DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C: 09-12

DATE: **November 7, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Update of State Operations Manual (SOM) Chapter 5/Release of Person-Identifiable Data Related to Restraint/Seclusion Deaths to Protection and Advocacy Organizations.

Memorandum Summary

- S&C-08-23, issued May 30, 2008, updated Section 5140 of the SOM, concerning handling of hospital reports of deaths associated with the use of restraint or seclusion.
- Sections 5140.3 and 5140.4 are being revised further to streamline the process for disclosing restraint/seclusion death report data to Protection and Advocacy (P&A) organizations. New Exhibits are added to facilitate the implementation of Data Use Agreements with P&As.

S&C-08-23 dated May 30, 2008 updated the SOM provisions governing Hospital restraint/seclusion death reporting, including the process for disclosing death report information to P&A organizations. The Centers for Medicare & Medicaid Services (CMS) has developed a more efficient, less burdensome process for releasing person-identifiable data to P&As. Under the revised process, a P&A must obtain one CMS-approved Data Use Agreement (DUA), Form CMS-R-0235, which will govern all disclosures of person-identifiable hospital restraint/seclusion death report information to that P&A by the CMS Regional Office (RO). In implementing this process we are eliminating the need for a P&A to submit a DUA update for each individual request for data. ROs will be responsible for maintaining a record of each disclosure, as well as all death report worksheets. We have requested records management guidance on the retention period for the worksheets; in the meantime, ROs are to retain all worksheets until we provide further notice.

The revised P&A disclosure process is described in detail in updated SOM sections 5140.3 and 5140.4, an advance copy of which is attached, along with copies of the standard CMS DUA and related new SOM Exhibits. The final version of the SOM will be released at a later date and may differ slightly from this copy.

If you have questions regarding the revised procedures for Hospital restraint/seclusion-associated death reports, please contact Kimberly DeMichele at Kimberly.DeMichele@cms.hhs.gov

Effective Date: Immediately. Please ensure that all personnel are appropriately informed within 30 days of this memorandum.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments (4)

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal – ADVANCE COPY **Date:**

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 5, Section 5140, Hospital Restraints/Seclusion Death Reporting and Investigation.

I. SUMMARY OF CHANGES: Chapter 5, Section 5140, Hospital Restraints/Seclusion Death Reporting and Investigation, was updated to reflect changes in policies and procedures related to new and amended regulations at 42 CFR 482.13(e), (f), and (g). In addition, new Exhibits 292 through 295 have been added to facilitate implementation of the Data Use Agreement Process described in Section 5140.4.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Section 5140.1
D	Section 5140.2 – this section is now reserved
R	Section 5140.3
R	Section 5140.4
N	Exhibit 292
N	Exhibit 293
N	Exhibit 294
N	Exhibit 295

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx 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.**

5140.1 - Background

(Rev.)

The Centers for Medicare & Medicaid Services (CMS) hospital restraint and seclusion requirements are found in the Hospital COP, Patients' Rights at 42 CFR 482.13, Standards (e),(f) *and (g)*. *(See also 71 FR 71378, December 6, 2006)*

The hospital's reporting requirement *for* death*s associated with the use of* restraint *or* seclusion is located at 42 CFR 482.13(*g*) and states*:*

> ***"Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint.***
>
> *(1) The hospital must report the following information to CMS:*
>
> *(i) Each death that occurs while a patient is in restraint or seclusion.*
>
> *(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.*
>
> *(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.*
>
> *(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.*
>
> *(3) Staff must document in the patient's medical record the date and time the death was reported to CMS."*

Hospitals are required to report a restraint/seclusion death via telephone to their CMS RO.

The interpretive guidelines found in the Hospital Appendix A at 42 CFR 482.13(e) – (g) discuss in detail what is considered a restraint or seclusion, the requirements governing hospital use of restraint or seclusion, and these reporting requirements.

5140.2 – *[Reserved]*

5140.3 - Responsibilities

(Rev.)

Regional Offices (ROs)

The RO maintains a Hospital Restraint/Seclusion Death Report Worksheet for each case reported.

The RO is also responsible for data entry into the Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) Restraint/Seclusion Death Module and for maintenance of Data Use Agreement files related to disclosures to Protection and Advocacy agencies. (see Process discussion below).

Each RO designates one contact person and a backup person who serves as the point of contact, coordination, and communication regarding reporting, investigation and follow-up for the death-reporting requirement under Patients' Rights.

State Agencies (SAs)

Hospitals report patient deaths associated with restraint or seclusion, as previously discussed, to their CMS RO*, not to the SA*. Any hospital patient restraint or seclusion death report received by a SA directly from a hospital (or other source) *must be* forwarded immediately *by the SA* to its RO.

The SA conducts a complaint investigation related to a patient death associated with a hospital's use of restraints or seclusion only when the RO authorizes the investigation.

SAs are to *assist ROs in educating* the hospitals in their State *about their obligation to report to* their RO any death that *meets the reporting requirements found at 42 CFR 482.13(g).* State Agencies are to provide hospitals with their RO contact name and telephone number, as well as the hospital reporting procedures contained in this policy.

SAs respond to requests from Protection and Advocacy (P&A) organizations, or any other parties, for information on survey findings related to specific cases identified by the requestor. SAs handle these requests in accordance with the SA's Data Use Agreement (DUA) with CMS.

5140.4 - Process

(Rev.)

*T*he RO evaluates the information *required to be reported* by the hospital *under 42 CFR 482.13(g)* to determine *whether* the situation *warrants an on-site investigation. The RO uses the Hospital Restraint/Seclusion Death Report Worksheet when recording the hospital's telephonic report. The RO may not require any hospital to complete and submit a hard copy of the worksheet. However, a hospital may volunteer to submit a completed worksheet in lieu of providing the requested information telephonically. The RO may provide a template worksheet to hospitals that volunteer to submit their reports via a completed worksheet.*

Using the worksheet detail provided by the hospital, the RO evaluates whether the case might involve a violation of 42 CFR 482.13(e) through 42 CFR 482.13(g) and authorizes an on-site investigation if there appears to be a possible violation. It is likely that the majority of hospital reports of deaths associated with the use of seclusion or restraint will ***not*** *require an on-site investigation.* If the *RO determines that the* restraint/seclusion death report *requires on-site investigation*, within 2 working days of receiving the report, the RO *enters the reported information into the ACTS restraint/seclusion module and* immediately notifies the SA to authorize a *complaint* survey to investigate the hospital's compliance with the Patient's Rights *CoP* at 42 CFR 482.13*(e), (f), or (g), including the reported case.* The SA *accesses the ACTS restraint/seclusion module to see the details of the reported case prior to conducting the on-site* investigation. The SA should complete *the* investigation within 5 working days of receipt of survey authorization from the RO.

In addition to completing the ACTS Restraint/Seclusion module for all cases that are authorized for on-site investigation, the RO also completes this module for all cases reported by hospitals to the RO during the months of April, October, and January, regardless of whether an on-site investigation was authorized, in order to provide a detailed and representative data base that supports analysis of deaths associated with hospital use of restraint and seclusion.

Notice to Protection and Advocacy Organizations

At the same time that the RO notifies the SA and *authorizes* the *on-site* survey, *the RO also provides written notification, by mail or email, to* the appropriate *Protection and Advocacy (*P&A*) organization within the State where the hospital is located*. *Notification is provided only in those cases for which an on-site survey is authorized.* The RO provides the following information to the P&A: hospital's name, hospital's address, *date the restraint/seclusion-associated death occurred, patient's diagnosis, and type(s) of restraint/seclusion used.* THIS IS THE **ONLY** INFORMATION TO BE SUPPLIED TO *P&A* ORGANIZATIONS *ON AN UNSOLICITED BASIS*. *No individual identifiers are to be provided.* The names and *addresses for* each State's P&A can be located at the *following website, at the drop down menu entitled "Get Help in Your State:" www.ndrn.org .*

After reviewing the summary provided by the RO, consistent with the ACTS Notice of a Modified or Altered System of Records (SOR), published May 23, 2006, in the Federal Register (SOR 09-70-0565), the P&A may request more detailed information relating to that case, including the name of the deceased contained in the ACTS restraint/seclusion module and the worksheet for the case. The P&A must have an approved CMS Data Use Agreement (DUA), Form CMS-R-0235, (Exhibit 292) in place before the RO may release a copy of the worksheet and/or information from the ACTS restraint/seclusion module.

Form CMS-R-0235 may be submitted by a P&A to CMS in advance of any specific request for person-identifiable data. Once the P&A has an approved DUA and has submitted a copy of it to the RO, that DUA applies to all subsequent disclosures to the P&A of person-identifiable data in response to requests for hospital restraint/seclusion death information to the RO. It is not necessary for the P&A to submit a DUA update for each individual request.

In order to get an approved DUA, the P&A must complete and submit a signed CMS DUA, Form CMS-R-0235, including an initialed DUA ACTS SOR- P&A Attachment (Exhibit 293) to the Director, Division of Privacy Compliance, Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. That Division will

review the DUA, assign a unique DUA identifier to it, and return a signed copy to the P&A. When completing the Form, P&As must note the following in particular:

- *Line 5 of the DUA must state "Restraint/Seclusion Hospital Death Reports." The "Years" and "System of Record" columns should be left blank.*
- *Line 12 must state "CMS DUA: ACTS SOR Attachment – P&A."*
- *The DUA must be signed by the P&A official whom the P&A designates as "Custodian," i.e., the individual who will have actual possession of and responsibility for the data released under the DUA.*
- *A P&A may designate more than one Custodian, but if it does so, each individual must complete and sign a Multi-Signature Addendum Form (Exhibit 294).*

For each disclosure of personally identifiable data to a P&A that has an approved DUA, the RO must complete the DUA Tracking Addendum (Exhibit 295), sequentially listing each case file disclosed. Disclosure of person-identifiable data is permitted only for those cases where the:

- *RO has previously notified the P&A, without providing person-identifiable data, of a hospital restraint/seclusion death report for which a SA survey has been authorized; or*
- *P&A identifies in its request an individual and hospital by name and requests restraint/seclusion death report information that may have been submitted by that hospital with respect to that individual.*

The DUA Tracking Addendum must show the DUA number of the primary P&A DUA. The RO must enter the ACTS Intake Number, Requestor's Name and Title, Name of the P&A, Address, Telephone Number and E-Mail Address, (if applicable). Because the RO is responsible for tracking all disclosures made, the RO must sign the Addendum for each disclosure. ROs must ensure that the responsibilities related to processing hospital restraint/seclusion death reports are clearly articulated and implemented within the RO.

Custodians may be added or deleted over the life of the primary DUA. To add a new Custodian under an existing DUA, the P&A must submit the following to the RO: a letter from the P&A describing the activities planned for the new Custodian and the length of time over which the Custodian will serve, and a Multi-Signature Addendum signed by the appropriate official from the P&A. The Multi-Signature Addendum must show the DUA number of the existing primary P&A DUA. The P&A must assign a case number to all Multi-Signature Addendums beginning with "1" and adding consecutively thereafter. CMS will use this number to track the number of Custodians in each P&A. When a P&A seeks to delete an existing Custodian, it must send the RO a letter to this effect. The RO will strike out the name of the deleted Custodian from the DUA or Multi-Signature Addendum that added that Custodian, dating and initialing the deletion. The letter from the P&A removing the Custodian must be kept on file.

P&A requests for information about the on-site survey should be submitted to the SA and handled by the SA in accordance with the SA's ACTS DUA agreement with CMS.

`Exhibit 293

DUA # [ ]

CMS DUA: ACTS SOR Attachment - P&A

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

This Attachment describes how the CMS Data Use Agreement (DUA) applies to 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 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 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 294
DUA Multi-Signature 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 death report data to an alternate or additional Custodian designated by the Protection and Advocacy organization (P&A).

Prior to the Regional Office (RO) releasing person-identifiable restraint/seclusion hospital death report data to a state-mandated P&A authorized to investigate such incidents/complaints, the P&A must have a valid Data Use Agreement (DUA), signed by the P&A-designated Custodian and approved by CMS, on file with the RO. The "Custodian" is the individual within the P&A who will have actual possession of and responsibility for the data files and who will be an official of the P&A. If an alternate or additional Custodian is designated by the P&A, that individual must submit a signed Multi-Signature Addendum Form to the RO.

On behalf of the below-named P&A, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to the terms and provisions of the aforementioned existing DUA.

_____
Name of Custodian (typed or printed)

_____
Agency/Organization

_____
Street Address

_____
City/State/ZIP Code

_____
Telephone (Include Area Code) *E-Mail Address (if applicable)*

_____
Signature *Date*

_____

Exhibit 295
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 and 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)* *(Release Date)*	_____ *(RO Signature)* *(Release Date)*

INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA) FORM CMS-R-0235

(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

This agreement must be executed prior to the disclosure of data from CMS' Systems of Records to ensure that 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, or access to, specified data files containing protected health information and individual identifiers.

Directions for the completion of the agreement follow:

Before completing the DUA, please note the language contained in this agreement cannot be altered in any form.

- First paragraph, enter the Requestor's Organization Name.
- Section #1, enter the Requestor's Organization Name.
- Section #4 enter the Study and/or Project Name and CMS contract number if applicable for which the file(s) will be used.
- Section #5 should delineate the files and years the Requestor is requesting. Specific file names should be completed. If these are unknown, you may contact a CMS representative to obtain the correct names The System of Record (SOR) should be completed by the CMS contact or Project Officer. The SOR is the source system the data came from.
- Section #6, complete by entering the Study/Project's anticipated date of completion.
- Section #12 will be completed by the User.
- Section #16 is to be completed by Requestor.
- Section #17, enter the Custodian Name, Company/Organization, Address, Phone Number (including area code), and E-Mail Address (if applicable). The Custodian of files is defined as that person who will have actual possession of and responsibility for the data files. **This section should be completed even if the Custodian and Requestor are the same.** This section will be completed by Custodian.
- Section #18 will be completed by a CMS representative.
- Section #19 should be completed if your study is funded by one or more other Federal Agencies. The Federal Agency name (other than CMS) should be entered in the blank. The Federal Project Officer should complete and sign the remaining portions of this section. If this does not apply, leave blank.
- Sections #20a AND 20b will be completed by a CMS representative.
- Addendum, CMS-R-0235A, should be completed when additional custodians outside the requesting organization will be accessing CMS identifiable data.

Once the DUA is received and reviewed for privacy and policy issues, a completed and signed copy will be sent to the Requestor and CMS Project Officer, if applicable, for their files.

DATA USE AGREEMENT

DUA # _____

(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

CMS agrees to provide the User with data that reside in a CMS Privacy Act System of Records as identified in this Agreement. In exchange, the User agrees to pay any applicable fees; the User agrees to use the data only for purposes that support the User's study, research or project referenced in this Agreement, which has been determined by CMS to provide assistance to CMS in monitoring, managing and improving the Medicare and Medicaid programs or the services provided to beneficiaries; and the User agrees to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability and Accountability Act. In order to secure data that reside in a CMS Privacy Act System of Records; in order to ensure the integrity, security, and confidentiality of information maintained by the CMS; and to permit appropriate disclosure and use of such data as permitted by law, CMS and _____ *(Requestor)* _____ enter into this agreement to comply with the following specific paragraphs.

1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS), and _____ *(Requestor)* _____, hereinafter termed "User."

2. This Agreement addresses the conditions under which CMS will disclose and the User will obtain, use, reuse and disclose the CMS data file(s) specified in section 5 and/or any derivative file(s) that contain direct individual identifiers or elements that can be used in concert with other information to identify individuals. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 5 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS point-of-contact or the CMS signatory to this Agreement shown in section 20.

3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.

4. The User represents, and in furnishing the data file(s) specified in section 5 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

Name of Study/Project

CMS Contract No. *(If applicable)*

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, that have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 5 will be put.

The User agrees not to disclose, use or reuse the data covered by this agreement except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing or as otherwise required by law, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement. The User affirms that the requested data is the minimum necessary to achieve the purposes stated in this section. The User agrees that, within the User organization and the organizations of its agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this section (i.e., individual's access to the data will be on a need-to-know basis).

5. The following CMS data file(s) is/are covered under this Agreement.

File	Years(s)	System of Record

6. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s)) including those files that directly identify individuals and those that can be used in concert with other information to identify individuals may be retained by the User until, *Date* hereinafter known as the "Retention Date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 4 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, the User agrees to destroy such data. The User agrees to destroy and send written certification of the destruction of the files to CMS within 30 days. The User agrees not to retain CMS files or any parts thereof, after the aforementioned file(s) are destroyed unless the appropriate Systems Manager or the person designated in section 20 of this Agreement grants written authorization. The User acknowledges that the date is not contingent upon action by CMS.

   The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon notice of termination by User, CMS will cease releasing data from the file(s) to the User under this Agreement and will notify the User to destroy such data file(s). Sections 3, 4, 6, 8, 9, 10, 11, 13, 14 and 15 shall survive termination of this Agreement.

7. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it.The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems **(http://www.whitehouse.gov/omb/circulars/a130/a130.html)** as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" **(http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf);** and, Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" **(http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf)**. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in section 5 is prohibited. Further, the User agrees that the data must not be physically moved, transmitted or disclosed in any way from or by the site indicated in section 17 without written approval from CMS unless such movement, transmission or disclosure is required by a law.

8. The User agrees to grant access to the data to the authorized representatives of CMS or DHHS Office of the Inspector General at the site indicated in section 17 for the purpose of inspecting to confirm compliance with the terms of this agreement.

9. The User agrees not to disclose direct findings, listings, or information derived from the file(s) specified in section 5, with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity. Examples of such data elements include, but are not limited to geographic location, age if > 89, sex, diagnosis and procedure, admission/discharge date(s), or date of death.

   The User agrees that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in section 4 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 5 or any data derived from such files) must adhere to CMS' current cell size suppression policy. This policy stipulates that no cell (eg. admittances, discharges, patients) less than 11 may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell less than 11. By signing this Agreement you hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for CMS review. If you are unsure if you meet the above criteria, you may submit your written products for CMS review. CMS agrees to make a determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries

10. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement to do so, the User shall not attempt to link records included in the file(s) specified in section 5 to any other individually identifiable source of information. This includes attempts to link the data to other CMS data file(s). A protocol that includes the linkage of specific files that has been approved in accordance with section 4 constitutes express authorization from CMS to link files as described in the protocol.

11. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in section 20 of this Agreement.

12. The parties mutually agree that the following specified Attachments are part of this Agreement:

    _____

13. The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement or another written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement, CMS, at its sole discretion, may require the User to: (a) promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return data files to CMS or destroy the data files it received from CMS under this agreement. The User understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

    The User agrees to report any breach of personally identifiable information (PII) from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to the CMS Action Desk by telephone at (410) 786-2850 or by e-mail notification at **cms_it_service_desk@cms.hhs.gov** within one hour and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined above, the User shall bear the cost and liability for any breaches of PII from the data file(s) while they are entrusted to the User. Furthermore, if CMS determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, the User agrees to carry out these remedies without cost to CMS.

14. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of $1,000, they shall be fined under Title 18 or imprisoned not more than 1 year, or both.

15. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

16. On behalf of the User the undersigned individual hereby attests that he or she is authorized to legally bind the User to the terms this Agreement and agrees to all the terms specified herein.

Name and Title of User *(typed or printed)*		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
Signature	Date	

17. The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and will be the person responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

    The Custodian hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

Name of Custodian *(typed or printed)*		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
Signature	Date	

18. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in section 4 follow(s). (To be completed by CMS staff.) _____

19. On behalf of _____ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS's data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all questions of such interpretation or compliance with the terms of this Agreement to the CMS official named in section 20 (or to his or her successor).

Typed or Printed Name	Title of Federal Representative
Signature	Date
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*

20. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS.

    On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Name of CMS Representative *(typed or printed)*		
Title/Component		
Street Address		Mail Stop
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
A. Signature of CMS Representative		Date
B. Concur/Nonconcur — Signature of CMS System Manager or Business Owner		Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner		Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner		Date