
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 67

Date: October 18, 2010

NOTE: Transmittal 64, dated October 8, 2010, is being rescinded and replaced by Transmittal 67, dated October 18, 2010 to correct the link for Exhibit 352, in the table of contents. The previous link showed 362 instead of 352. All other material remains the same.

SUBJECT: Revision of Various Exhibits and the Table of Contents

I. SUMMARY OF CHANGES: Several Exhibits are being revised to reflect current policy, two new exhibits are being added, and the Table of Contents is being updated.

REVISED/NEW MATERIAL – EFFECTIVE DATE: October 18, 2010
IMPLEMENTATION DATE: October 18, 2010

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	Table of Contents
R	Exhibit 134/Model Letter Transmitting Requirements to a Hospital Requesting Change in Status to a Critical Access Hospital
R	Exhibit 151/Model Letter Requesting a Plan of Correction Following an Initial Critical Access Hospital (CAH) Survey
R	Exhibit 152/Model Letter Critical Access Hospital (CAH) Termination Letter
R	Exhibit 165/Notice to a Provider that Agreement Was Accepted
N	Exhibit 165a/Notice to a Deemed Provider/Supplier that Agreement Was Accepted
R	Exhibit 166/Notice of Approval of Supplier of Services
R	Exhibit 182/Notice of Termination to Supplier
R	Exhibit 189/Notification: Approval of Voluntary Termination of a Supplier
R	Exhibit 191/Notification to Supplier That Has Ceased or is Ceasing Operation
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 293/CMS DUA: ACTS SOR Attachment – P&A
R	Exhibit 295/DUA Disclosure Tracking Addendum
N	Exhibit 352/Notice to a Provider/Supplier That Agreement Was Not Accepted

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2010 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.**

Medicare State Operations Manual

Chapter 9 - Exhibits

Exhibits

(Rev. 67, 10-18-10)

Exhibit	Description	Download
165a	Notice to a Deemed Provider/ Supplier that Agreement was Accepted	http://www.cms.gov/manuals/downloads/som107_exhibit_165a.pdf
352	Notice to a Provider/supplier that Agreement was not Accepted	http://www.cms.gov/manuals/downloads/som107_exhibit_352.pdf

EXHIBIT 134

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

MODEL LETTER TRANSMITTING REQUIREMENTS TO A HOSPITAL REQUESTING CHANGE IN STATUS TO A CRITICAL ACCESS HOSPITAL

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

Dear _____:

The Regional Office of the Centers for Medicare and Medicaid Services (CMS-RO) and the State Agency have received information that your hospital is requesting a change in Medicare provider status to critical access hospital (CAH). The purpose of this letter is to inform you of the requirements and procedures that are required to become certified as a Medicare CAH.

To be eligible for certification as a CAH, the hospital must first be designated as eligible in writing by the State. In addition the following criteria must be met.

- Location in a rural area. If the hospital is located within a metropolitan statistical area (MSA) the hospital must apply to CMS for reclassification under a State statute or regulation that has been codified in law that would define your location to be rural for your State rural health programs. If located within an MSA, you must provide the CMS RO with a letter requesting reclassification, along with a copy of the State law that would qualify the hospital to be reclassified as rural under 42 CFR 412.103.
- The provider must be a current Medicare-participating hospital, an otherwise qualified closed hospital, or a hospital that was previously down-sized to a rural health clinic, as defined at 42 CFR 485.610(a).
- The hospital must be located in a State that has established a Medicare Rural Hospital Flexibility Plan.
- The hospital must currently be in compliance with the Medicare hospital Conditions of Participation (CoPs).
- As specified at 42 CFR 485.610(c), the hospital must be located more than a 35 mile drive from any other hospital or CAH, or 15 miles in mountainous terrain or in areas with only secondary roads available.
 - *Off-campus provider based locations created or acquired on or after January 1, 2008 are subject to 42CFR 485.610(e)(2) and must meet the provider-based requirements at 42 CFR 413.65 and the minimum distance criteria from another hospital or CAH specified at 42 CFR 485.610(c).*
- The hospital must operate not more than 25 beds for inpatient care.
- The hospital must provide acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient, as required by 42 CFR 485.620(b).

- The facility may choose to offer skilled nursing facility (SNF) - level care in swing beds under a specific swing-bed approval, upon demonstration of compliance with the swing-bed requirements, found at 42 CFR 485.645. Swing beds do count toward the 25-bed limit but do not have a length of stay restriction and are not used to compute the facility length of stay average.
- The hospital may also provide services in a maximum 10-bed psychiatric distinct part unit (DPU) and/or a maximum 10-bed rehabilitation DPU after demonstrating compliance with 42 CFR 485.647. These units are exempt from the 25 bed limit and are not used to compute the facility annual average inpatient length of stay.
- The hospital must comply with all other CAH CoPs found at 42 CFR 483 Subpart F, including provision of emergency services 24 hours a day and 7 days a week.
- The hospital must complete the forms that are included with this letter and return the package to the SA.
- The hospital must successfully complete an initial survey demonstrating compliance with the CAH CoPs at 42 CFR 485 Subpart F.

Your facility may not receive reimbursement for services as a CAH prior to the Medicare effective date for certification in the Medicare program issued by the CMS RO.

Please do not hesitate to contact this office at (*telephone number of SA*) if you have any questions regarding the CAH survey process or any of the documentation requested.

Sincerely,

State Agency Representative

Enclosures: **(list as appropriate)**

cc:

Fiscal Intermediary/Medicare Administrative Contractor
Regional Administrator
State Department of Health

EXHIBIT 151

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

MODEL LETTER **REQUESTING** A PLAN OF CORRECTION FOLLOWING AN INITIAL CRITICAL ACCESS HOSPITAL (CAH) SURVEY

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

Dear _____:

Enclosed you will find the Form CMS-2567 "Statement of Deficiencies and Plan of Correction." This form enumerates deficiencies found during the initial Medicare 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.

The Plan of Correction must contain the following:

- What measures will be put into place or what systematic changes will be made to ensure the deficient practice does not recur, including the anticipated implementation date (a reasonable time-frame is allowed); and
- How the corrective action will be monitored to ensure compliance: what quality assurance indicators will be put into place and who will be responsible to oversee their monitoring.

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 CAH to the CMS regional office (CMS- 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 CAH. The CMS-RO will determine the effective date of CAH certification.

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. Please be specific as to how the deficient practice will be corrected. Failure to do so will result in the plan being returned for revision, creating a delay in the approval of your plan of correction.

Sincerely,

State Agency Representative

Enclosure: Form CMS-2567

cc:

Fiscal Intermediary/Medicare Administrative Contractor
Regional Administrator
State Department of Health

EXHIBIT 152

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

MODEL LETTER CRITICAL ACCESS HOSPITAL (CAH) TERMINATION LETTER

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

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

Dear _____:

After a careful review of the facts, the Centers for Medicare and Medicaid Services (CMS) has determined that (**insert name of CAH**) no longer meets the requirements for participation as a CAH provider of services in the Medicare program under Title XVIII of the Social Security Act.

To participate in the Medicare program as a CAH, a provider must meet the applicable provisions of §1820 of the Act and be in compliance with the Conditions of Participation (CoPs) at 42 CFR Part 485 Subpart F. If the CAH has swing-bed approval, the provider must also comply with the skilled nursing facility requirements for CAHs at 42 CFR §485.645. If the CAH has distinct part units, the provider must also comply with the requirements for CAHs at 42 CFR §485.647.

The (**name of State agency**) certifies to the CMS-Regional Office (CMS-RO) whether a CAH meets the CoPs. Based on the record of the State agency's visits, findings, and recommendations, we find that (**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 (***termination date***). The Medicare program will no longer make payment for CAH services to patients admitted after the termination date. For patients admitted prior to the termination date, payment may continue to be made for a maximum of 96 hours for inpatient services furnished on or after the termination date.

For swing-bed patients receiving a SNF level of care that are admitted prior to the termination date, payment may continue to be made for a maximum of 30 days after the termination date. You should submit a list of names and Medicare claim numbers of beneficiaries in your CAH on the termination date to the (**CMS-RO name and address**) as soon as possible.

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

You may take steps to meet the participation requirements. The **(name of State agency)** is available to provide assistance in order to accomplish this.

If you wish to be readmitted to the program following termination, you must demonstrate that you are able to maintain compliance. Readmission to the program will not be approved until you are able to demonstrate compliance for a period of not less than **(insert number of days)** consecutive days.

If you do not believe this determination is correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, *Departmental Appeals Board*. Procedures governing this process are set out in the 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. To expedite handling, the request may be made to:

Associate Regional Administrator or Equivalent
Street Address
City, State, Zip Code

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. We will forward your request to the Departmental Appeals Board.

At your option, you may instead submit a hearing request directly, accompanied by a copy of this letter to:

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 copy of your request should be provided to the State agency.

If you have any questions concerning this letter, please contact **(insert contact information)**.

Sincerely,

Associate Regional Administrator/Equivalent

Enclosure: Form CMS-2567 Statement of Deficiencies

cc:

Fiscal Intermediary/Medicare Administrative Contractor
State Department of Health
CMS Regional Office

EXHIBIT 165

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

NOTICE TO A PROVIDER THAT AGREEMENT WAS ACCEPTED

(Date)

Provider Name
Street Address
City, State, ZIP Code

Re: CMS CERTIFICATION NUMBER (CCN) [enter CCN assigned to the facility]

Dear (Provider Name):

Your agreement for participation as a (**identify type of provider**) under the Medicare program has been accepted by the Centers for Medicare & Medicaid Services (CMS). Your effective date of Medicare participation is (**date**). Enclosed is one copy of the completed agreement for your records.

Your participation is contingent upon compliance with all Federal civil rights requirements, as determined by the Office of Civil Rights.

Please include the CCN shown above on all forms and correspondence related to your Medicare participation.

Your Medicare Administrative Contractor (MAC) has been notified of your certification for Medicare participation. They will contact you shortly regarding billing procedures.

If you believe that this notice is incorrect in any aspect, you may request that it be reconsidered. The request for reconsideration must be submitted in writing to this office within sixty (60) days of receipt of this notice. You may submit any information that you believe has a bearing on the issue in question.

If you have any questions, please contact (Name and contact information of RO Staff).

We welcome your participation and look forward to working with you.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure: Form CMS-1561
Cc: State Survey Agency

EXHIBIT 165a

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

**NOTICE TO A DEEMED PROVIDER/SUPPLIER
THAT AGREEMENT WAS ACCEPTED**

(Date)

Provider /Supplier Name

Address

City, State, ZIP Code

Dear (Provider/Supplier Name):

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

Your agreement for participation as a deemed status (identify type of provider/supplier) under the Medicare program has been accepted by the Centers for Medicare & Medicaid Services (CMS). This is based on the accreditation status granted by (Accreditation Organization) and its recommendation that you meet the applicable requirements for Medicare participation, based on its survey findings.

Your participation is contingent upon compliance with all Federal civil rights requirements as determined by the Office of Civil Rights. (NOTE: Include this paragraph only for deemed providers, such as Hospitals, Critical Access Hospitals, Home Health Agencies and Hospices.)

Your effective date of Medicare participation is (date). Enclosed is a copy of the completed agreement for your records.

Please include the CCN shown above on all forms and correspondence related to your Medicare participation.

Your Medicare Administrative Contractor (MAC) has been notified of your certification for Medicare participation. They will contact you shortly regarding billing procedures.

If you believe that this notice is incorrect in any aspect, you may request that it be reconsidered. The request for reconsideration must be submitted in writing to this office within sixty (60) days of receipt of this notice. You may submit any information that you believe has a bearing on the issue in question.

Page 2

If you have any questions, please contact (Name and contact information of RO Staff).

We welcome your participation and look forward to working with you.

Sincerely yours,

*Associate Regional Administrator
(or its equivalent)*

Enclosure: Form CMS-1561

*cc: Accreditation Organization
State Survey Agency*

EXHIBIT 166

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

NOTICE OF APPROVAL OF SUPPLIER OF SERVICES

(Date)

Supplier Name
Street Address
City, State, ZIP Code

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

Dear (*Supplier Name*):

Your request for approval as a supplier of (*list service(s)*) under the Medicare program has been approved. Your effective date of Medicare participation is (*date*).

Your Medicare Administrative Contractor (MAC) has been notified of your certification for Medicare participation. They will contact you shortly regarding billing procedures

You should report to the *Medicare Administrative Contractor* and the State Agency any changes in staffing, services or other characteristics which may affect your compliance with the Conditions *for Coverage or Conditions for Certification, as applicable*. The State Agency will survey you periodically to determine that the Conditions for Coverage *or Conditions for Certification* services are still met.

Please include the CCN shown above on all forms and correspondence relating to the Medicare program.

If you believe that this notice is incorrect in any aspect, you may request that it be reconsidered. The request for reconsideration must be submitted in writing to this office within sixty (60) days of receipt of this notice. You may submit any information that you believe has a bearing on the issue in question.

If you have any questions, please contact (Name and contact information of RO Staff).

We welcome your participation and look forward to working with you.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

EXHIBIT 182

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

NOTICE OF TERMINATION TO SUPPLIER

(Date)

Supplier Name
Address
City, State, ZIP Code

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

Dear (Supplier Name):

After a careful review of the facts, the Centers for Medicare & Medicaid Services has determined that **(name)** no longer meets the *(Conditions for Coverage) or(Conditions for Certification) of (supplier type)*. The Conditions for Coverage are issued as regulations of the Centers for Medicare & Medicaid Services in accordance with the provisions of Title XVIII of the Social Security Act. You must be in compliance *with these Conditions* in order for your services to Medicare beneficiaries to be reimbursed under the Medicare program. The **(State agency)**, which has surveyed your facility to assist us, has furnished information from which we have determined that you no longer meet these requirements:

(State reason(s) for termination.)

It is necessary, therefore, that we terminate coverage of your *(supplier type)* services effective **(date)**. We will arrange to publish a routine notice in the **(local newspaper)**. You will be advised of the publication date of the notice. This action, and the reasons therefore, will also be made known to the professional users of your services.

If you believe that this determination is not correct, you may request a hearing before an administrative law judge of the *Department of Health and Human Services Departmental Appeals Board. Procedures governing this process are set out in the regulation 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. To expedite handling the request may be made to:*

Associate Regional Administrator or Equivalent
Street Address
City, State, Zip Code

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. We will forward your request to the Departmental Appeals Board.

Page 2

(Name)
(Date)

At your option, you may instead submit a hearing request directly, accompanied by a copy of this letter to:

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

Attention: Director, Departmental Appeals Board

A copy of your request should be provided to the State Agency.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

EXHIBIT 189

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

**NOTIFICATION: APPROVAL OF VOLUNTARY TERMINATION
OF A SUPPLIER**

(Date)

Supplier Name

Address

City, State, ZIP Code

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

Dear (Supplier Name):

Your request to terminate your Medicare coverage as a supplier of services has been accepted. Accordingly, your coverage under the program will be terminated effective **(date)**.

Optional

Since this action may be of interest to the public, we will publish a notice in the local newspaper with the widest circulation as soon as possible but at least 15 days before the effective termination date. The notice will give the effective date of termination and state that payment for services will not be made on or after that date. This action will be made known to professional users of your services.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

EXHIBIT 191

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

NOTIFICATION TO SUPPLIER THAT HAS CEASED OR IS CEASING OPERATION

(Date)

Supplier Name

Address

City, State, ZIP Code

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

Dear (Supplier Name):

We have been notified that your **(facility type) (closed, will close)** on **(date of closing)**. Therefore, your participation in the Medicare program **(terminated, will terminate)** effective with that date. No payment can be made under the Medicare program for services rendered on or after **(date of closing)**

Optional

Since this action may be of interest to the public, we will publish a notice in the local newspaper with the widest circulation as soon as possible. The notice will give the effective date of termination and the state that payment for **(supplier type)** services will not be made on or after that date. This action will be made known to professional users of your services.

If your **(supplier type) reopens** and you again wish to be covered under the Medicare program, you *must submit a new application to enroll in the Medicare program.*

Please let us know if you have any questions concerning this action.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

EXHIBIT 196

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

**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/
*CONDITIONS FOR CERTIFICATION***

(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 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)**

Enclosure
CMS Form-2567

Exhibit 293

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

DUA #

CMS DUA: ACTS SOR Attachment - P&A

[Attachment to CMS Data Use Agreement (Form CMS-R-0235) for Disclosures to Protection and Advocacy Organizations (P&A) Consistent With the ACTS System of Record (SOR)]

This Attachment describes how the CMS Data Use Agreement (DUA) applies to the Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) System of Record (SOR) with respect to disclosure to a State-mandated Protection and Advocacy (P&A) organization of data related to a hospital report of a death associated with *the* use of restraint or seclusion.

Clarifications to DUA Sections:

The section references found below refer to the CMS DUA (Form CMS-R-0235) that must be signed by each P&A organization accessing hospital restraint and seclusion-related death report information.

- The reference to the Health Insurance Portability and Accountability Act in the introductory paragraph is not applicable.
- Section 4: CMS Contract # is not applicable. This DUA applies to an entity designated by a State to serve as a State-mandated P&A organization.
- Section 4: In its entirety, the second paragraph concerning the use of data for a study or research, etc. is not applicable for purposes of this Agreement. The permissible data uses can be found below in this Attachment.
- Section 5: All Hospital Restraint/Seclusion Death Report Worksheets for which on-site investigations are authorized are covered by the DUA and will continue to be covered as long as the ACTS SOR exists.
- Section 6: This completion date is not applicable to the use of data under the ACTS SOR.
- Section 9: This section does not apply to the use of ACTS SOR data for investigative purposes and/or reports by a state-designated P&A organization.

Permissible Data Uses:

The ACTS SOR permits certain disclosures to assist a State-mandated P&A organization that provides legal representation and other advocacy services to beneficiaries. Under the DUA, the Requestor, as a State-mandated P&A organization, may use hospital restraint/seclusion death report data released to it to investigate such incidents. This and any other disclosure or use of personally identifiable information under the ACTS SOR is governed by the terms of the DUA and, thereby, terms of the Privacy Act of 1974, Centers for Medicare & Medicaid Services (CMS) data release policies, and the ACTS SOR Notice of May 23, 2006.

Requestor's Initials and Date

The language contained in this Attachment cannot be altered in any form.

Exhibit 295

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

DUA Disclosure Tracking Addendum

Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy Organizations

This Addendum to DUA # _____ must be executed prior to the disclosure of any person-identifiable restraint/seclusion hospital death report data to ensure the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule, and CMS data release policies. It must be completed prior to the release of, and access to, specified data files containing personal information and individual identifiers.

When Regional Offices (ROs) release person-identifiable hospital death report data to a state-mandated Protection and Advocacy (P&A) Agency/Organization authorized to investigate such incidents/complaints, the P&A must have a signed Data Use Agreement (DUA) on file with CO and the RO. The RO is responsible for tracking all disclosures made. *The* RO representative making the disclosure of person-identifiable data must sign this Addendum.

The following individual(s) have requested and been granted access to the CMS restraint/seclusion hospital death report data for investigations and associated activities.

_____ (Intake Number)	_____ (Intake Number)
_____ (Name of Requesting Custodian)	_____ (Name of Requesting Custodian)
_____ (Title)	_____ (Title)
_____ (Agency/Organization)	_____ (Agency/Organization)
_____ (Street Address)	_____ (Street Address)
_____ (City/State/ZIP Code)	_____ (City/State/ZIP Code)
_____ (Phone No. and E-Mail Address, if applicable)	_____ (Phone No. and E-Mail Address, if applicable)
_____ (RO Signature)	_____ (RO Signature)
_____ (Release Date)	_____ (Release Date)

Exhibit 352

(Rev. 67, Issued: 10-18-10, Effective: 10-18-10, Implementation: 10-18-10)

***NOTICE TO A PROVIDER/SUPPLIER THAT AGREEMENT WAS NOT
ACCEPTED***

(Date)

Provider/Supplier Name
Street Address
City, State, ZIP Code

Dear (Provider/Supplier Name):

Your application for participation as a (identify type of provider/supplier) in the Medicare program has been denied by the Centers for Medicare & Medicaid Services (CMS). This decision was based on the recommendation received from (State Survey Agency or Accreditation Organization). That information indicated that you did not meet all Medicare (identify provider/supplier type) (indicate Conditions of Participation, Conditions for Coverage, or Conditions for Certification).

If you believe this determination is incorrect, you may ask that it be reconsidered in accordance with the provisions of 42 CFR 498.22. Your request must be submitted in writing to this office within 60 days from the date of receipt of this letter. You may submit with your request for reconsideration any additional information you believe to be pertinent to this decision.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

CC: Accreditation Organization (if applicable)
State Survey Agency
MAC