

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of new system of records.

The provisions in this system of records are unique to the OASIS data set, and therefore, are not necessarily representative of current or future HCFA system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records. The proposed system is titled "Home Health Agency Outcome and Assessment Information Set (HHA OASIS), HHS/HCFA/CMSO, 09-70-9002." HCFA proposes to establish a new system of records containing data on the physical, mental, functional, and psychosocial status of all patients receiving the services of Home Health Agencies (HHAs) that are approved to participate in the Medicare and/or Medicaid programs. Information retained in this system for those individuals who have only non-Medicare and non-Medicaid payment sources will be in a non-patient identifiable format.

The primary purposes of the system of records are to provide for the development, validation, and refinements of the Medicare Prospective Payment System and to study and help ensure the quality of care provided by HHAs. Information retrieved from this system of records will be used to aid in administration of the survey and certification of Medicare/Medicaid HHAs; enable regulators to provide HHAs with data for their internal quality improvement activities; support agencies of the State government to determine, evaluate and assess overall effectiveness and quality of HHA services provided in the State; aid in the administration of Federal and State HHA programs within the State; monitor the continuity of care for patients who reside temporarily outside of the State; support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; support constituent requests made to a Congressional representative; support litigation involving the agency; and support research, evaluation, or epidemiological projects related to the prevention of disease or disability, or

the restoration or maintenance of health, and for payment related projects. We have provided background information about the proposed system in the "Supplementary Information" section below. Although the Privacy Act requires only that the "routine use" portion of the system be published for comment, HCFA invites comments on all portions of this notice. See "Effective Dates" section for comment period.

EFFECTIVE DATES: HCFA filed a new system of records report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on June 15, 1999. We have requested a waiver of the OMB 40-day advance notice period for this system of records. If OMB grants the waiver, the system of records is effective on June 18, 1999. If OMB does not grant the waiver, we will implement the system on July 28, 1999. In any event, we will not disclose any information under a routine use until 40 days after publication. We may defer implementation of this system of records or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDL), HCFA, Room N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 am.-3 pm., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Helene Fredeking, Director, Division of Outcomes and Improvements, Center for Medicaid and State Operations, HCFA, 7500 Security Boulevard, S2-14-26, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-7304.

SUPPLEMENTARY INFORMATION:

Description of the Proposed System of Records.

A. Glossary of OASIS Terms OASIS Data Set

The OASIS data set is the sum of the identifiers and information.

Identifiers

Identifiers are the data elements that can be used to determine a patient's identity.

These are: patient's name, social security number, Medicare number and Medicaid number.

OASIS Information

OASIS information includes the clinical items listed below and case mix adjusters (e.g. age, sex, race, residence, etc.).

Patient History
Living Arrangements
Supportive Assistance
Sensory Status
Integumentary Status
Respiratory Status
Elimination Status
Neuro/Emotional/Behavioral Status
Activities of Daily Living/Instrumental Activities of Daily Living (ADL/IADLs)
Medications
Equipment Management
Emergent Care
Discharge

Masked Identifiers

A masked identifier is created when an encrypted value is substituted for an identifier prior to transmission of data. Thus the government receives non-identifiable data (see below). Only the HHA has identifiable data.

Identifiable Data

Identifiable data includes individual records with OASIS information and identifiers.

Non-Identifiable Data

Non-identifiable data includes individual records with OASIS information and masked identifiers or OASIS information without identifiers.

B. Statutory and Regulatory Basis for System of Records

Sections 1102(a), 1871, 1861(o), 1861(z), and 1891(b) of the Social Security Act authorize the Administrator of HCFA to require HHAs participating in the Medicare and Medicaid programs to complete a standard, valid, patient assessment data set; i.e., the OASIS, as part of their comprehensive assessments and updates when evaluating adult, non-maternity patients as required by § 484.55 of the Conditions of Participation. On March 10, 1997, we published in the **Federal Register**, at 62 FR 11035, a proposed rule with an opportunity for public comment, titled "Medicare and Medicaid Programs: Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies." On January 25, 1999, some provisions of this rule were published as a Final Rule in the **Federal Register**, titled "Medicare and Medicaid Program:

Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies." The rule required that all HHAs participating in the Medicare and Medicaid programs be required to complete a standard, valid, patient assessment data set; i.e., the OASIS, as part of their comprehensive assessments and updates when evaluating adult, non-maternity patients as required by § 484.55 of the Conditions of Participation. Also published in the **Federal Register**, was an interim final rule with comment titled "Medicare and Medicaid: Reporting Outcome and Assessment Information Set." This interim rule established an additional requirement of the Conditions of Participation for HHAs approved to participate in Medicare and/or Medicaid, to encode and report OASIS electronically into a national database. Information retained in this system for those individuals who have only non-Medicare and non-Medicaid payment sources will be in a non-patient identifiable format and will be used only for statistical purposes and to ensure quality of care for all patients. Information on Medicare and Medicaid patients will be identified for quality of care and reimbursement purposes.

OASIS also serves as the backbone of the home health prospective payment system. The Balanced Budget Act of 1997 requires Medicare to implement a prospective payment system for HHAs by October 1, 2000. OASIS not only contains data items that indicate quality, but information necessary to develop a reliable prospective payment system that pays HHAs appropriately according to the different level of services patients need. If HCFA opted not to use OASIS for the prospective payment system, HCFA would have had to collect another set of data items from HHAs.

The system of records will contain clinical assessment information (OASIS records) for all Medicare and Medicaid patients receiving the services of a Medicare and/or Medicaid approved HHA, except pre-partum and post-partum patients, patients under 18 years of age, and patients receiving other than personal care or health care services; i.e., housekeeping services and chore services. The OASIS data set contains statistically proven valid and reliable items which have been shown to be effective in measuring outcomes for patients receiving home health services.

C. Purpose for System of Records

In 1987, Congress changed the Social Security Act to require HCFA to survey the quality of care and services

furnished by HHAs using a "standardized, reproducible assessment instrument." The next year, HCFA entered into a contract with the University of Colorado to develop an assessment instrument that would help oversee the quality of care patients receive in HHAs and improve HHA performance. University of Colorado researchers, doctors, and clinicians developed the Outcome Assessment Instrument Set (OASIS) as the standardized, reproducible assessment instrument.

OASIS is not an interview or a survey. Rather, it is part of an assessment of the patient that is conducted by a registered nurse or therapist. To determine the type of care a patient needs, HHAs already do an assessment of each patient's physical and emotional condition. HHAs will continue to do these comprehensive assessments, but now they will report a portion of that assessment to HCFA so that we can perform several critical functions, such as calculating the appropriate amount for the government to pay for home health services or ensuring HHAs are providing the highest quality of care for the entire agency and for each individual patient.

Home health patients are one of the most vulnerable populations because services are provided in the homes where it is difficult to oversee the quality of services provided. For the first time, OASIS will allow HCFA to measure how well HHAs care for their patients. HHAs caring for Medicare beneficiaries will submit OASIS data through secure communications to HCFA, which will analyze the information to develop performance profiles for each agency. This process is similar to what we now do for managed-care plans—a system that has been widely praised by consumers and health-care professionals.

These "performance reports" can serve several important purposes: (1) HHAs can use them to identify their own weaknesses and improve the quality of care they provide; (2) HCFA can use them to identify HHAs that provide substandard care and then require such agencies to correct problem areas or risk losing Medicare funding; and (3) patients may be able to use this information in the form of "report cards" as a means of comparing HHAs in their area. All patient-specific information will be kept confidential with access carefully limited to ensure that privacy remains protected.

OASIS represents a significant advancement in home health care. It will ensure accurate payments to HHAs under the new prospective payment

system, improve quality of patient care and allow HCFA to monitor the quality of care it purchases for its beneficiaries.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The OASIS will be completed on all patients, except those in a category exempted by administrative policies and procedures, who receive services from an HHA certified for Medicare and Medicaid payments. The OASIS data set includes identifiers. It also includes information on:

- Patient History
- Living Arrangements
- Supportive Assistance
- Sensory Status
- Integumentary Status
- Respiratory Status
- Elimination Status
- Neuro/Emotional/Behavioral Status
- Activities of Daily Living/Instrumental Activities of Daily Living (ADL/IADLs)
- Medications
- Equipment Management
- Emergent Care
- Discharge

Identifiers are patient name, social security number, Medicare number and Medicaid number. A masked identifier is one in which an encrypted value is substituted for an identifier so that recipients of the information cannot identify the individual.

The OASIS information will be submitted by the HHA to the government for all patients, except prepartum and postpartum patients, patients under 18 years of age, and patients receiving personal care or health care services; i.e., housekeeping services and chore services. Identifiers will be included for all patients receiving services paid for by Medicare traditional fee-for-service, Medicaid traditional fee-for-service, Medicare HMO/managed care or Medicaid HMO/managed care. For patients with only a non-Medicare or non-Medicaid payment source, the HHA will submit OASIS information with masked identifiers and will retain the identifier and masked identifier at the HHA. In other words, the patient identifier for non-Medicare and non-Medicaid patients will only be known and retained by the HHA and not by the government.

B. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose which is compatible with the purpose(s) for which the

information was collected. Any such disclosure of data is known as a "routine use." The government will only release OASIS information that can be associated with an individual HHA patient as provided for under "Section III.A. Entities Who May Receive Disclosures Under Routine Use." Both identifiable and non-identifiable data may be disclosed under a routine use. Identifiable data includes individual records with OASIS information and identifiers. Non-identifiable data includes individual records with OASIS information and masked identifiers or OASIS information with identifiers stripped out of the file.

We will only disclose the minimum personal data necessary to achieve the purpose of OASIS. HCFA has the following policies and procedures concerning disclosures of information which will be maintained in the system. In general, disclosure of information from the system of records will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after HCFA:

(a) Determines that the use or disclosure is consistent with the reason that the data is being collected; e.g., developing and refining payment systems and monitoring the quality of care provided to patients.

(b) Determines:

(1) That the purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

(2) That the purpose for which the disclosure is to be made 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; and

(3) That there is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

(c) Requires the information recipient to:

(1) Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

(2) Remove or destroy at the earliest time all patient-identifiable information; and

(3) Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

(d) Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. Entities Who May Receive Disclosures Under Routine Use

The routine use disclosures in this system may occur only to the following seven (7) categories of entities (i.e., the entities which can get identifiable data only if we apply the policies and procedures in Section II.B. above). In addition, our policy will be to prohibit release even of non-identifiable data, beyond the seven listed categories, if there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the home health agency enrollees could, because of the small size, use this information to deduce the patient identity).

1. To the Department of Justice (DOJ), court or adjudicatory body when:

(a) The agency or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

(d) The United States Government; is a party to litigation or has an interest in such litigation, and by careful review, HCFA determines that the records are both relevant and necessary to the litigation and the use of such records by the DOJ, court or adjudicatory body is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

Whenever HCFA is involved in litigation, or occasionally when another party is involved in litigation and HCFA's policies or operations could be affected by the outcome of the litigation, HCFA would be able to disclose information to the DOJ, court or adjudicatory body involved. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which HCFA collects the information.

2. To agency contractors, or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

We contemplate disclosing information under this routine use only in situations in which HCFA may enter into a contractual or similar agreement with a third party to assist in accomplishing HCFA functions relating to purposes for this system of records.

HCFA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. HCFA must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards (like ensuring that the purpose for which the disclosure is to be made 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 and those stated in II.B. above), are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract and to return or destroy all information at the completion of the contract.

3. To the agency of a State Government, or established by State law, for purposes of determining, evaluating and/or assessing overall or aggregate cost, effectiveness, and/or the quality of HHA services provided in the State; for developing and operating Medicaid reimbursement systems; or for the purpose of administration of Federal/State HHA programs within the State. Data will be released to the State only on those individuals who are either patients under the services of a HHA within the State, or are legal residents of the State, regardless of the location of the HHA in which the patient is receiving services.

State government components in partnership with HCFA will use OASIS information to enhance the monitoring of HHAs' performance in providing patient care. States will also use this information to study the cost effectiveness and quality of Medicaid programs. In addition some States will use OASIS information for case mix Medicaid reimbursement systems. States will use OASIS data to monitor the continuity of care delivered to patients who, for whatever reason, temporarily reside in another State and receive HHA services during that stay.

4. To another Federal or State agency (e.g. State survey agencies and State Medicaid agencies) to contribute to the accuracy of HCFA's health insurance operations (payment, treatment and coverage) and/or to support State agencies in the evaluations and monitoring of care provided by HHAs.

Other State agencies in their administration of a Federal health

program may require OASIS information in order to support evaluations and monitoring of quality of care for special populations or special care area, including proper reimbursement for services provided. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purpose for which HCFA collects the information.

5. To a Peer Review Organization (PRO) in order to assist the PRO to perform Title XI and Title XVIII functions relating to assessing and improving HHA quality of care. PROs will work with HHAs to implement quality improvement programs, provide consultation to HCFA, its contractors, and to State agencies. The PROs will provide a supportive role to HHAs in their endeavors to comply with Medicare Conditions of Participation; will assist the State agencies in related monitoring and enforcement efforts; assist HCFA and help regional home health intermediaries in home health program integrity assessment; and prepare summary information about the nation's home health care for release to beneficiaries.

6. To an individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The OASIS data will provide the research, evaluations and epidemiological projects a broader, longitudinal, national perspective of the status of HHA patients. HCFA anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to HHA patients and the policy that governs the care.

7. To a member of Congress or to a Congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a Member of Congress in resolving some issue relating to a matter before HCFA. The Member of Congress then writes HCFA, and HCFA must be able to give sufficient information to be responsive to the inquiry.

IV. Compatibility of the Proposed Routine Uses

The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. Our disclosure regulation allows us to disclose information under a routine use

when the disclosure will be used to administer one of our programs or a similar program of another government agency, or when disclosure is required by law.

In all of the routine use disclosures described above, the recipient of the information will use the information in connection with a matter relating to one of HCFA's programs; e.g., disclosures related to the administration of the survey and certification of Medicare/Medicaid HHAs, disclosures to contractors assisting HCFA with an administrative function, or disclosure in connection with litigation relating to, or affecting, a program administered by HCFA.

V. Safeguards

The HHS OASIS system will conform with applicable law and policy governing the privacy and security of Federal automated information systems. These include but are not limited to: the Privacy Act of 1984, Computer Security Act of 1987, the Paperwork Reduction Act of 1995, the Clinger-Cohen Act of 1996, and OMB Circular A-130, Appendix III, "Security of Federal Automated Information Resources." HCFA has prepared a comprehensive system security plan as required by OMB Circular A-130, Appendix III. This plan conforms fully to guidance issued by the National Institute for Standards and Technology (NIST) in NIST Special Publication 800-18, "Guide for Developing Security Plans for Information Technology Systems." Paragraphs A-C of this section highlight some of the specific methods that HCFA is using to ensure the security of this system and the information within it.

A. *Authorized users:* Personnel having access to the system have been trained in Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data. In addition, HCFA is monitoring the authorized users to ensure against excessive or unauthorized use. Records are used in a designated work area or work station and the system location is attended at all times during working hours.

To assure security of the data, the proper level of class user is assigned for each individual user as determined at the State agency level. This prevents unauthorized users from accessing and modifying critical data. The system

database configuration includes five classes of database users:

- Database Administrator class owns the database objects; e.g., tables, triggers, indexes, stored procedures, packages, and has database administration privileges to these objects;
- Quality Control Administrator class has read and write access to key fields in the database;
- QI Report Generator class has read-only access to all fields and tables;
- Policy Research class has query access to tables, but are not allowed to access confidential patient identification information; and
- Submitter class has read and write access to database objects, but no database administration privileges. This class is used by the OASIS data submission applications to receive and validate HHA file uploads.

B. *Physical Safeguards:* All server sites have implemented the following minimum requirements to assist in reducing the exposure of computer equipment and thus achieve an optimum level of protection and security for the HHA OASIS system:

Access to all servers is controlled, with access limited to only those support personnel with a demonstrated need for access. Servers are to be kept in a locked room accessible only by specified management and system support personnel. Each server requires a specific log on process. All entrance doors are identified and marked. A log is kept of all personnel who were issued a security card, key and/or combination which grants access to the room housing the server, and all visitors are escorted while in this room. All servers are housed in an area where appropriate environmental security controls are implemented, which include measures implemented to mitigate damage to Automated Information System (AIS) resources caused by fire, electricity, water and adequate climate controls.

Protection applied to the workstations, servers and databases include:

- User Log ons—Authentication is performed by the Primary Domain Controller/Backup Domain Controller of the log on domain.
- Workstation Names—Workstation naming conventions may be defined and implemented at the State agency level.
- Hours of Operation—May be restricted by Windows NT. When activated all applicable processes will automatically shut down at a specific time and not be permitted to resume until the predetermined time. The appropriate hours of operation are determined and implemented at the State agency level.

- Inactivity Lockout—Access to the NT workstation is automatically locked after a specified period of inactivity.
- Warnings—Legal notices and security warnings display on all servers and when servers are accessed by workstations.
- Remote Access Security—Windows NT Remote Access Service (RAS) security handles resource access control. Access to NT resources is controlled for remote users in the same manner as local users, by utilizing Windows NT file and sharing permissions. Dial-in access can be granted or restricted on a user-by-user basis through the Windows NT RAS administration tool.

There are several levels of security found in the HHA OASIS system. Windows NT provides much of the overall system security. The Windows NT security model is designed to meet the C2-level criteria as defined by the U.S. Department of Defense's Trusted Computer System Evaluation Criteria document (DoD 5200.28-STD, December 1985). Netscape Enterprise Server is the security mechanism for all HHA transmission connections to the system. As a result, Netscape controls all HHA information access requests. Anti-virus software is applied at both the workstation and NT server levels.

Access to different areas on the Windows NT server are maintained through the use of file, directory and share level permissions. These different levels of access control provide security that is managed at the user and group level within the NT domain. The file and directory level access controls rely on the presence of an NT File System (NTFS) hard drive partition. This provides the most robust security and is tied directly to the file system. Windows NT security is applied at both the workstation and NT server levels.

C. Procedural Safeguards: All automated systems must comply with Federal laws, guidance, and policies for information systems security as stated previously in this section. Each automated information system should ensure a level of security commensurate with the level of sensitivity of the data, risk, and magnitude of the harm that may result from the loss, misuse, disclosure, or modification of the information contained in the system.

VI. Effect of the Proposed System of Records on Individual Rights.

HCFA proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system

will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

HCFA will monitor the collection and reporting of OASIS data. OASIS information on patients is completed by the HHA and submitted to HCFA through standard systems located at the State agencies. Accuracy of the data is important since incorrect information could result in the wrong reimbursement for services and a less effective process for assuring quality of services. HCFA will utilize a variety of onsite and offsite edits and audits to increase the accuracy of OASIS data.

HCFA will take precautionary measures (see item V. above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights including not collecting patient identifiable data for non-Medicare and non-Medicaid patients. Therefore, HCFA anticipates no adverse effect on any of these rights. HCFA will collect only that information necessary to perform the system's functions. In addition, HCFA will make disclosure of identifiable data from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act.

To secure data that resides in a HCFA Privacy Act System of Records; to ensure the integrity, security, and confidentiality of information maintained by HCFA; and to permit appropriate disclosure and use of such data as permitted by law, HCFA and the non-HCFA recipient of the data, hereafter termed "User," enter into an agreement to comply with the following specific requirements. The agreement addresses the conditions under which HCFA will disclose and the user will obtain and use the information contained in the system of records. The parties mutually agree that HCFA retains ownership rights to the data and that the user does not obtain any right, title, or interest in any of the data furnished by HCFA. 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. The user shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data disclosed from the system of records to any person. The user agrees that access to the data shall be limited to the minimum number of individuals necessary to achieve the purpose stated in the protocol and to those individuals on a need to know

basis only. If HCFA determines or has reasonable belief that the user has made an unauthorized disclosure of the data, HCFA in its sole discretion may require the user to: (a) Promptly investigate and report to HCFA any alleged or actual unauthorized disclosures; (b) promptly resolve any problems identified by the investigation; (c) submit a formal response to any allegation of unauthorized disclosures; (d) submit a corrective action plan with steps to prevent any future unauthorized disclosures; and (e) return data files to HCFA. If HCFA determines or has 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.

The Privacy Act provides criminal penalties for certain violations. The Act provides that "Any officer or employee of an agency, who by virtue of his [or her] employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific materials is so prohibited, willfully discloses the material in any manner to a person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000." (5 U.S.C. 552a(i)(1)). The Act also provides that "Any person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than \$5,000." (5 U.S.C. 552a(i)(3)). The agency's contractor and any contractors' employees who are covered by 5 U.S.C. 552a(m)(1) are considered employees of the agency for the purposes of these criminal penalties.

HCFA, therefore, does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

Dated: June 11, 1999.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

09-70-9002

SYSTEM NAME:

Home Health Agency Outcome and Assessment Information Set (HHA OASIS).

SECURITY CLASSIFICATION

None.

SYSTEM LOCATION:

HCFA Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244-1850. HCFA contractors and agents at various locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will contain clinical assessment information (OASIS records) for all patients receiving the services of a Medicare and/or Medicaid approved Home Health Agency (HHA), except prepartum and postpartum patients, patients under 18 years of age, and patients receiving other than personal care or health care services; i.e., housekeeping services and chore services. Identifiable information will be retained in the system of records only for those individuals whose payments come from Medicare or Medicaid.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records will contain individual-level demographic and identifying data, as well as clinical status data for patients with the payment sources of Medicare traditional fee for service, Medicaid traditional fee for service, Medicare HMO/managed care or Medicaid HMO/managed care.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Secs. 1102(a), 1154, 1861(o), 1861(z), 1863, 1864, 1865, 1866, 1871, 1891(b) of the Social Security Act.

PURPOSE(S):

In 1987, Congress changed the Social Security Act to require HCFA to survey the quality of care furnished by HHAs using a "standardized, reproducible assessment instrument." Through a contract with the University of Colorado, the OASIS was developed by researchers, doctors, and clinicians as the standardized, reliable assessment instrument. OASIS represents a significant advancement in home health care. Home health patients are one of the more vulnerable populations because services are provided in the homes where it is difficult to oversee the quality of services provided. OASIS will ensure accurate payments to HHAs under the prospective payment system, improve quality of patient care, and allow HCFA to monitor the quality of care that it purchases for its beneficiaries.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which HCFA may release

information from the HHA OASIS without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. Also, HCFA will require each prospective recipient of such information, except those otherwise covered by the Privacy Act, to agree in writing to certain conditions to ensure the continuing confidentiality and security, including physical safeguards of the information.

Disclosures may be made:

1. To the Department of Justice (DOJ), court or adjudicatory body when:

(a) The agency or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

(d) The United States Government; is a party to litigation or has an interest in such litigation, and by careful review, HCFA determines that the records are both relevant and necessary to the litigation and the use of such records by the DOJ, court or adjudicatory body is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

2. To agency contractors, or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

3. To the agency of a State Government, or established by State law, for purposes of determining, evaluating and/or assessing overall or aggregate cost, effectiveness, and/or the quality of HHA services provided in the State; for developing and operating Medicaid reimbursement systems; or for the purpose of administration of Federal/State HHA programs within the State. Data will be released to the State only on those individuals who are either patients under the services of a HHA within the State, or are legal residents of the State, regardless of the location of the HHA in which the patient is receiving services.

4. To another Federal or State agency (e.g. Department of Defense, Veterans

Administration, state survey agencies and state Medicaid agencies) to contribute to the accuracy of HCFA's health insurance operations (payment, treatment and coverage) and/or to support state agencies in the evaluations and monitoring of care provided by HHAs.

Other Federal or State agencies in their administration of a Federal health program may require OASIS information in order to support payment evaluations, and monitoring quality of care for special populations or special care area, including proper reimbursement for services provided. Releases of information would be allowed if the proposed use(s) for the information proved compatible with the purpose for which HCFA collects the information.

5. To a Peer Review Organization (PRO) in order to assist the PRO to perform Title XI and Title XVIII functions relating to assessing and improving HHA quality of care.

6. To an individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

7. To a member of Congress or to a Congressional staff member in response to an inquiry of the Congressional Office made at the written request of the constituent about whom the record is maintained.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**STORAGE:**

All records are stored on magnetic media.

RETRIEVABILITY:

The Medicare and Medicaid records are retrieved by health insurance claim number, social security number or by State assigned Medicaid number.

SAFEGUARDS:

HCFA has safeguards for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and systems security requirements. Employees who maintain records in the system are instructed not to release any data until the intended recipient agrees to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, HCFA has physical safeguards in place to reduce the

exposure of computer equipment and thus achieve an optimum level of protection and security for the HHA OASIS system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines; e.g., security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management (IRM) Circular #10, Automated Information Systems Security Program; HCFA Automated Information Systems (AIS) Guide, Systems Securities Policies; and OMB Circular No. A-130 (revised), Appendix III.

RETENTION AND DISPOSAL:

HCFA and the repository of the National Archive and Records Administration (NARA) will retain identifiable OASIS assessment data for

a total period not to exceed fifteen (15) years.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Center for Medicaid and State Operations, HCFA, 7500 Security Boulevard, Baltimore, Maryland, 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, health insurance claim number, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), social security number (SSN) (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay), address, date of birth, and sex.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should

also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

The Outcome and Assessment Information Set.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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