HEALTH CARE FINANCING ADMINISTRATION DATA USE POLICY AND PROCEDURES

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HEALTH CARE FINANCING ADMINISTRATION DATA USE POLICY AND PROCEDURES

INTRODUCTION

This section is intended to provide basic information on the use of Health Care Financing Administration (HCFA) data within the Agency, including contractors, and in external organizations. This section outlines the policies and procedures to be followed when advising internal and external organizations about appropriate methods and requirements for obtaining approval for their usage of such data and the methodology for the receipt of these data.

Many of the files discussed in this guide contain person-specific data on Medicare and Medicaid providers, beneficiaries, and recipients including individual identifiers such as UPIN, name, Social Security Number, or other elements that would permit the identity of an individual to be deduced (e.g., date of birth, age, race, sex residence, ZIP code). Data with beneficiary or physician identifiers are subject to the Privacy Act and HCFA's policy and procedures. As such, the information is confidential and is to be used only for reasons compatible with the purposes for which the data are collected. HCFA's policies and procedures seek to ensure that files containing physician and/or beneficiary identifiers are used only when specifically necessary and in accordance with the disclosure provisions of the Privacy Act. The policies in this section encompass use of data and data files from Privacy Act Systems of Records for which notices have been published in the Federal Register and which are maintained by HCFA. Further information about HCFA Data Release Policies and Procedures may be obtained by contacting the Office of Information Services (OIS), Enterprise Databases Group (EDG), Division of Data Liaison and Distribution (DDLD) data use policy hotline at (410) 786-3690.

LEGISLATIVE AUTHORITIES

Release of Medicare and Medicaid data is determined primarily by the Freedom of Information Act (FOIA), 5 U.S.C. 552; the Privacy Act of 1974, as amended, 5 U.S.C. 552a; and Section 1106(a) of the Social Security Act. The FOIA generally requires that Agency records be available to the public while the Privacy Act generally prohibits release of data with individual identifiers (or with the identity of the individual deducible under certain circumstances). This apparent conflict is resolved through the exemptions under the FOIA and the disclosure exceptions under the Privacy Act. In addition to Medicare and Medicaid data, HCFA may authorize the collection of Peer Review Organization (PRO) data under Section 1160 of the Social Security Act (42 U.S.C. Section 1320c-9).

Freedom of Information Act (FOIA)

FOIA establishes the public's statutory right of access to government records. Specifically, FOIA requires that records in the possession, custody and control of Federal agencies be disclosed, upon request, unless one of the nine FOIA exemptions apply.

FOIA covers existing agency records in both hard copy and electronic format. Under FOIA, an agency need not create documents that do not exist. However, FOIA recognizes that electronic records found in a database may require the application of codes or some form of programming to locate and retrieve the information. The search for and retrieval of computerized records, via new computer programs and/or data-retrieval efforts, does not amount to the creation of records. Writing special programs to combine elements from several existing records or to derive percentages, ratios, etc. would be considered creating a record.

Under FOIA, a requester may choose the form or format in which he wants a record to be disclosed. When a requester wants a HCFA computerized record to be disclosed in a format other than that normally extracted from the agency's database, HCFA determines whether the record is "readily reproducible" in the new format with "reasonable efforts."

Subsection (b) of FOIA sets forth the nine exemptions that can be invoked to protect records or portions of records from release under FOIA. The exemptions most often applicable to HCFA records are exemptions (b)(2), (b)(4), (b)(5), (b)(6) and (b)(7). The types of records/information that each of these exemptions protects is briefly explained below.

> Exemption (b)(2) - internal personnel rules and practices of an agency, i.e., utilization review parameters
>
> Exemption (b)(4) - trade secrets and commercial or financial information obtained from a person that is privileged or confidential
>
> Exemption (b)(5) - intra-governmental records that would be subject to a generally-recognized discovery privilege
>
> Exemption (b)(6) - information contained in personnel or medical or similar files the disclosure of which would constitute a "clearly unwarranted invasion of personal privacy"
>
> Exemption (b)(7) - law enforcement records

The other exemptions under subsection (b) not specified above protect secret or classified information; information exempted from disclosure by statute; information related to the regulation or supervision of financial institutions; and geological and geophysical information and data concerning wells.

FOIA does not cover records that are published or made available for inspection and copying. Consequently, Public Use Files (PUFs) are not subject to the FOIA, since these files are produced and offered for sale as part of the regular program activity of the Agency.

Only the HCFA Freedom of Information Officer may determine whether to release or deny HCFA records subject to FOIA. All FOIA requests should be forwarded to the Freedom of Information Officer, Division of Freedom of Information and Privacy, Enterprise Databases Group, Office of Information Services, N2-04-27, 7500 Security Boulevard, Baltimore, Maryland, 21244.

Privacy Act

Without the written consent of the subject individual, the Privacy Act prohibits release of protected information maintained in a system of records unless 1 of the 12 disclosure exceptions apply. Only data on living individuals are protected. (Information on corporations or institutions is never protected; information on deceased individuals is generally not protected.)

Social Security Act

Section 1106(a) of the Social Security Act also applies to the release of individual identifiable data. Generally, it prohibits individuals from obtaining data under false pretenses and applies criminal penalties.

HCFA DATA USE POLICIES AND PROCEDURES

This section specifies the conditions and procedures that should be followed in order to authorize the use of HCFA data.

Use of Identifiable Data with Individual's Consent

An individual may have access to any record maintained on him/her in a system of records. HCFA needs the following in order to process this type of request:

- Written request including the specific records being requested
- Verification of the individuals's identity
- Completed consent statement (See copy of consent statement at the end of this section)

The following six conditions must apply to the consent statement:

- The consent must be in writing, signed by the Medicare beneficiary, and dated.
- The consent must be directed to the HCFA or the responsible Medicare contractor(s).

- The consent must specify the information to be disclosed with some particularity (e.g., Part B claims records for the period July 1990 through December 1990), but need not list each claim number or the name of every provider.
- The consent must specify the individual, organization, or class of individuals or organizations to which the record may be disclosed.
- The consent should specify a time frame during which the record may be disclosed (e.g., 1 year from the date the statement was executed). If no time frame is given, we must assume that the consent is for a one-time only disclosure.
- The consent should be presented within a reasonable length of time after its execution. If there is reason to believe that the consent is not timely, HCFA staff should verify the consent with the consenting beneficiary (e.g., HCFA staff should contact the beneficiary if the authorization was executed more than 90 days prior, where medical records are involved, or more than 1 year earlier where only non-medical records are sought).

No fee will be levied.

Use of Identifiable Data Without Individual's Consent

Requests submitted to HCFA for identifiable data to be released under the Privacy Act (i.e., without the individual's consent) should be forwarded to the Office of Information Services (OIS), Enterprise Databases Group, Division of Data Liaison and Distribution (DDLD), N2-04-27, 7500 Security Boulevard, Baltimore, Maryland, 21244. DDLD is the Agency point of contact for Privacy Act data requests. As such, DDLD will review these requests for adherence to Privacy Act requirements, will develop and maintain an official file containing documentation that HCFA has complied with legal and Agency requirements, and will address payment issues.

The Privacy Act

The Privacy Act of 1974 protects the confidentiality of person-specific records that are maintained by the Federal Government and retrieved by a unique indicator. It contains 12 conditions of disclosure under which these records may be released without the written consent of the individual.

Systems of Records

The Privacy Act defines a system of records as a group of any records under the control of a Federal agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Additionally, the Privacy Act requires that the Federal government inform the public of any collection of information about its citizens from which data are retrieved by a unique identifier as described above. Federal agencies fulfill this requirement to inform the public via the publication of a system notice in the Federal Register. This notice describes the system of records and gives the public an opportunity to comment. The Federal agency must also send a report to Congress

and to the Office of Management and Budget (OMB).

The system notice contains a listing of the prescribed limited circumstances under which person-specific records contained in that system may be released. These circumstances are called routine uses. Routine uses must be compatible with the purpose for which the records are collected and maintained.

Privacy Act Disclosure Exceptions

The Privacy Act allows Federal agencies to release person-specific data without the individual's consent if one of the twelve disclosure exceptions apply. These disclosure exceptions are:

(1) *To employees of the Department of Health and Human Services (DHHS)*- DHHS employees can obtain person-specific data on a "need to know" basis. Employee access to HCFA data should occur only in those situations in which these data are integral to the completion of their official duties as a DHHS employee. Employees are obligated to protect these data from wrongful disclosure. HCFA policies are:

a. If the requestor is within HCFA, an "Internal Data Request Form" should be completed and forwarded to OIS. No Data Use Agreement (DUA) is necessary and no charge is levied for the data.

b. If the requestor is within DHHS, the following should be submitted:

- **!** A written request from the DHHS project officer.
- **!** A completed Data Use Checklist (A copy of the Data Use Checklist is attached at the end of this section).
- **!** A DUA signed by the project officer and principal investigator (if a research project) and data processing contractor, if applicable (A copy of the DUA is attached at the end of this section).
- **!** If use is for research, a copy of the study protocol should be sent to HCFA by the requesting DHHS Agency - HCFA accepts the DHHS Agency's approval of the protocol (This protocol does <u>not</u> have to be reviewed and approved by HCFA).
- **!** HCFA should be reimbursed for its processing costs per the current fee schedule.

(2) *Disclosure is required by the Freedom of Information Act (FOIA)*- The Privacy Act mandates release of data required by FOIA; however, there is a FOIA exemption that permits denial of requests for records whose release constitutes a "clearly unwarranted invasion of personal privacy." This exemption requires HCFA to refuse to release most requests for records otherwise protected by the

Privacy Act. However, if the use to which the record would be put actually would carry important benefits to beneficiaries or society in general, the exemption may not apply and the records may be released if 1 of the 12 conditions of disclosure in the Privacy Act as outlined here apply. HCFA is reimbursed for its costs in handling these requests per the current fee schedule.

(3) *For a routine use*- Each system of records has its own system notice which contains routine uses specific to that system of records. These must be compatible with the purposes for which data were collected.

The routine use which allows release of HCFA data for research is the research routine use. HCFA's requirements for release of data under the research routine use are:

- A written request on organization letterhead
- A completed Data Use Checklist
- A DUA signed by the project officer, principal investigator, and data processing contractor, if applicable
- A study protocol (to be reviewed by HCFA if not a DHHS request) which demonstrates the need for identifiable records to complete the study (A sample is attached at then end of this section)
- Evidence of sufficient funding
- Payment of processing costs per the current fee schedule

Examples of other routine uses are:

- Data Processing Contractor Routine Use
- State Agency Cost Containment and Quality and Effectiveness of Care Routine Use (Refer to the section entitled "Use of Identifiable Data Under a Routine Use" for more information.)

(4) *To the Bureau of the Census for Census-Taking purposes*- Data may be released to the Census Bureau for census-taking purposes including making population estimates between census-taking and as a cross check of persons missing in census counts of aged persons. Release for census purposes is specifically permitted by this special disclosure exception in the Privacy Act. HCFA is reimbursed for its costs in handling these requests. Release of data to the Census Bureau for research which the Census undertakes to assist other Federal agencies or for other purposes must be authorized under the provisions of another routine use. A charge will be levied for data supplied.

(5) *Statistical Data*- Data that contain no individual identifiers or data elements that would permit the identity of a beneficiary to be deduced may be released as

statistical data.

(6) *To the National Archives*

(7) *For a Civil or Criminal Law Enforcement Activity*- HCFA releases identifiable information in response to requests from any governmental agency for law enforcement activities authorized by Federal, State, or local law upon the request of the head of the law enforcement agency, specifying the data needed and the law to be enforced.

For release of identifiable data under this disclosure provision, HCFA requires the following:

- A written request from the head of the law enforcement agency or delegated official which includes the law to be enforced and the data needed
- The civil or criminal court case number
- A DUA
- Payment or payment instrument to reimburse HCFA for data processing costs incurred

(8) *For the Health and Safety of the individual*- HCFA may assist in the location of individuals where their health and safety are involved.

(9) *To either House of Congress or Congressional Committee*- Data may be used by either House of Congress or, for purposes falling under its jurisdiction, by any Congressional committee, subcommittee, or joint committee. Data are furnished as needed.

HCFA requires the following for release under this routine use:

- A written request on Congressional or Committee letterhead
- A DUA

No charge is levied.

(10) *To the General Accounting Office (GAO)*- HCFA cooperates fully with GAO. Requests must be made in writing, and the data must be relevant to the proposed project.
For use of data under this routine use, HCFA requires:

- A written request
- A DUA (requested, not required)

No charge is levied.

(11) *Pursuant to a Court Order*- OGC guidance is to be obtained on court orders. Generally, HCFA will comply when the Secretary is a party to the court proceedings, the information is needed in a criminal proceeding, or release would be permitted under one of the other preceding guidelines. A copy of the court order would be required.

(12) *To a Consumer Reporting Agency under the Debt Collection Act.*

HCFA cooperates fully with GAO, the Office of the Inspector General (OIG), the Physician Payment Review Commission (PPRC), and the Medicare Payment Advisory Commission (MEDPAC). HCFA requests DUAs from these organizations in order to fulfill the requirement that all data releases be tracked.

Use of Identifiable Data Under a Routine Use

Identifiable data may be used without the beneficiary's consent for "routine uses" which have been published in the Federal Register as part of the notice of the system of records that contains the requested data. Routine uses must be compatible with the purposes for which the data in the system were initially collected. Most of HCFA's routine uses are necessary in order to operate the Medicare/Medicaid programs, e.g., release to state welfare agencies, peer review Organizations, providers and suppliers, state audit agencies, and the Justice Department for litigation. A number of HCFA systems have routine uses for release of data for Agency approved research, for analysis of Medicare payment policies, for data processing by contractors, for determination of the quality and effectiveness of hospital care, for state agency cost containment and quality and effectiveness of care projects, for Medicare hospital mortality analysis, and for other uses compatible with the purpose for which the system of records was developed. An outline of common routine uses follows.

Each system notice names a manager of the system of records. This manager incurs a measure of liability in ensuring that the data contained within that system are handled in accordance with the requirements as stated in the notice or the Privacy Act itself. It is the system manager (or his/her designee) who has the authority and responsibility to approve use of data extracted from that system. It should also be noted that there is a charge for data released under a routine use.

Research Routine Use

Identifiable data may be used by an individual or organization for a health-related research, evaluation, or epidemiologic project when certain criteria are met and a specific process is followed.

Criteria:

- Purpose requires individually identifiable records.
- Project is of sufficient importance to warrant effect, or risk, on beneficiary privacy.
- There is reasonable probability that use of data will accomplish the purpose, i.e., project is soundly designed and properly financed.
- Data will be protected and identifiers removed as soon as possible.
- Requestor signs agreement to abide by HCFA's data use policies and procedures.

Procedures to Obtain Data for Research Purposes:

When a request is submitted to HCFA explaining purposes of the project, data needed, and how data would be used, the following documentation should accompany the request:

- Copy of research or evaluation protocol or detailed project plan showing the need for identifiable records
- Copy of form (face sheet of grant/contract/cooperative agreement) showing that the project is adequately funded
- A completed Data Use Checklist
- A completed and signed DUA

Documentation will be reviewed to determine that the project is of such significance that it warrants the release of identifiable data, that the requested data are available, and that HCFA's data use policies and procedures are met.

When the names and/or addresses of beneficiaries are requested to solicit them for participation in a research project not funded by HCFA, a letter over the Administrator's signature must be sent to each beneficiary. HCFA policy does not permit the inclusion of any additional materials with the mailing of the letters. The requestor must allow 7-10 days after mailing the letters before contacting the beneficiaries. This will permit the beneficiaries adequate time to receive the letters and determine their interest in the study. (See Contacting Beneficiaries.)

State Agency Cost Containment and Quality and Effectiveness of Care Routine Use

HCFA may approve the use of data with individual identifiers by a qualified state agency for purposes of determining, evaluating and/or assessing cost, effectiveness, and/or quality of health care services provided in the state. Release of data is governed by the routine use published in the system notice. The agency must meet the criteria listed below and also follow the procedures specified below:

Criteria:

- Requesting organization must be an agency of a state government or established by state law.
- The data must be requested and used for the purpose of determining, evaluating and/or assessing cost, effectiveness, and/or the quality of health care services provided in the State.
- Use or disclosure of the data must not violate legal limitations under which the data were provided, collected, or obtained.
- Once received by the agency, data must be exempt from disclosure under any state/local FOIA.
- The project requires data with individual identifiers
- Agency purpose must be of sufficient importance to warrant effect and/or risk on beneficiary's privacy.
- It must be reasonable to expect that the requesting agency will be able to accomplish its purpose for using the data.

State agencies must follow the procedures below to obtain data:

- Documentation that it is a part of the state government or established by State law
- A copy of its project plan that provides detail about goals, strategy, and activities that are being carried on and/or planned to accomplish goals including methodology in which HCFA data would be used
- Evidence that data would be exempt from any state or local FOIA
- A completed Data Use Checklist
- Original signed DUA stipulating that the state agency:

    - Will not use data for other purposes
    - Will not publish data in a form permitting deduction of individual identities
    - Will submit a copy of aggregated data or proposed tables to HCFA prior to any publication
    - Will make no further disclosure except as allowed in the DUA
    - Will establish reasonable safeguards to protect data

As with other data released outside of HCFA, there is a charge for data released to states.

Congressional Office Routine Use

Data with individual identifiers may be used by a Congressional office in response to an inquiry made by the individual to the Congressman. A separate provision of the Privacy Act authorizes release to the Congress itself or to a committee of the Congress. This routine use is included in systems of records notices for all of HCFA's major data systems.

Bureau of the Census Routine Use

Data may be used by the Census Bureau to enable the Bureau to process research and statistical data for Social Security Administration projects. A separate provision of the Privacy Act authorizes release of data for census purposes.

Justice Department (or Court or Other Tribunal) Routine Use

This routine use authorizes use of identifiable data by the Department of Justice (or a court) in litigation where the Department of Justice has agreed to represent an employee of DHSS in his/her official or private capacity.

Data Use Requirements When Identifiable Data Are Being Requested by Users Within HCFA

Data to be Used Within HCFA

Employees of the Agency may have access to HCFA data based on the first disclosure exception of the Privacy Act. This access to HCFA data should occur only in those situations in which these data are integral to the completion of their official duties as a HCFA employee. Employees are obligated to protect these data from wrongful disclosure.

Data Requested by a HCFA Employee for HCFA-sponsored Purpose to be Released to a Contractor/Grantee

- There must be a **disclosure exception** of the Privacy Act or **a routine use** in the appropriate Privacy Act system of records that allows for disclosure of these data. This is HCFA's legal authorization to release the data.

- Data can be released to HCFA contractors and grantees. An Internal Data Request Form and DUA should be completed and signed by the HCFA project officer. These should be submitted to DDLD. DDLD will perform the privacy review and authorize the release of the data once all requirements are met.

Data Use Requirements When Identifiable Data Are Being Requested by Outside Users

! There must be a **disclosure exception** of the Privacy Act or **a routine use** in the appropriate Privacy Act system of records that allows for disclosure of these data. This is HCFA's legal authorization to release the data.

! If data are being requested by a federal agency and will be used in-house at that or another Federal agency, a Privacy Act system of records for that agency must be in place prior to the shipment of data.

! A **written request** on organization letterhead (from the federal project officer, if federally funded) must be forwarded to HCFA that explains the following:

- The purpose for which the data are needed
- A description of the project and/or methodology in which the data will be used
- The specific data files being requested
- Criteria for data selections or searches

! A completed **Data Use Checklist**.

! An original signed **DUA** must be submitted for all files requested. This agreement specifies that the requestor and recipient of the data will comply with the following:

- Use data only for purposes specified in the agreement
- Not release any files(s) without prior written HCFA approval
- Safeguard the physical files
- Not publish any information that identifies an individual or allows an individual's identity to be deduced
- Return or destroy file(s) by a specified date

! Evidence of sufficient funding (grant award fact sheet if Federally funded).

! If data are being requested for a research project, a copy of an appropriate protocol or study design must be sent to HCFA. HCFA will evaluate the purpose for which the disclosure is to be made to determine the following:

- The purpose cannot reasonably be accomplished unless the record is provided in individually identifiable form.
- The purpose is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring.
- There is reasonable probability that the objective for the use would be accomplished, i.e., the project is soundly designed and properly financed.

If the request is being made by an agency within DHHS, HCFA does not have to review and approve the protocol.

! If beneficiary names and addresses are being released for the purpose of contacting beneficiaries, a Beneficiary Notification Letter that is signed by the HCFA Administrator must be prepared, cleared and include the following:

- Explains that HCFA is cooperating with the researcher by providing names and addresses of potential study participants.
- Briefly describes the project and stresses that no adverse impact on Medicare benefits will occur if the beneficiary chooses not to participate.
- Contains a contact name and toll-free or collect telephone number which the Medicare beneficiaries can call to obtain additional information about the study or to have any questions answered.

Note that physicians names and addresses may also be released. If they are to be contacted, a letter must go to the physicians to be contacted prior to any contact by the requesting entity. See the attachments entitled "Samples of Notification Letters" at the end of this chapter. (See the Section entitled "Contacting Beneficiaries" for more information.)

! Payment of processing fees.

Secondary Uses of HCFA Data

Secondary uses of HCFA data can be separated into three categories. These are (1) Reuse of HCFA data, (2) Third Party Access, and (3) Re-release of HCFA data. This section will discuss each of these individually.

Reuse of HCFA Data

Reuse of HCFA data occurs when a requestor is given permission to use HCFA data obtained for one purpose for a second purpose. A requestor who has already obtained HCFA data for a specified purpose may use these data for another project if the second project meets the requirements of the Privacy Act and the requestor meets Agency requirements. The requestor must apply for written permission from HCFA for the additional use. This application package should include a formal written request, a completed Data Use Checklist, either a study design or project plan, and a signed DUA for the new project. The protocol will have to be reviewed and approved by the Agency prior to our authorizing the reuse of the data. This authorization will be in the form of a letter which expressly gives HCFA's permission to reuse the data. Since HCFA usually does not incur any data processing costs in this type of request, no additional charges are levied.

Third Party Access

Third Party Access occurs when a third party is given permission to access data originally obtained from HCFA by a data requestor. A third party may gain access to HCFA data which was originally released to a different data requestor if:

- The third party has requested and received written permission from HCFA for such third party access. This process includes the submission of a formal written request, a completed data use checklist, a study protocol or project plan for the new project, and the signing of a DUA which includes the project name and signatures of appropriate individuals responsible for maintaining these data. A letter of consent from the original HCFA data recipient must be submitted to HCFA as well.

- The data will remain at the data center where it was initially installed. These data will not be transmitted to any other site via Internet, File Transfer Protocol (FTP), modem transfer, or any other means of copying data unless express prior written permission has been obtained from HCFA.

- Data to be used in a third party access scenario will be in the original HCFA format. The data, therefore, would include no modifications, new variables, new coding categories, etc. HCFA cannot support study findings resulting from non-HCFA standard data and analysis routines.

- Individuals who have obtained HCFA data agree that they will not charge another requestor for accessing the HCFA data at their site.

- Grantees and recipients of other funding agree not to allocate grant monies for acquisition of data if they are granted permission to use HCFA data under this policy. If they are given permission, there will be no payment to HCFA for these data, thus no grant monies are to be expended for purchase of these data.

- Third Party Access of HCFA data will not create an unfair commercial advantage among the entities using these data. This will be ascertained by HCFA.

Re-release of HCFA Data

HCFA receives letters from organizations in which permission is requested to re-release HCFA data that has been reformatted into statistical or aggregated information by the recipient. Statistical information, as defined by HCFA, is considered to be in the public domain. The key in these instances is to ensure that the statistical or aggregated information meets HCFA's definition of public use information. This definition is based on the requirement that recipients must agree not to publish or otherwise disclose the data in a form raising unacceptable possibilities that beneficiaries could be identified (i.e., the data must not be beneficiary-specific and must be

aggregated to a level where no data cells have 10 or fewer beneficiaries.). In order to assure that these two requirements are being met and that identifiable or identifying information is not released, HCFA must review reports and files to be re-released. This review ensures that the reports or files contain no data elements or combination of data elements that could allow for the deduction of the identity of a Medicare beneficiary or a physician and that the level of cell size aggregation meets the stated requirement. Only after such a review has occurred and HCFA has approved the re-release of the reformatted HCFA file IN WRITING is the data recipient legally authorized to re-release the data. This is delineated in the agreement signed by the data recipient.

DATA USE AGREEMENTS

DUAs are an integral part of the data use approval process. The agreements delineate the confidentiality requirements of the Privacy Act and HCFA's data use policies and procedures. The agreement serves as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements. Additionally, the agreements serve as a control mechanism through which HCFA can track the location of its data and the reason for the release of the data.

HCFA has developed a number of standard DUAs, all of which are designed to ensure the following:

- Requestors use HCFA data only for the purpose(s) cited in the request.
- Requestors will not release HCFA data to other organizations without prior written HCFA approval.
- Requestors will take reasonable steps to implement appropriate procedural, administrative, technical, and physical safeguards to prevent unauthorized use.
- Requestors do not publish any information that identifies individual beneficiaries or physicians or permits the identity of a beneficiary or physician to be deduced.
- A limit is established on the period of time a requestor may retain HCFA's data before the data must be destroyed or returned to the Agency.

Expired Data Use Agreements

It is the responsibility of the Requestor and Custodian to be certain that the file(s) is returned when agreements have expired. HCFA performs the ongoing task of following up on expired DUAs.

The following three options are offered:

- If the project has ended, the data must be either returned to HCFA or destroyed. If the data are to be returned, the tapes or cartridges should be mailed to the following address:

  Health Care Financing Administration
  HCFA Data Center
  Attention: Data Release Area
  7500 Security Boulevard
  Baltimore, MD 21244-1850

The data are to be accompanied by a cover letter delineating the study or project name and the Volume/Serial numbers which have been returned.

If the data are to be destroyed, a "Certificate of Destruction" (copy attached at the end of this section) should be completed on organizational letterhead and forwarded to:

  Director, Division of Data Liaison and Distribution
  Enterprise Databases Group
  Office of Information Services
  Health Care Financing Administration
  N2-04-27
  7500 Security Boulevard
  Baltimore, MD 21244-1850

- If the project is still active and additional time is needed for wrap-up activities, a one year extension may be granted. This request for extension will only be granted if the original expiration date has occurred within the past year; otherwise, the agreement will be closed and a new agreement will be negotiated.

- If the project is still active and more than one year is needed to complete the project, the agreement will be closed and a new agreement negotiated.

CONTACTING BENEFICIARIES

General

Requests for data from enrollment records are received from a variety of sources. The data are used to support studies that could affect the quality and efficiency of health care delivery to beneficiaries. Occasionally, these requestors ask for beneficiary names and addresses for the purpose of contacting this population in order to conduct interviews with the beneficiary and, in certain instances, initiate other activities involving the beneficiary's direct participation. HCFA may approve these types of requests if all Agency policies and procedures for use of data have been followed.

Requests

Written requests for beneficiary sample files from which beneficiaries can be contacted for research purposes should be directed to the appropriate system manager or their designee. Since the identity of individual beneficiaries is the substance of the file, requestors must follow the beneficiary protection procedures which are detailed in this section (i.e., provide a completed data use checklist, research protocol, sign a DUA, provide a sample beneficiary notification letter, and reimburse HCFA for processing costs).

Requests for data may include HCFA's drawing of the sample from the Medicare population. The population can be tailored to the requirements of the project/study by using combinations of variables such as age, sex, race, and geographic code (state, county, ZIP Code).

Beneficiary Notification Letters

A Beneficiary Notification Letter (BNL) is needed whenever a beneficiary is going to be contacted using data supplied by HCFA. The BNL is a letter over the HCFA Administrator's signature. It briefly describes the research project and explains that there will be no adverse affect on Medicare benefits. The letter contains a name and collect or toll free telephone number (study contact) that beneficiaries may call with any questions. The requestor must duplicate the letter and mail it to each beneficiary 7-10 days prior to any contact by study personnel. Language for this letter is very specific; therefore, a draft sample is available (see attachment). Occasionally there is a need for a provider (either physician or institution) notification letter. The same basic requirements exist for these letters.

Processing

There is a prescribed format for finder files of known beneficiaries which the requestor would provide to HCFA that is available on request. Finder files of Health Insurance Claim Numbers (HICs) and Social Security Numbers (SSNs) should be submitted in separate files. If a requestor wishes to select specific beneficiaries but does not have the HIC or SSN, HCFA has the

capability of locating the beneficiary by an alphabetic search of the name field. In this case, the names and certain other identifying information should be submitted to HCFA in a separate file. The necessity for adhering to strict procedures for protecting beneficiary privacy and the time consumed in file search operations ordinarily prevents a turn-around time of less than 6 weeks for enrollment data requests. Additional information regarding finder files may be obtained by calling the DSAF Help line on (410) 786-0159.

Charges

As with all data provided to components outside of HCFA, there are charges associated with these data requests.

RESEARCH DATA ASSISTANCE CENTER (ResDAC)

The Research Data Assistance Center (ResDAC) is a HCFA contractor that provides free assistance to academic and non-profit researchers interested in using Medicare and/or Medicaid data for their research. ResDAC is staffed by a consortium of epidemiologists, health services researchers, biostatisticians, and health informatics specialists from the University of Minnesota, Boston University, Dartmouth Medical School, and the Morehouse School of Medicine. ResDAC offers services for researchers with all levels of experience using HCFA data. Free telephone assistance is furnished by researchers with expertise in analyzing Medicare and Medicaid data. ResDAC provides expert advice on the appropriate use of HCFA data files, and can offer guidance for acquiring data from HCFA. ResDAC offers basic, intermediate, and advanced hands-on workshops using Medicare and Medicaid data several times per year at multiple locations across the United States.

For more information about assistance and workshops, contact ResDAC via the Internet at http://www.resdac.umn.edu, via e-mail at resdac@tc.umn.edu, or by telephone at 888-9-RESDAC (888-973-7322).

Attachment 1

CONSENT TO DISCLOSE INDIVIDUALLY IDENTIFIABLE INFORMATION

TO: HEALTH CARE FINANCING ADMINISTRATION

Name:_____
(Last Name) (First Name) (M.I.)

Social Security Number: _____
(Or Other Unique Identifier---Specify type as HIC or RRB)

Date of Birth: _____

I authorize the Health Care Financing Administration to release information about myself as stated on this form.

This information may be released to:

_____

_____

_____

_____

For the purpose of:

_____

_____

_____

The specific types of information and years authorized are as follows. (Check appropriate file and designate year(s)):

FILE	YEAR(S) FROM - THROUGH
/ / Inpatient Hospital	_____ - _____
/ / Outpatient Hospital	_____ - _____
/ / Home Health Agency	_____ - _____
/ / Hospice	_____ - _____
/ / Skilled Nursing Facility	_____ - _____
/ / Physician/Supplier	_____ - _____
/ / Durable Medical Equipment	_____ - _____
/ / Clinical Laboratory	_____ - _____
/ / Other _____	_____ - _____
/ / Other _____	_____ - _____
/ / Other _____	_____ - _____

My authorization to release these records begins as of _____.
(Date)

My authorization to release these records terminates as of _____.
(Date)
(A specific date must be stated)

Except as expressly indicated below, I am authorizing data disclosure of all information pertaining to me as indicated above. The specific limitations I am placing on disclosure of such information are as follows (the absence of an express limitation implies none):

_____

_____

For clarification or verification of this request, I may be contacted at:

ADDRESS: _____

_____

_____

TELEPHONE: _____

_____ _____

Signature of Beneficiary or Legal Guardian ("A parent or legal guardian furnishing consent for the above-identified individual must furnish proof of parentage or the individual's legal guardianship, respectively.") **(Date)**

Signature of Witness **(Date)**

ADDRESS: _____

_____

Attachment 2

Health Care Financing Administration
Sample Study Protocol - August 1999

INTRODUCTION

Title:

The researcher should be succinct in titling their project. Use keywords, phrases, or descriptors that will highlight the population of interest, the medical problems of concern, and the health policy issues of importance.

Objectives:

The objectives should pinpoint what the researcher plans to do and expects to achieve. The number of objectives should be relatively few and listed in approximate order of priority or importance. The objectives listed should underscore the major elements of work that are realistically achievable.

Background:

The background should succinctly highlight gaps in the current knowledge or practice in the field of study. The researcher must show that he or she understands the important studies that form the foundation for the protocol and indicate how the project will go beyond them. Please include a literature review. The literature review need not be lengthy, but it should be reasonably comprehensive and up-to-date. The researcher is not expected to review all the relevant literature in great detail; if he or she is conversant with other bibliographies or literature reviews, they should be cited. If there is no literature or body of knowledge in the area proposed for study, this should be stated.

Importance:

There are two main points that should be addressed here: the significance of the question or study issue proposed and the significance of the researcher's particular project. This is the place to make a strong case for the importance of the project being proposed. For example, the proposed study may add to the general body of knowledge, expand the possible ways to organize and deliver health services to meet a particular human need, or it may do both. The point is to deliver a credible, straightforward argument for the contributions that the work will make.

RESEARCH QUESTIONS AND METHODS

Hypotheses/Study Issues:

If there are hypotheses to test, they should be stated explicitly. If there are no specific hypotheses, the application should discuss the issues that prompted the researcher to undertake the project.

Study Design:

The basic objective is to describe how the project will operate. In some studies, Medicare or Medicaid data will be used to supplement other data. In this instance, the researcher should briefly state the design of the overall project and then describe in detail how the HCFA data being requested will be used in the study. Uppermost in the reviewers' minds are the questions of how each piece of information relates to the hypotheses to be tested, issues to be studied, or program(s) to be demonstrated. It is a good idea to consult an epidemiologist, statistician, econometrician, or some other person well acquainted with basic research methodology when planning the design and analysis of the project. The study design must present a solid chain of reasoning. The study design, at a minimum, should:

- Describe the sample population to be studied and the method to be used to select or identify the study population in the data files.

- Discuss the issue of precision or power of the study and the strength of its eventual conclusions. If applicable, indicate whatever power calculations might have been done to justify the sample size and comment whether the sample size will permit accurate generalization to larger populations.

- Give a specific description of the match between what is to be investigated and the data files and variables to be used in the analysis.

- Briefly state the dependant (or response) variables, the independent (treatment or explanatory) variables, and the factors that may need to be measured or accounted for because they might otherwise confound the analyses.

- If relevant, discuss the project's cross-sectional aspects (comparisons in one time period) and longitudinal aspects (comparisons over time).

Data Limitations:

It is important to note potential limitations of the data in relation to the proposed study and to identify the efforts that will be made to address those issues. For example, noting that the data does not contain information regarding services not covered by, or billed to, Medicare and how

that might affect the results. It is better to show that consideration has been given to what the potential limitations are rather than have reviewers assume that the researcher was not aware any existed.

Database Management:

The protocol should explicitly address how the data files will be held, managed, and processed. For example, who will have the main responsibility for organizing, storing, and archiving the data? Who will maintain computer data tapes and make needed work files available to those who will analyze the data? How will the privacy of information of beneficiaries in the files be guarded and guaranteed?

EVALUATION AND ANALYSIS PLAN

Analysis Plan:

In this section, the application should explain, as clearly as possible, how the data would be analyzed. This section should convince reviewers that the proposed methods are consistent with the hypotheses/issues to be studied and the data to be collected, and it should persuade them that the data will support the level of analysis planned.

Analytic Methods:

This section should discuss specifically what analytic methods are expected to be used to address which questions. It is often helpful to give examples of the analyses or to show what the tables of results might look like. Often, discussing hypothetical findings based on likely values of the data which will eventually be collected is a useful device for making the analysis plan seem less abstract. The goal is to try to aid reviewers in visualizing the data set that will be compiled, so that they can think along with the researcher about what methods of analyses seem appropriate and reasonable to address the hypotheses/issues to be studied.

WORK PLAN

Description of Tasks:

The proposed work should be sufficiently well planned that the researcher can specify a set of tasks that will cover all the activities needed to complete the project. The aim is to identify all the tasks to be accomplished regarding study design and analysis. In addition, note that one task will probably involve producing a final report. Every task noted here should have some corresponding description in the study design and/or analysis plan section(s) to show how it will be accomplished; every major activity targeted for completion should have a corresponding task.

Time Schedule:

The application should provide a Gantt chart or some other diagram to illustrate when the tasks outlined above will be completed, in what order, and how long they are expected to take. This is commonly done in terms of elapsed months (e.g., for a 2-year study, months 0 through 24 would be one axis of your chart). It is helpful to adopt some conventional symbols, such as an asterisk or triangle, to show when specific milestones are to be achieved.

Level of Effort of Personnel:

This section is commonly shown as a table, in which the researcher lists the key individuals (by name or by task) and the number of days they will devote to each task.

For multi-year projects, the researcher should show total days in each year. Total days per year should be equivalent to whatever percentage of time is shown for these individuals in the budget document. Note that reviewers pay attention to these figures. Too little time for key personnel suggests that the researcher may have an unrealistically optimistic view of what can be accomplished.

QUALIFICATIONS OF KEY STAFF

To the extent possible, persons the researcher believes are crucial to a successful project should be named in this section. Even very good projects will look dubious to reviewers if the principal investigator or critical staff are "to be named." The qualifications of key personnel named in this section should be discussed. A paragraph or two per person describing their background and experience most pertinent to this project will suffice.

This or a parallel section could also be used to describe any experience the researcher's organization has had in conducting similar projects, especially insofar as that experience will be available as backup and support for the key staff.

If the researcher has special data collection or analytic needs, this is the place to indicate that the researcher has the right personnel for the job. Often, these individuals can be consultants rather than project staff. For instance, the project may require a physician for certain tasks and a statistician or economist for other tasks. To the degree possible, the application should indicate who these people are or say what types of individuals will be recruited later.

IMPLEMENTATION POTENTIAL

This is not a long section, typically, but it is an important one. It is where the researcher discusses the expected use, generalizability, applicability, and dissemination of the work.

EXECUTIVE SUMMARY

The final protocol should be accompanied by a one page Executive Summary that includes a highly condensed version of the study objectives, background, importance, and design (including requested data files). This summary will be the cover page of the research protocol and should be detailed enough to allow any HCFA representative reviewing the executive summary to understand the study being proposed.

Attachment 3

HEALTH CARE FINANCING ADMINISTRATION (HCFA)
DATA USE CHECKLIST - JUNE 1999

All requestors of HCFA confidential data must complete this checklist. Please complete all applicable sections of this checklist and attach all required documentation.

Section 1- Administrative Information

Requestor
Organization_____
Contact_____
Title_____
Street Address_____
_____
City/State/ZIP Code_____
Phone Number/FAX Number_____
E-Mail Address_____
Funder
Organization_____
Contact_____
Title_____
Street Address_____
_____
City/State/ZIP Code_____
Phone Number/FAX Number_____
E-Mail Address_____
Custodian
Organization_____
Contact_____
Title_____
Street Address_____
_____
City/State/ZIP Code_____
Phone Number/FAX Number_____
E-Mail Address_____

Sub-Contractor(s)
Organization_____
Contact_____
Title_____
Street Address_____

_____
City/State/ZIP Code_____
Phone Number/FAX Number_____
E-Mail Address_____

Sub-Contractor(s)
Organization_____
Contact_____
Title_____
Street Address_____

_____
City/State/ZIP Code_____
Phone Number/FAX Number_____
E-Mail Address_____

Section 2 - Required Documents

* Documents required for new requests for the use of HCFA data.

Document	Yes	No	Comments
1. Request Letter from Project Officer * (If Federally funded only.)	___	___	_____ _____
2. Written Request * - Purpose - Description of methodology - Data requirements	___	___	_____ _____
3. Data Use Checklist *	___	___	_____ _____
4. Study Plan or Protocol *	___	___	_____ _____
5. Evidence of Funding *	___	___	_____ _____
6. Data Use Agreements *	___	___	_____ _____

7. Draft Beneficiary Notification Letter ___ ___ _____
   (Only if you are contacting beneficiaries _____
   and are obtaining the address information
   from HCFA.)

8. Other ___ ___ _____
   - Cost Estimate _____
   - Copy of Prior Correspondence w/HCFA
   - Letters of Support
   - Payment

Section 3 - Study/Project Information

Study/Project Name (This is how HCFA will identify the project.):
_____
_____
_____
_____
Grant/Contract Number:_____

Description of Project:_____
_____
_____
_____
_____
_____
_____

Section 4 -Funding and Method of Reimbursement

Total Funding Amount: _____
Funding Amount for Data (Amount of money set aside specifically for the purchase of the data.):
_____
___

Type of Reimbursement
_____ Check/Money Order (Made payable to HCFA)
_____ Purchase Order (Only from Federal Agencies and must have Agency Locator Code)
_____ Inter/Intra-Agency Agreement

Agency Locator Code:
_____
Inter/Intra-Agency Agreement Number (If known.):
_____

Reimbursement should be sent to : Health Care Financing Administration
OIS/EDG/DDLD
N2-04-27
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**Include Copy of Cost Statement with reimbursement.

Section 5 - Finder File Information

A. Finder File Information (Furnished by Requestor)

File Name:_____No. of Records:_____

Media: (Check the appropriate line)

3480 Tape Cartridge_____

Diskette_____

Variables Used to Develop Finder File (i.e., SSNs, HICs, RRBs for Numeric Search; Names and Dates of Birth for Alpha Search)

_____

_____

Notes:(1) Finder Files must be provided using IBM standard label 3480 tape cartridges, or 3 ½ inch diskette; (2) SSN, HIC, and RRB finder files must be submitted as separate files in 14 byte record lengths; and (3) Name searches must be provided in 47 byte record lengths. See attached record layouts.

B. Finder File Criteria (When Finder File to be Developed by HCFA)

State specifically the elements/codes and files to be used as selection criteria.

_____

_____

Section 6 - Types of Data Requested

Please check the files being requested and indicate the years.

Enrollment Data (Indicate the Years)

____ Denominator (1984-Current):_____

____ Beneficiary Name and Address (Current Information Only)

Alive Only ___ Alive and Dead ___

____ Beneficiary Vital Status (Current Information Only)

Alive and Dead ___ Dead Only ___

____ Group Health Plan File (1985-Current):_____

Utilization Data (Indicate the Years)

Historical Data:

____ MEDPAR (1991-Current):_____

Record Length: 500 Packed____ 500 Unpacked ____

Stays: Long Stay/Short Stay____ Skilled Nursing Fac.____

Standard Analytical Files

____ Inpatient (1991-Current):_____

____ Skilled Nursing Facility (1991-Current): _____

____ Outpatient (1991-Current):_____

HHA (1991-Current):_____

____ Hospice (1991-Current):_____

____ Clinical Lab (1991-Current):_____

____ Physician/Supplier (1991-Current):_____

____ Durable Medical Equipment (1994-Current):_____

Physician Data (Indicate the Years)

____ UPIN Master (MPIER) (Current):_____

UPIN Validation Quarterly:_____

____ UPIN Validation Annually (1991-Current):_____

____ Physician Summary (1991-Current):_____

____ Physician Sample 100% (1991-Current):_____

Other/Miscellaneous Data (Indicate the Years)

____ Medicare Current Beneficiary Survey

Access to Care (1991-1997):_____ Cost and Use (1992-1996):_____

____ State Medicaid Research Files

State(s) :_____Year(s)

:_____

____ Area Resource File (1992-1996)

____

CMHS:_____

Public Use Files or Beneficiary Encrypted Files or Other Files:

____ File(s) and Year(s):_____

_____

_____

Section 7 - Output File Options

A. IBM Standard Label 3480 Tape Cartridge in EBCDIC Format :_____

3 ½" Diskette(Vital Status and Names and Address files only):_____

Notes: (1) All tapes and cartridges are in EBCDIC format with IBM Standard Labels, and (2) Diskette files are limited to 2 diskettes for each file, 4 diskettes per request.

B. Variable Length Records:_____
Multiple Linked Files, Fixed Block Records (Standard Analytical Files only)_____
(If this format is selected, you must check the necessary trailers from the chart below.)

Choose up to 7 trailers for cartridge output. Fixed portion is included and does not count as a trailer selection.

Trailers	Inpatient/ SNF	Outpatient	Physician/ Supplier	DME	HHA	Hospice
Claim Edit Codes						
Patch						
MCO Period						
Payer ID						
Demo						
Diagnosis Codes						
Procedure Codes			NA	NA	NA	
Related Conditions Codes			NA	NA		
Related Occurrence Codes			NA	NA		
Occurrence Span Codes			NA	NA		
Claim Value Codes			NA	NA		
Revenue Center Codes			NA	NA		
Line Item	NA	NA			NA	NA

Section 8 - Shipping Information

Organization_____
Contact_____
Title_____
Street Address_____
_____
City/State/ZIP Code_____
Phone Number/FAX Number_____
E-Mail Address_____

Method of Dissemination:

Regular Mail:_____

Pick Up at HDC:_____

Express Carrier:_____

Carrier Name:_____

Account Number:_____

Contact:_____

Title:_____

Telephone:_____

_____

_____

Signature of Requestor Date

HCFA RECORD SPECIFICATIONS

14 Byte HIC Finder File

Field name	Field Size	Location	Remarks
Health Insurance Claim Number	11	1 - 11	User Supplied Search Argument
Filler	2	12 - 13	Blank or Requestor' s Identifier
Sex	1	14	0 = Unknown 1 = Male 2 = Female

14 Byte SSN Finder File

Field name	Field Size	Location	Remarks
Social Security Number	9	1 - 9	User Supplied Search Argument
Filler	2	10 - 13	Blank or Requestor' s Identifier
Sex	1	14	0 = Unknown 1 = Male 2 = Female

47 Byte Alpha Finder File

Field name	Field Size	Location	Remarks
Last Name	6	1 - 6	Six positions of name excluding spaces and/or special characters.
First Name	6	7-12	Same as above.
Middle Initial	1	13	If available, if not space.
SSN	9	14-22	If available.
Filler	2	23-24	
Sex Code	1	25	1 = Male 2 = Female
Date of Birth	8	26-33	MMDDYYYY
Output Media Indicator	1	34	Space = Tape Reel 1 = 3480 Cartridge 2 = 3 ½ diskette
Filler	4	35-38	
Requestor' s ID Name	8	39-46	Spaces if not needed on the match file (output).
Record ID	1	47	'X'

Attachment 4

DUA #_____

DATA USE AGREEMENT

(AGREEMENT FOR USE OF HEALTH CARE FINANCING ADMINISTRATION (HCFA) DATA CONTAINING INDIVIDUAL-SPECIFIC INFORMATION)

In order to secure data that resides in a HCFA Privacy Act System of Records, and in order to ensure the integrity, security, and confidentiality of information maintained by the HCFA, and to permit appropriate disclosure and use of such data as permitted by law, HCFA and _____ enter into this agreement to comply with the following specific paragraphs.

1. This Agreement is by and between the Health Care Financing Administration (HCFA) , a component of the U.S. Department of Health and Human Services, and_____, hereinafter termed "User."

2. This Agreement addresses the conditions under which HCFA will disclose and the User will obtain and use the HCFA data file(s) specified in section 7. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 7 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 HCFA point-of-contact specified in section 5 or the HCFA signatory to this Agreement shown in section 22.

3. The parties mutually agree that HCFA 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 HCFA.

4. 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 personally 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 HCFA within fifteen (15) days of any change of custodianship. The parties mutually agree that HCFA may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

_____
(Name of Custodian)

_____
(Company/Organization)

_____
(Street Address)

_____
(City/State/ZIP Code)

_____
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

5, The parties mutually agree that the following named individual will be designated as "point-of-contact" for the Agreement on behalf of HCFA.

_____
(Name of Contact)

_____
(Title/Component)

_____
(Street Address)

_____
(Mail Stop)

_____
(City/State/ZIP Code)

_____
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

6. The User represents and warrants, and in furnishing the data file(s) specified in section 7 HCFA relies upon such representation and warranty, that such data file(s) will be used solely for the following purpose(s).

_____
_____
_____
_____
_____

The User represents and warrants further that the facts and statements made in any study or research protocol or project plan submitted to HCFA for each purpose are complete and accurate. Further, the User represents and warrants that said study protocol(s) or project plans, as have been approved by HCFA or other appropriate entity as HCFA may determine, represent the total use(s) to which the data file(s) specified in section 7 will be put.

The User represents and warrants further that, except as specified in an Attachment to this Agreement or except as HCFA shall authorize in writing, the User shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. The User agrees that, within the User organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section and to those individuals on a need-to-know basis only.

7. The following HCFA data file(s) is/are covered under this Agreement.

File	Year(s)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

8. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s), including any file that maintains or continues identification of individuals) may be retained by the User until _____, hereinafter known as the "retention date." The User agrees to notify HCFA within 30 days of the completion of the purpose specified in section 6 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, HCFA will notify the User either to return all data files to HCFA at the User's expense or to destroy such data. If HCFA elects to have the User destroy the data, the User agrees to certify the destruction of the files in writing within 30 days of receiving HCFA's instruction. A statement certifying this action must be sent to HCFA. If HCFA elects to have the data returned, the User agrees to return all files to HCFA within 30 days of receiving notice to that effect. The User agrees that no data from HCFA records, or any parts thereof, shall be retained when the aforementioned file(s) are returned or destroyed unless authorization in writing for the retention of such file(s) has been received from the appropriate Systems Manager or the person designated in item No. 22 of this Agreement. The User acknowledges that stringent adherence to the aforementioned retention date is required, and that the User shall ask HCFA for instructions under this paragraph if instructions have not been received after 30 days after the retention date.

9. 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 established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems, which sets forth guidelines for security plans for automated information systems in Federal agencies. 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 7 is prohibited. Further, the User agrees that the data must not be physically moved or transmitted in any way from the site indicated in item number 4 without written approval from HCFA.

10. The User agrees that the authorized representatives of HCFA or DHHS Office of the Inspector General will be granted access to premises where the aforesaid file(s) are kept for the purpose of inspecting security arrangements confirming whether the User is in compliance with the security requirements specified in paragraph 9.

11. The User agrees that no findings, listing, or information derived from the file(s) specified in section 7, with or without identifiers, may be released if such findings, listing, or information contain any combination of data elements that might allow the deduction of a beneficiary's identification without first obtaining written authorization from the appropriate System Manager or the person designated in item number 22 of this Agreement. Examples of such data elements include but are not limited to geographic indicator, age, sex, diagnosis, procedure, admission/discharge date(s), or date of death. The User agrees further that HCFA shall be the sole judge as to whether any finding, listing, information, or any combination of data extracted or derived from HCFA's files identifies or would, with reasonable effort, permit one to identify an individual or to deduce the identity of an individual to a reasonable degree of certainty.

12. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in item number 22 of this Agreement to do so, the User shall make no attempt to link records included in the file(s) specified in section 7 to any other identifiable source of information. This includes attempts to link to other HCFA data file(s). The inclusion of linkage of specific files in a study protocol approved in accordance with section 6 is considered express written authorization from HCFA.

13. User agrees to submit a copy of all findings within 30 days of making such findings to HCFA. The parties mutually agree that the User has "made findings" with respect to the data covered by this Agreement when the User conveys any report or other writing to any third party (including but not limited to any manuscript submitted for publication) concerning any purpose specified in section 6 (regardless of whether the report or other writing expressly refers to such purpose, to HCFA, or to the files specified in section 7 or any data derived from such files). The User agrees further to submit its findings to the National Technical Information Service (NTIS, 5285 Port Royal Road, Springfield, Virginia 22161) within 30 days of receiving notice from HCFA to do so.

14. 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 22 of this Agreement.

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

_____

_____

_____

_____

16. The User agrees that in the event HCFA determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid file(s) that is not authorized by this Agreement or other written authorization from the appropriate System Manager or the person designated in item number 22 of this Agreement, HCFA in its sole discretion may require the User to: (a) promptly investigate and report to HCFA the User's determinations regarding any alleged or actual unauthorized disclosure; (b) promptly resolve any problems identified by the investigation; (c) if requested by HCFA, submit a formal response to an allegation of unauthorized disclosure; (d) if requested by HCFA, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and (e) if requested by HCFA, return data files to HCFA. The User understands that as a result of HCFA's determination or reasonable belief that unauthorized disclosures have taken place, HCFA may refuse to release further HCFA data to the User for a period of time to be determined by HCFA.

17. 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 $1,000 or by imprisonment not exceeding 1 year, or both, may apply with respect to any disclosure of information in the file(s) specified in section 7 that is inconsistent with the terms of this Agreement. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(1) and (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 guilty under the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Further, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641, which provides that 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, they shall be fined not more than $10,000 or imprisoned not more than 10 years, or both. In addition, the User and any individual employed or affiliated therewith, may be subject to civil suit under the Privacy Act for damages which occur as a result of willful or intentional actions which violate an individual's rights under the Privacy Act.

18. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in section 7, and acknowledges having received notice of potential criminal, administrative, or civil penalties for violation of the terms of the Agreement.

19. On behalf of the User 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 and Title of Individual - Typed or Printed)

_____
(Company/Organization)

_____
(Street Address)

_____
(City/State/ZIP Code)

_____
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

_____
(Signature) (Date)

20. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees personally and in a representative capacity to comply with all of the provisions of this Agreement on behalf of the User.

_____
(Typed or Printed Name and Title of Custodian of File(s)

_____
(Signature) (Date)

21. 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 HCFA data, agrees to support HCFA in ensuring that the User maintains and uses HCFA'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 question of such interpretation or compliance with the terms of this Agreement to the HCFA official named in section 22 (or to his or her successor).

_____
(Typed or Printed Name and Title of Federal Representative)

_____
(Signature) (Date)

_____
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

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

_____
(Typed or Printed Name and Title of HCFA Representative)

_____
(Signature) (Date)

23. The disclosure provision(s) that allows the discretionary release of HCFA data for the purpose(s) stated in paragraph 6 follow(s). (To be completed by HCFA staff.)

_____
_____
_____

Attachment 5

CERTIFICATION OF DESTRUCTION

I, _____, representing
(Name of Requestor or Custodian)

_____ certify that the
(Name of Organization)

following Health Care Financing Administration records have been destroyed.

Name of File	Data Set Name	DUA#	Vol./Ser.	Years of Data

This destruction certificate closes the corresponding DUAs.

_____
(Typed Name and Title)

_____
(Signature and Date)

Attachment 6

SAMPLE BENEFICIARY NOTIFICATION LETTER

Dear Medicare Beneficiary:

The Health Care Financing Administration (HCFA) administers the Medicare program. HCFA is cooperating with the (researcher organization) and the (funding organization) by providing them with a list of potential participants for a study which involves Medicare beneficiaries as well as others. Such studies will help the researchers learn more about several serious diseases.

You are one of approximately 38 million Americans with health insurance under the Medicare program. Your name was selected at random to participate in this study. In a few weeks, you will be contacted by a representative of (actual organization doing interview) to determine if you are willing to participate. If you are willing, the interviewer will arrange to come talk to you. That person will want to ask you questions about your diet, the jobs you have held, and your health history. The interview will be conducted in person and should take, at most, about 2 hours of your time.

You do not have to participate in this study. Your decision to participate or not will have no effect on your Medicare benefits. All information you and the other participants provide is protected by the Privacy Act.

If you have any questions about the study, please feel free to call (contact name), collect (or provide toll free phone number), at (phone number including area code). Thank you for your cooperation.

Sincerely,

Nancy-Ann Min Deparle
Administrator

Attachment 7

SAMPLE PHYSICIAN NOTIFICATION LETTER

The Health Care Financing Administration (HCFA) administers the Medicare program. HCFA is cooperating with the (Research Organization) and the (Funding Organization) on a study which involves Medicare beneficiaries. The study is designed to examine the care of patients with cardiovascular disease in an effort to improve health outcomes. Previous research has found that the use of cardiac procedures among minorities, patients of lower socioeconomic status, and women is much lower than among other groups of patients. This study will investigate whether this pattern represents an inappropriate use of care among these populations or other populations. This is potentially a very important study from both a research and a public policy perspective. Nationwide, approximately 5,000 patients and their physicians have been randomly selected to participate. The Peer Review Organization (PRO) in each State will be collecting data from hospitals. In some cases, records of echocardiagrams or exercise tolerance tests performed by physicians on an ambulatory basis will also be sought from physicians' offices.

One of your patients has been selected for medical chart review. If you agree to participate in this study, you will be asked by the PRO to provide the results of one of several diagnostic tests for this patient. Your Medicare reimbursement will not be affected by whether or not you agree to participate. The data collected during this study will not be used for peer review monitoring purposes nor will it affect any payments for study participants, physicians, or facilities participating in this study.

We at HCFA have taken great care to preserve the confidentiality of the Medicare claims data. The research team will be employing rigid control of the data file that links physician and patient names to study forms. Neither you nor your patients will be identified in any reports, whether public or private.

If you have any questions about the study, please feel free to call (Study Contact) on (111) 111-1111 at the (Research Organization). Thank you for your cooperation.

Sincerely,

Nancy-Ann Min Deparle
Administrator

Attachment 8

SAMPLE FACILITY NOTIFICATION LETTER

The Health Care Financing Administration (HCFA) administers the Medicare program. HCFA is cooperating with (Research Organization) and the (Funding Organization) on a study which involves Medicare beneficiaries. The study is designed to examine the care of patients with cardiovascular disease in an effort to improve health outcomes. Previous research has found that the use of cardiac procedures among minorities, patients of lower socioeconomic status, and women is much lower than among other groups of patients. This study will investigate whether this pattern represents an inappropriate use of care among these populations or other populations. This is potentially a very important study from both a research and a public policy perspective. Nationwide, approximately 5,000 patients and their physicians have been randomly selected to participate. The Peer Review Organization (PRO) in each State will be collecting medical charts from hospitals. In some cases, records of echocardiograms or exercise tolerance tests performed by physicians on an ambulatory basis will also be sought from physicians' offices.

One of your facility's patients has been selected for medical chart review as part of this study. Your Medicare reimbursement will not be affected by whether or not you agree to participate. The data collected during this study will not be used for peer review monitoring purposes nor will it affect any payments for study participants, physicians, or facilities participating in this study.

We at HCFA have taken great care to preserve the security and privacy of the Medicare claims data. The research team will be employing rigid control of the data file that links provider and patient names to study forms. Neither your hospital nor your patients will be identified in any reports, whether public or private.

Of you have any questions about the study, please feel free to call (Study Contact) on (111) 111-1111 at the (Research Organization). Thank you for your cooperation.

Sincerely,

Nancy-Ann Min Deparle
Administrator