# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

**Transmittal 148** **Date: October 9, 2015**


**SUBJECT: Revisions and Deletion to the State Operations Manual (SOM) Chapter 9 Exhibits**

**I. SUMMARY OF CHANGES:** Revisions to Chapter 9 Exhibits reflect changes in procedures for submitting appeals to the Departmental Appeals Board (DAB). Exhibit 255B is being deleted as its content is not appropriate for a template letter.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: October 9, 2015**
**IMPLEMENTATION DATE: October 9, 2015**

***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:**
**(R = REVISED, N = NEW, D = DELETED)**

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|---|---|
| R | 9/Exhibits/Exhibit 152 Model Letter Critical Access Hospital (CAH) Termination Letter |
| R | 9/Exhibits/Exhibit 181 Notice To Hospital Provider Of Involuntary Termination |
| R | 9/Exhibits/Exhibit 182 Notice Of Termination To Non-Deemed Supplier |
| R | 9/Exhibits/Exhibit 195 Model Notice Announcing To Deemed, Accredited Provider/Supplier That The Facility Does Not Comply With All The Conditions Of Participation, Coverage Or Certification And That There Is Immediate And Serious Threat To Patient Health And Safety |
| R | 9/Exhibits/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/Exhibits/Exhibit 211 Model Letter For A Violation Of 42 CFR 489.24 and/or The Related Provisions Of 42 CFR 489.20 Notice Of Termination |
| D | 9/Exhibits/Exhibit 255B Model Letter Notification of Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application (Form CMS 855) |

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.**
**Funding for implementation activities will be provided to contractors through the regular budget process.**

## IV. ATTACHMENTS:

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

# EXHIBIT 152

***(Rev.148, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)***

## MODEL LETTER
## CRITICAL ACCESS HOSPITAL (CAH) TERMINATION LETTER

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Name/Title of Responsible Individual
Name of *CAH*
Street Address
City, State, Zip Code

Re: CMS Certification Number (CCN) **[enter CCN assigned to the Facility]**

Dear_____:

The Centers for Medicare & Medicaid Services (CMS) has *evaluated* ***(insert name of CAH)*** *for its compliance with the CAH Conditions of Participation (CoPs) and* has determined that *it* no longer meets the requirements for participation as a CAH provider of services in the Medicare program.

*The Social Security Act (the Act) requires that all Medicare-participating CAHs* meet the applicable provisions *under Title XVIII, Section* 1820 of the Act. *CAHs are also required* to be in compliance with the CoPs at 42 CFR Part 485, Subpart F.

*CMS has determined* that (***insert*** **name of CAH**) does not meet the requirement(s) contained in (**insert specific requirements that have not been met and a brief explanation of the circumstances of noncompliance**).

The date on which your Medicare provider agreement terminates is (***insert*** **termination date**). The Medicare program will no longer make payment*s* for CAH services *provided* to patients *who receive services at the CAH* after the termination date. *However, in accordance with 42 CFR 489.55(a)(1), Medicare payments may continue for a maximum of thirty days after the termination date for Medicare beneficiaries admitted prior to* ***(insert termination date)*** *for either inpatient acute care services or skilled nursing facility (SNF)-level swing bed services.*

***(Insert name of CAH)*** should submit a list of names and Medicare claim numbers of beneficiaries *receiving acute inpatient and SNF-level services* in *the* CAH on the termination date to the CMS ***(insert city of Regional Office here)*** R*egional* O*ffice* as soon as possible *to facilitate payment for the services the CAH has provided to these beneficiaries.*

*CMS* will publish a public notice of termination in the (***insert*** **name of local newspaper**). You will be advised of the publication date for the notice.

***(If this is the first notice after the survey and termination is not based on failure to meet the distance and rural location requirements, add the following:*** *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, 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", and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag". 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 CAH 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 deficiency(ies) 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 that the necessary corrections have been made. If CMS determines that the reasons for termination remain, you will be informed in writing, including the effective date of termination. If corrections have been made and your facility is in substantial compliance with the CAH CoPs, 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 with the applicable CoPs. Readmission to the program will not be approved until CMS is reasonably assured that you are able to sustain compliance. Please note that it is not possible to be readmitted to the program as a CAH. Facilities must first be enrolled and certified as a hospital before they can seek CAH status.*

***(In the case of the termination of a necessary provider CAH add the following:** Further, termination of your current Medicare agreement includes termination of your grandfathered necessary provider CAH status. Should you seek to convert from a hospital to a CAH in the future, you would be required to demonstrate compliance with all of the CAH CoPs, including the CAH Status and Location requirements at 42 CFR 485.610.)*

*If you disagree with this termination action,* you *or your legal representative* may request a hearing before an administrative law judge of the Department of Health and Human Services,

Departmental Appeals Board *(DAB).* Procedures governing this process are set out in 42 CFR 498.40, et seq. *You must file your hearing request electronically by using the DAB's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov,* no later than sixty (60) days *after receiving* this letter. *Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request must also be submitted electronically to:*

***(INSERT REGIONAL OFFICE CONTACT INFORMATION)***

*Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:*

*Department of Health & Human Services*
*Departmental Appeals Board, MS 6132*
*Director, Civil Remedies Division*
*330 Independence Avenue, S.W.*
*Cohen Building – Room G-644*
*Washington, D.C. 20201*
*(202) 565-9462*

A request for a hearing should identify the specific issues, findings of fact and conclusions of law *with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. At an appeal hearing, y*ou may be represented by counsel at your own expense.

If you have any questions *regarding this matter,* please contact *the CMS (***insert *city*)** *Regional Office by phone at* ***(insert phone number)*** *or by e-mail at* ***(insert email address)***.

Sincerely,

Associate Regional Administrator/Equivalent

Enclosures: Form CMS-2567 Statement of Deficiencies ***(when applicable; an RO determination of failure to meet distance and rural location requirements would not have a 2567)***
*DAB E-filing Instructions*

cc:
State *Survey Agency*
*Accrediting Organization* ***(when applicable)***

# EXHIBIT 181

***(Rev. 148, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)***

## NOTICE TO HOSPITAL PROVIDER OF INVOLUNTARY TERMINATION

(**Date**)

*Name/Title of Responsible Individual*
*Name of Hospital*
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN) ***[enter CCN assigned to the Facility]***

Dear _____:

The Centers for Medicare & Medicaid Services (CMS) *has evaluated (**insert name of hospital**) for its compliance with the hospital Conditions of Participation (CoPs) and* has determined that the (**name of *hospital***) no longer meets the requirements for participation as a Medicare provider established under Title/XVIII of the Social Security Act (the Act).

To continue to participate in the Medicare program, a hospital must meet all of the statutory provisions of section 1861(e) of the Act and be in compliance with the Conditions of Participation (CoPs) found at 42 CFR Part 482.

*CMS has determined that (**name of hospital**) does not meet the requirement(s) contained in (**insert specific requirements that have not been met and a brief explanation of the circumstances of noncompliance**).*

The date on which the agreement terminates is (*insert* **date of termination**). The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after (**date of termination**). *However, in accordance with 42 CFR 489.55(a)(1), Medicare* payment*s* may continue for a maximum of 30 days *after the termination date for Medicare beneficiaries admitted prior to (**insert termination date**) for either inpatient acute care services or skilled nursing facility (SNF)-level swing bed services.*

***(Insert name of* hospital)** *should submit* a list of names and Medicare claim numbers of beneficiaries *receiving inpatient and SNF-level services in the* hospital on *the termination date to the CMS **(insert city of Regional Office here)** Regional Office as soon as possible* to facilitate payment for *the services the hospital has provided to* these *beneficiaries.*

*CMS* will publish a public notice in the (***insert name of* local newspaper**). You will be advised of the publication date for the notice.

***(If this is the first notice after the survey, add the following:** 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, 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", and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag". 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 deficiency(ies) 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 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 you *disagree with* this termination *action,* you *or your legal representative* may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 CFR 498.40, et seq. *You must file your hearing request electronically by using the DAB's Electronic Filing System (DAB E-File) at* https://dab.efile.hhs.gov no later than sixty (60) days *after receiving* this letter. *Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request must also be submitted electronically to:*

***(INSERT REGIONAL OFFICE CONTACT INFORMATION)***

*Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:*

*Department of Health & Human Services*
*Departmental Appeals Board, MS 6132*
*Director, Civil Remedies Division*
*330 Independence Avenue, S.W.*
*Cohen Building – Room G-644*
*Washington, D.C. 20201*
*(202) 565-9462*

A request for a hearing should identify the specific issues, findings of fact and conclusions *of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. At an appeal hearing,* you may be represented by counsel at your own expense.

*If you have any questions regarding this matter, please contact the CMS (**insert city**) Regional Office by phone at (**insert phone number**) or by e-mail at (**insert email address**).*

Sincerely,

Associate Regional Administrator/Equivalent

*Enclosures: Form CMS-2567 Statement of Deficiencies*
*DAB E-filing Instructions*

*Cc:*

*State Survey Agency*
*Accrediting Organization (when applicable)*

# EXHIBIT 182

*(Rev. 148, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

## NOTICE OF TERMINATION TO *NON-DEEMED* SUPPLIER

(**Date**)

Supplier Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN)**[enter CCN assigned to the facility]**

Dear (**Supplier Name**):

The Centers for Medicare & Medicaid Services (CMS) has determined that (**name**) no longer meets the *requirements for participation in the Medicare program. We have reviewed the (**date**), (**State Agency name**) survey report and we are in agreement with the enclosed findings, which show that the following Medicare **(Conditions for Coverage or Certification)** were out of compliance:*

*(**List Conditions**)*

The Conditions for *(***Coverage or Certification***, **as applicable)*** are regulations *adopted by* the ***CMS*** in accordance with the provisions of Title XVIII of the Social Security Act. You must be in compliance with these Conditions in order *to participate in the Medicare program.*

*The Medicare supplier agreement of your (**supplier type**) will be terminated on (**date**). CMS* will publish notice *of this termination in the* **(local newspaper)** *on (**date**).*

***(If this is the first notice after the survey, add the following:** 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, 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", and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag". 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 deficiency(ies) 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 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 you *disagree with this termination action,* you *or your legal representative* may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 CFR 498.40, et seq. *You must file your hearing request electronically by using the DAB's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov,* no later than sixty (60) days *after receiving* this letter. *Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request must also be submitted electronically to:*

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*Cohen Building – Room G-644*
*Washington, D.C. 20201*
*(202) 565-9462*

A request for a hearing should identify the specific issues, findings of fact and conclusions *of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. At an appeal hearing,* you may be represented by counsel at your own expense.

*If you have any questions regarding this matter, please contact the CMS (**insert city**) Regional Office by phone at **(insert phone number)** or by e-mail at **(insert email address**).*

Sincerely yours,

Associate Regional Administrator*/E*quivalent

*Enclosures: Form CMS-2567 Statement of Deficiencies*
*DAB E-filing Instructions*

# EXHIBIT 195

*(Rev. 148, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)*

## MODEL NOTICE ANNOUNCING TO DEEMED, ACCREDITED PROVIDER/SUPPLIER THAT THE FACILITY DOES NOT COMPLY WITH ALL THE CONDITIONS OF PARTICIPATION, COVERAGE OR CERTIFICATION AND THAT THERE IS IMMEDIATE AND SERIOUS THREAT TO PATIENT HEALTH AND SAFETY

(**Date**)

Facility Administrator Name
Facility Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN) **[enter CCN assigned to the facility]**

Dear (**Administrator Name**):

Section 1865 of the Social Security Act (the Act) provides that entities accredited by a *Centers for Medicare & Medicaid Services-* (CMS-) recognized national accreditation organization may be "deemed" to meet the Medicare health and safety conditions. Section 1864 of the Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to conduct surveys of accredited entities participating in the Medicare program.

A survey was conducted at (**name of facility** on (**date**). *That survey identified* an immediate *jeopardy which poses a* serious threat to the health and safety of patients. Specifically, the facility*'s noncompliance with the following constitutes an immediate jeopardy*:

(**Cite Conditions of Participation (CoPs)/Conditions for Coverage or Certification (CfCs) *for which an IJ was cited***).

***[Add the following when applicable:]*** *In addition, the survey also identified substantial noncompliance with the following conditions:*

***(Cite Other Conditions of Participation (CoPs)/Conditions for Coverage or Certification (CfCs))***

When a facility, regardless of its accreditation status, is found to be out of compliance with one or more CoPs/CfCs and *an* immediate *jeopardy* exists, a determination must be made that the facility no longer meets the requirements for participation as a provider of services in the Medicare program. Such a determination has been made in the case of (**name of facility**) and, accordingly, the Medicare provider agreement between (**name of facility)** and the Secretary is being terminated. This termination will be effective (**date**).
(Add, in the case of 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 *acute* inpatient *or swing bed* 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.**)**

*CMS* will publish a public notice in the (**local newspaper**). You will be advised of the publication date for the notice.

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, 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", and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag". 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 deficiency(ies) 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 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 you *disagree with this termination action,* you *or your legal representative* may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 CFR 498.40, et seq. *You must file your hearing request electronically by using the DAB's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov,* no later than sixty (60) days *after receiving this letter. Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request must also be submitted electronically to:*

***INSERT REGIONAL OFFICE CONTACT INFORMATION***

*Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:*

*Department of Health & Human Services*
*Departmental Appeals Board, MS 6132*
*Director, Civil Remedies Division*
*330 Independence Avenue, S.W.*
*Cohen Building – Room G-644*
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*(202) 565-9462*

*A request for a hearing should identify the specific issues, findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. At an appeal hearing,* you may be represented by counsel at your own expense.

*If you have any questions regarding this matter, please contact the CMS (**insert city**) Regional Office by phone at (**insert phone number**) or by e-mail at (**insert email address**).*

Sincerely yours,

*Associate Regional Administrator/E*quivalent

Enclosure: Form CMS-2567 Statement of Deficiencies
*DAB E-filing Instructions*

CC: Accrediting Organization
State *Survey* Agency

# EXHIBIT 196

***(Rev. 148, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)***

**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 immediate 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 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 R*egional* O*ffice* involved**) to facilitate payment for services to these individuals.**)**

*CMS* 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, 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", *and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag".* 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 deficiency(ies) 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 you *disagree with this action imposed on your facility,* you *or your legal representative* may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 CFR 498.40, et seq. *You must file your hearing request electronically by using the DAB's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov,* no later than sixty (60) days *after receiving this letter. Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request must also be submitted electronically to:*

***INSERT REGIONAL OFFICE CONTACT INFORMATION***

*Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:*

*Department of Health & Human Services*
*Departmental Appeals Board, MS 6132*
*Director, Civil Remedies Division*
*330 Independence Avenue, S.W.*
*Cohen Building – Room G-644*
*Washington, D.C. 20201*
*(202) 565-9462*

A request for a hearing should identify the specific issues, findings of fact and conclusions of law with which you disagree. *It should also specify the basis for contending that the findings and conclusions are incorrect. At an appeal hearing,* you may be represented by counsel at your own expense.

*If you have any questions regarding this matter, please contact the CMS (**insert city**) Regional Office by phone at (**insert phone number**) or by e-mail at (**insert email address**).*

Sincerely yours,

*Associate* Regional *Administrator/Equivalent*

Enclosure*s*: CMS Form-2567 Statement of Deficiencies
*DAB E-filing Instructions*

CC: State Survey Agency
Accrediting Organization

# EXHIBIT 211

***(Rev. 148, Issued: 10-09-15, Effective: 10-09-15, Implementation: 10-09-15)***

## MODEL LETTER FOR A VIOLATION OF 42 CFR 489.24 AND/OR THE RELATED PROVISIONS OF 42 CFR 489.20 NOTICE OF TERMINATION

(**Date**)

Hospital*/Critical Access Hospital (CAH)* Name
Address
City, State, ZIP Code

**Re: CMS Certification Number (CCN)**

Dear (**Hospital*/CAH CEO*** **Name**):

In order to participate in the Medicare program, a hospital *or CAH* must meet the requirements established under title XVIII of the Social Security Act (the Act) and must also meet the additional requirements established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) authorizes the Secretary to terminate the provider agreement of a hospital *or CAH* that fails to meet these provisions.

After a careful review of the facts, we have determined that (***facility name***) no longer meets the requirements for participation as a provider of services in Medicare. Our review of the (**date**) survey conducted by the (**State Survey Agency**) indicates that your hospital violated:

(**Select as appropriate**)

•The requirements of 42 CFR 489.24, based on: **(*select all that apply:* failure to screen, treat, appropriately transfer, or accept an individual who required the hospital's specialized capabilities; or delay in examination or treatment*; or imposing* a penalty or adverse action against a physician *or* qualified medical person *for refusal to authorize transfer of an unstabilized individual, or against any* hospital employee *for reporting an EMTALA violation*)**.

•The related anti-dumping provisions of 42 CFR 489.20, based on failure to: ***(select all that apply:*** **have and enforce policies to ensure compliance with the requirements of §1867 of the Act, maintain transfer records, maintain an on-call list of physicians, maintain a central emergency services log, report *receipt of an inappropriate transfer,* or meet the *signage* requirements)**.

The deficiencies cited by the (**State Survey Agency**) are listed on the enclosed Form CMS-2567, Statement of Deficiencies and Plan of Correction.

*In accordance with* 42 CFR 489.53, a hospital *or CAH* that violates the provisions of 42 CFR 489.24 and/or the related provisions of *42 CFR* 489.20 is subject to termination of its provider

agreement in accordance with §1866(b) of the Act. Consequently, we are terminating your participation in the Medicare program.

The date on which your agreement terminates is (**date**). The Medicare program will not make payment for hospital services furnished to patients admitted on or after (**termination date**). For patients admitted prior to (**termination date**), payment may continue to be made for up to 30 days for covered inpatient *and, when applicable, skilled nursing facility-level swing bed* services furnished on or after (**termination date**). A list showing the names and health insurance claim numbers of the Medicare patients remaining in your facility on (**day before termination date**) should be forwarded to (**RO contact and address**).

As the requirements for participation in the Medicaid program under 42 CFR 440.10(a)(3)(iii) include meeting Medicare requirements, we *will notify* the appropriate State officials concerning your hospital's violation of 42 CFR 489.20 and/or 42 CFR 489.24.

(**Insert for 42 CFR 489.24 violation:** We are also notifying the Office of Inspector General, which has responsibility for the enforcement of the civil monetary penalties prescribed by §1867 of the Act).

**(Insert for referral to OCR:** In addition, we are notifying the regional Office of Civil Rights, which may take action under the Hill- Burton Subpart G Community Service regulations at 42 CFR 124.603(b)(1).)

***(If this is the first notice after the survey, add the following:*** *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, 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", and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag". 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 deficiency(ies) 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 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 you *disagree with this termination action,* you *or your legal representative* may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 CFR 498.40, et seq. *You must file your hearing request electronically by using the DAB's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov,* no later than sixty (60) days *after receiving this letter. Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request must also be submitted electronically to:*

***INSERT REGIONAL OFFICE CONTACT INFORMATION***

*Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:*

*Department of Health & Human Services*
*Departmental Appeals Board, MS 6132*
*Director, Civil Remedies Division*
*330 Independence Avenue, S.W.*
*Cohen Building – Room G-644*
*Washington, D.C. 20201*
*(202) 565-9462*

A request for a hearing should identify the specific issues, findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. *At an appeal hearing,* you may be represented by counsel at your own expense.

If you have any questions *regarding* this *matter,* please contact *the CMS (**insert city**) Regional Office by phone at (**insert phone number**) or by e-mail at (**insert email address**).*

Sincerely,

Associate Regional Administrator*/E*quivalent

Enclosure*s*: Form CMS-2567, Statement of Deficiencies
*DAB E-filing Instructions*

CC:
State Survey Agency
State Medicaid Agency
OIG (if appropriate)
OCR/FO (if appropriate)
Accredit*ing* Organization