompliance*, surveys of *deemed status* providers/suppliers*. CMS uses such surveys as a means of validating the accrediting organization's survey and accreditation 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 *substantial noncompliance* found through the validation survey.

_____
Signature of Authorizing Individual

_____
Printed/Typed Name of Authorizing Individual

_____
Name of Provider/Supplier

_____
Date

Exhibit 353
(Rev. 117, Issued: 06-06-14)

Report of a Hospital Death Associated with Restraint or Seclusion

(Form CMS-10455)

http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10455.pdf