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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; System of Records

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is modifying an existing system of records maintained by the Centers for Medicare & Medicaid Services (CMS), titled "Hospice Item Set (HIS) System," System No. 09-70-0548. The amended System of Records Notice (SORN) reflects changes to now include real time data collection at the time of patient assessments to improve the understanding of patient care needs and care coordination. CMS is also changing the name of the system of records to "Hospice Outcomes and Patient Evaluation (HOPE)" and making other modifications which are explained in the Supplementary Information section. The HOPE system collects standardized hospice patient data to measure and improve care quality, support regulatory and reporting requirements, and enable research and policy functions.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this modified system of records notice is effective upon publication, with the exception of the routine uses, which are effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, subject to comments received during the 30-day comment period.

ADDRESSES: The public should submit written comments on this notice, by mail or email, to Barbara Demopulos, CMS Privacy Act Officer,7500 Security Blvd., N1-14-56, Baltimore, MD 21244-1850, or barbara.demopulos@cms.hhs.gov. Comments will be available for public viewing at the same location. To review comments in person, please contact Barbara Demopulos.

FOR FURTHER INFORMATION CONTACT: General questions about the modified system of records should be addressed to: Jermama Keys, Health Insurance Specialist, Division of Chronic and Post-Acute Care (DCPAC), Center for Clinical Standards and Quality (CCSQ), Centers for Medicare & Medicaid Services (CMS), 7500 Security Blvd., Mail Stop S3-02-01, Baltimore, MD 21244-1850. Office: 410-786-7778 or email jermama.keys@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Reason for modifying System of Records 09-70-0548

The primary reason for this modification is to highlight the inclusion of real time data collection from hospice providers at the time of patient assessments while the beneficiary is receiving hospice services, and not only at the point of admissions and discharges from hospice care.

II. Modifications made to the System of Records Notice (SORN)

The modified SORN published in this notice differs from the existing SORN in these respects:

- The name of the System of Records has been changed from Hospice Item Set (HIS) System to Hospice Outcomes and Patient Evaluation (HOPE).

- The Authority section has been corrected to cite sections 1814(i)(5)(C) and 1861(dd)(2)(G) of the Social Security Act (42 U.S.C. 1395f(i)(5)(C) and 1395x(dd)(2)(G), respectively) instead of section 1814(i).

- The Purpose(s) section now mentions that the records in this system of records are collected in the HOPE tool by Medicare-certified hospice providers, during scheduled

patient assessments or at the point of the patient's admission/discharge from hospice care, or at other times, such as when entering data from the patient's medical records. The list of secondary purposes for which the records are used is now indicated as "Hospice Quality Reporting Program (HQRP) and patient health and safety purposes", in accordance with information collection activities authorized under section 1861(dd)(2)(G) of the Social Security Act. (general purposes such as breach incident response are no longer listed).

- The Categories of Individuals section has been revised to refer to hospice patients as "hospice patients, most of whom are Medicare beneficiaries" instead of as "hospice patients and Medicare beneficiaries"; to clarify that "individual" providers means "sole practitioner" providers, and that the providers are "Medicare-certified"; and to remove contact persons for a hospice, because a record retrieved by a hospice contact person's name or other personal identifier would be, for Privacy Act purposes, a record about the hospice.

- The Categories of Records section now lists additional data elements about hospice patients, i.e., ethnicity, preferred language, and Medicare Beneficiary Identifier (MBI), and the data element "gender" has been changed to "sex." The data elements about sole practitioner providers now includes signature.

- The Records Source Categories section no longer mentions software and computer programs that a hospice may use to "transmit" the information to CMS (it is now limited to people and records that are the "sources" of the information). It now lists the patient's caregivers and the hospice provider's observations and assessments as additional sources of information about a hospice patient, and it mentions that information about a hospice patient may be collected during scheduled assessments or at the point of the patient's admission/discharge from hospice care, or at other times.

- The Routine Uses section has been revised as follows:

    - The introductory paragraph at the start of the section now adds that the routine uses are in addition to other disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b), which can also be made without the subject individual's consent.

    - The wording of routine use 4 has been improved. It authorizes disclosures to support an individual or organization in conducting research or in understanding and improving payment initiatives.

    - The wording of routine use 5 has been improved, including clarifying a statutory cite to read "Part B of Title XI of the Social Security Act (42 U.S.C. 1320c et seq.)" instead of "Part B of Title XI of the Act." It authorizes disclosures to support Quality Improvement Organizations with various review and outreach activities.

    - Routine use 6, now describes how this disclosure assists national accrediting organizations with approval for deeming authority for Medicare requirements for hospice services.

    - In routine use 7, which authorizes disclosures to the Department of Justice or a court or other adjudicatory body, "litigation" has been changed to "litigation or other proceedings" and redundant wording limiting the disclosures to information that is "compatible with the purpose for which the agency collected the records" has been removed as redundant (it is redundant because it repeats part of the definition of a routine use).

    - The two breach response-related routine uses that were added to the SORN in 2018 are now numbered as routine uses 10 and 11.

    - The note at the end of the Routine Uses section is now titled "Additional Circumstances Affecting All Routine Use Disclosures" instead of "Additional Circumstances Affecting Disclosure of PII Data."

- The Storage section now states that all records are "stored electronically" instead of "on magnetic media."

- The Retention and Disposal of Records section has been updated to appropriately identify the applicable disposition authority, DAA-0440-2015-0007-0001, Bucket 5, Beneficiary Records, which was updated in 2017 and provides a retention period of "10 years after cutoff but longer retention is authorized." The Safeguards section now mentions these additional safeguards that are used to protect the records from unauthorized access: security guards, cameras, badges, two-factor authentication, intrusion detection systems, privacy and security training, and secure destruction methods.

- The Record Access Procedures, Contesting Record Procedures, and Notification Procedures sections have been revised to no longer mention providing Health Insurance Claim Number (HICN) or Social Security number (SSN), but to require that requests include (in addition to name) current address, email address or other contact information, and signature, and the following information for identity verification purposes: date and place of birth, and either notarization of the signature or a statement signed under penalty of perjury.

- The SORN has been reformatted to conform to the "Full" SORN template prescribed in OMB Circular A-108, issued December 23, 2016.

Barbara Demopulos,

CMS Privacy Act Officer,

Division of Security, Privacy Policy & Oversight (DSPPO)

Information Security and Privacy Group (ISPG),

Office of Information Technology (OIT),

Centers for Medicare & Medicaid Services (CMS).

SYSTEM NAME AND NUMBER:

Hospice Outcomes and Patient Evaluation (HOPE), 09-70-0548.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of the component responsible for the system of records is: Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Blvd. North Building, First Floor, Baltimore, MD 21244-1850.

SYSTEM MANAGER(S):

The System manager is the Director, Division of Chronic & Post-Acute Care, Quality Measurement & Health Assessment Group, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Mail Stop S3-02-01, Baltimore, MD 21244-1850. Office: 410-786-7778 or email DCPACSTAFF@cms.hhs.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority to maintain this system of records is given under sections 1814(i)(5) and 1861(dd)(2)(G) of the Social Security Act (42 U.S.C. §§42 U.S.C. 1395f(i)(5) and 1395x(dd)(2)(G)).

PURPOSE(S) OF THE SYSTEM:

The records in this system of records are collected in the HOPE tool by Medicare-certified hospice providers during scheduled patient assessments or at the point of the patient's admission/discharge from hospice care, or at other times, such as, when entering data from the patient's medical records. The records are used for the primary purpose of addressing symptom management and improving the understanding of patient care needs and coordinating patient care. The HOPE tool also houses the data needed for the Hospice Quality Reporting Program (HQRP), which collects, compiles, and eventually publishes data measuring the quality of care provided to patients receiving hospice care.

CMS will or may also use information from the records for secondary HQRP purposes, including to: (1) support regulatory, reimbursement, and policy functions performed by Agency contractors, consultants, or CMS grantees; (2) assist Federal and state agencies and their fiscal agents to perform the statutory functions of the HQRP; (3) assist hospices with statutory reporting requirements; (4) support research, evaluation, or epidemiological projects related to end-of-life care, and for payment-related projects; (5) support the functions of Quality Improvement Organizations; as well as other routine uses described below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records are about these categories of individuals who participate in or are involved with the HQRP: (1) Hospice patients, most of whom are Medicare beneficiaries, who receive health care

services coordinated and managed by hospices; and (2) any individual (i.e., sole practitioner) provider of hospice services who is Medicare-certified and whose name or other personal identifier is provided as business-identifying information on the collection instrument.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained about a hospice patient include information related to the patient's condition, selected covariates about the condition, and patient/beneficiary identifying and demographic information such as the patient's name, sex, date of birth, Social Security Number (SSN), race, ethnicity, preferred language, Medicare Beneficiary Identifier (MBI) or Health Insurance Claim Number (HICN), and Medicaid number (MA number).

Records maintained about a sole practitioner provider of hospice services include the provider's name, address, National Provider Identifier (NPI), CMS Certification Number (CCN), personal contact information, signature, and tax identification number (which may be the provider's SSN, if used for business purposes).

RECORD SOURCE CATEGORIES:

Information about a hospice patient is collected by hospice providers directly from the patient or from the patient's caregivers or medical records or based on the hospice provider's observations and assessments of the patient, during scheduled patient assessments or at the point of the patient's admission/discharge from hospice care, or at other times. Any information about an individual (sole practitioner) provider is provided by that provider.

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

The Privacy Act at 5 U.S.C. 552a(b)(3) allows us to disclose information to parties outside the agency without the subject individual's consent for a purpose that is compatible with the

purpose(s) for which the information was collected, if a description of the disclosure is published as a "routine use" in the applicable System of Records Notice (SORN). The disclosures authorized by routine uses published pursuant to 5 U.S.C. 552a(b)(3) are in addition to other disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b), which can also be made without the subject individual's consent.

The following routine uses are published for this system of records:

1. To support Agency contractors, consultants, or CMS grantees engaged by the Agency to assist in the accomplishment of a CMS function related to the purposes for this collection and need to have access to the records to support CMS.
2. To assist another Federal Agency, an agency of a state government, an agency established by State law, or its fiscal agents with information that is necessary and/or required to perform the statutory functions of the HQRP.
3. To provide hospices with information they need to meet any statutory requirements of the HQRP, to assist with reports as required by CMS, and to enable the implementation of quality standards.
4. To support an individual or organization in conducting research, including evaluations and epidemiological projects related to end-of-life care, or in understanding and improving payment initiatives
5. To support Quality Improvement Organizations (QIOs) in connection with review of claims, or in connection with studies or other review activities conducted pursuant to Part B of Title XI of the Social Security Act (42 U.S.C. 1320c et seq.), and in performing affirmative outreach activities to assist individuals in establishing and maintaining their entitlement to Medicare benefits or health insurance plans.
6. To support national accrediting organizations with approval for deeming authority for Medicare requirements for hospice services (i.e., The Joint Commission, the Accreditation Commission for Health Care, Inc., and the Community Health

Accreditation Program). Information will be released to these organizations upon specific request, and only for those facilities that they accredit, that participate in the Medicare program, and that meet the following requirements:

a. Provide identifying information for hospices that have an accreditation status with the requesting deemed organization;
b. Submit a finder file identifying beneficiaries/patients receiving hospice services;
c. Complete a signed data exchange agreement or a CMS data use agreement; and
d. Safeguard the confidentiality of the data and prevent unauthorized access.

7. To provide information to the U.S. Department of Justice (DOJ) or a court or other adjudicatory body when (a) the Agency or any component thereof, or (b) any employee of the Agency in the employee's official capacity, or (c) any employee of the Agency in the employee's individual capacity where the DOJ has agreed to represent the employee, or (d) the United State Government, is a party to litigation or other proceedings or has an interest in the proceedings, and by careful review, CMS determines that the records are both relevant and necessary to the proceedings.
8. To assist a CMS contractor (including, but not limited to, Medicare Administrative Contractors, fiscal intermediaries, and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.
9. To assist another Federal agency or an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter,

discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

10. To appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records; (2) HHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HHS (including its information systems, programs, and operations), the federal government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.
11. To another federal agency or federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

Additional Circumstances Affecting All Routine Use Disclosures:

To the extent that the subject individual claims records in this system contain Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR Parts 160 and 164, Subparts A and E), disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information" (see 45 CFR 164.512(a)(1)).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records are secured across both physical and digital environments. Hard-copy records are maintained in restricted, locked facilities accessible only to authorized personnel. Electronic records are safeguarded using industry-standard encryption, firewalls, and multi-factor access controls. Portable electronic media containing personal data are strictly encrypted. All records are subject to strict retention schedules and are permanently destroyed or de-identified when no longer required..

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information may be retrieved by any of these personal identifiers: provider's TIN (which could be an SSN); NPI; CMS Certification Number (CCN); Patient's SSN or a Beneficiary's HICN; a patient's or beneficiary's name in combination with the patient's or beneficiary's date of birth.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The applicable schedule approved by the National Archives and Records Administration (NARA) is DAA-0440-2015-0007-0001 (Bucket 5, Beneficiary Records), which provides for beneficiary claims records to be cut off at the end of the calendar year and destroyed no sooner than 10 years after cutoff unless longer retention is authorized; however, beneficiary claims records are currently subject to a document preservation order and must be preserved indefinitely pending further notice from the U.S. Department of Justice.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Safeguards conform to the HHS Information Security and Privacy Program, https://www.hhs.gov/ocio/securityprivacy/index.html. Information is safeguarded in accordance with applicable laws, rules and policies, including the HHS Policy for Information Security and Privacy Protection (IS2P); the E-Government Act of 2002, which includes the Federal Information Security Modernization Act (FISMA) of 2014, 44 U.S.C. 3551 through 3558; all

pertinent National Institutes of Standards and Technology (NIST) Special Publications (SP), and OMB Circular A-130, Managing Information As a Strategic Resource.

Records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras, securing hard-copy records in locked file cabinets, file rooms or offices during off-duty hours, limiting access to electronic databases to authorized users based on roles and two-factor authentication (or user identification (ID) and password), using a secured operating system protected by encryption, firewalls, and intrusion detection systems, requiring encryption for records stored on removable media, and training personnel in Privacy Act and information security requirements. Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800-88, as revised.

RECORD ACCESS PROCEDURES:

An individual seeking access to records about the individual in this system of records must submit a written access request to the System Manager identified in the "System Manager(s)" section. An access request must contain the individual's full name, current address, email address or other contact information, and, for identity verification purposes, signature and date and place of birth. In addition, to verify the requester's identity, the signature must be notarized, or the request must include the individual's written certification that the individual is the person the individual claims to be and understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. An individual may also request an accounting of disclosures that have been made of the records about the individual, if any.

CONTESTING RECORD PROCEDURES:

An individual seeking to amend a record about the individual in this system of records must submit a written amendment request to the System Manager identified in the "System Manager(s)" section. The request must contain the same information required for an access request, and must reasonably identify the record, specify the information contested, state the corrective action sought, provide the reasons for the amendment, and include any supporting justification or documentation. The individual must verify his or her identity in the same manner required for an access request. The right to contest records is limited to information that is factually inaccurate, incomplete, irrelevant, or untimely (obsolete).

NOTIFICATION PROCEDURES:

An individual who wishes to know if this system of records contains records about the individual must submit a written request to the System Manager identified in the "System Manager(s)" section. The request must contain the same information required for an access request, and the individual must verify their identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

79 FR 19341 (Apr. 8, 2014); 83 FR 6591 (Feb.14, 2018)

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