

We encourage the participation of appropriate organizations with expertise in the use of ESAs for treatment of anemia in adults with CKD including patients on dialysis and patients not on dialysis.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating the meetings registration process. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your government—issued photographic identification), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

You must register for the Webinar portion of the meeting at <https://webinar.cms.hhs.gov/esamedcac119/event/registration.html> by the deadline listed in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 16, 2010.

Barry M. Straube,

CMS Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of New System of Records

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

ACTION: Notice of a New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is establishing a new system of records (SOR) titled, "Medicare and Medicaid Electronic Health Record (EHR) Incentive Program National Level Repository" System No. 09-70-0587. The final rule for the Medicare and Medicaid EHR Incentive Program implements the provisions of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111-5). Specifically, Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs) and Medicare Advantage (MA) Organizations participating in Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the "Health Information Technology for Economic and Clinical Health Act," or the "HITECH Act."

The final rule specified the initial criteria EPs, eligible hospitals and CAHs, and MA Organizations must meet in order to qualify for an incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. Also, the Office of the National Coordinator for Health Information Technology (ONC) issued a closely related final rule that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the establishment of certification programs for health information technology (HIT).

To register for the Medicare and Medicaid EHR Incentive Program, EPs,

eligible hospitals and CAHs, and MA Organizations will be required to provide the following information: Name, National Provider Identifier (NPI), business address and business phone for each EP, eligible hospital or CAH; Taxpayer Identification Number (TIN) to which the EP, eligible hospital or CAH wants the incentive payment to be made; For EPs, whether they choose to participate in the Medicare EHR Incentive Program or the Medicaid EHR Incentive Program; For eligible hospitals and CAHs, their CMS Certification Number (CCN); and other information as specified by CMS. EPs, eligible hospitals and CAHs will also have the option to provide their e-mail address at the time of registration. MA Organizations will be required to provide their contract number on behalf of their MA-affiliated EPs and hospitals. At this time, participation in the Medicare and Medicaid EHR Incentive Programs is voluntary for EPs, eligible hospitals and CAHs.

Per section 1886(n)(4)(B) of the Act, as added by section 4102(c) of the HITECH Act, the Secretary will post on the Internet Web site of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone numbers of the Medicare EPs, eligible hospitals and CAHs who are meaningful EHR users in the Medicare EHR Incentive Program. Sections 1853(m)(5) and 1853(l)(7) of the Act, as added by sections 4101(c) and 4102(c) of the HITECH Recovery Act, require the Secretary to post the same information for EPs and eligible hospitals participating in the MA program as would be required if they were in the Medicare FFS program. Additionally, the Secretary must post the names of the qualifying MA Organizations receiving the incentive payment or payments. The routine uses established with this system contain a proper explanation as to the need for the disclosure provisions and provide clarity to CMS' intention to disclose provider-specific information contained in this system.

The primary purpose of this system, called the National Level Repository or NLR, is to collect, maintain, and process information that is required for the Medicare and Medicaid EHR Incentive Program. Information in this system will also be disclosed to: (1) Support regulatory, incentive payments and policy functions such as evaluation and reporting, whether performed by the Agency or by an Agency contractor or consultant; (2) assist another Federal and/or state agency, agency of a state government, or an agency established by

state law; (3) assist in making the individual physician-level participation data available through an Agency website and by various other means of data dissemination; (4) assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology; (5) support litigation involving the Agency; (6) combat fraud, waste, and abuse in certain health benefits programs, and (7) assist in a response to a suspected or confirmed breach of the security or confidentiality of information. We have provided background information about this new system in the "Supplementary Information" section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for information about the comment period.

DATES: Effective Dates: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 29, 2010. To ensure that all parties have adequate time in which to comment, the new system, including routine uses, will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Information Security and Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N1-24-08, 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 a.m.—3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Rachel Maisler, Health Insurance Specialist, Office of E-Health Standards and Services, CMS, 7500 Security Boulevard, Mail-stop: S2-26-17, Baltimore, MD 21244-1850. Office: 410-786-5754, Facsimile: 410-786-1347, E-mail address: rachel.maisler@cms.gov.

SUPPLEMENTARY INFORMATION: Sections 4101(a), 4102(a) and 4102(a)(2) of the HITECH Act respectively add sections 1848(o), 1886(n) and 1814(l)(A)(3) to the Act to limit incentive payments in the Medicare Fee-for-service (FFS) EHR incentive program to an EP, eligible hospital or CAH that is a "meaningful EHR user." Sections 4101(c) and 4102(c) of the HITECH Act respectively add sections 1853(l) and 1853(m) which outline the application of incentive payments for certain MA-affiliated EPs and MA-affiliated hospitals. Section 4201(a)(2) of the HITECH Act added section 1903(t) to the Act to limit incentive payments in the Medicaid context to EPs, as defined at section 1903(t)(2)(A), who meet the requirements of 1903(t). As described in our final rule discussed below, these eligible professionals can receive an incentive payment for adoption or utilization of, or upgrade to, certified EHR technology in 2011, and can receive incentive payments in certain subsequent years if they demonstrate meaningful use of certified EHR technology.

In sections 1848(o)(2)(A) and 1886(n)(3) of the Act, the Congress specified three types of requirements for meaningful use in the Medicare context: (1) Use of certified EHR technology in a meaningful manner; (2) that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and (3) that, in using certified EHR technology, the provider submits to the Secretary information on clinical quality measures and such other measures selected by the Secretary.

In our final rule on the EHR incentive program, we stated that we are not limited to collecting only information pertaining to Medicare and Medicaid beneficiaries. Therefore, in our final rule, we require that, in order to demonstrate meaningful use, an EP, eligible hospital or CAH, or MA Organization must report aggregate information on clinical quality measures for all patients to whom clinical quality measures apply. As explained in the final rule for EHR incentive payments, for the 2011 payment year, we use an attestation methodology for the submission of summary information on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology.

For the Medicaid incentive program, as stated in our final rule, for their first year of payment, providers are not required to demonstrate meaningful use, and may receive an incentive payment by demonstrating adoption,

implementation, or upgrade to certified EHR technology. We expect that, for 2011, the majority of Medicaid providers will receive an incentive payment through this pathway. In their second, third, fourth, fifth and sixth payment year, Medicaid EPs and hospitals will be required to demonstrate meaningful use of certified EHR technology to qualify for an incentive payment.

As stated in our final rule, we will use a phased approach for meaningful use criteria, based on currently available technology capabilities and provider practice experience. We refer to the initial meaningful use criteria as "Stage 1." In the final rule, we require that EPs, eligible hospitals and CAHs, including MA-affiliated EPs and hospitals, demonstrate that they satisfy all the required meaningful use objectives and associated measures of the Stage 1 criteria during the reporting period for 2011 through attestation in order to receive incentive payments. In addition, we require that EPs, eligible hospitals and CAHs, and MA Organizations attest to the accuracy and completeness of the numerators and denominators for each of the applicable measures, and that the information submitted includes information on all patients to whom the measure applies.

To qualify as a meaningful EHR user for 2011, we require that EPs, eligible hospitals, or CAHs demonstrate that they meet all of the required meaningful use objectives and the associated measures using certified EHR technology. In order to receive an incentive payment, all EPs, eligible hospitals and CAHs must register for the program in the NLR and then attest that they have successfully demonstrated meaningful use of certified EHR technology after the completion of their EHR reporting period, which is defined at 75 FR 44566.

Section 1848(o)(3)(D) of the Act requires the Secretary to list, in an easily understandable format, the names, business addresses, and business phone numbers of the Medicare EPs for being meaningful EHR users under the Medicare FFS program on the Internet web site of CMS. Section 1886(n)(4)(B) of the Act requires the Secretary to list, in an easily understandable format, the names and other relevant data as determined appropriate, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on the CMS Internet web site. Sections 1853(m)(5) and 1853(l)(7) of the Act require the Secretary to post the same information for EPs and eligible hospitals in the MA program as would be required if they were in the Medicare

FFS program. Therefore, we collect the information necessary to post the name, business address and business phone numbers of all EPs, eligible hospitals and CAHs participating in the Medicare FFS and MA EHR Incentive Program,, and post this information on our Internet web site. The routine uses established with this system contain a proper explanation as to the need for the disclosure provisions and provide clarity to CMS' intention to disclose provider-specific information contained in this system.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for System

Authority for the collection, maintenance, and disclosures from this system is provided under §§ 1848(o), 1886(m), 1848(l), and 1853(m) of the Social Security Act which were added by the HITECH Act, respectively authorize incentive payments for EPs, eligible hospitals, CAHs and MA Organizations that successfully demonstrate meaningful use of certified EHR technology. Sections 1903(a)(3) and 1903(t) of the Social Security Act provides authority for the Medicaid EHR Incentive Program. These provisions are implemented by 75 FR 44314 and 42 CFR parts 412, 413, 422, collectively known as the Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule.

B. Collection and Maintenance of Data in the System

The National Level Repository (NLR) contains information on eligible professionals who receive Medicare incentives as meaningful users of certified EHR technology. Information in the NLR will be populated from other CMS systems, including the Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan & Provider Enumeration System (NPPES). The NLR will contain provider name, National Provider Identifier (NPI), business address and phone number, Taxpayer Identification Number (TIN) to which the EP, eligible hospital or CAH, or MA Organization wants the incentive payment to be made, and, for EPs, whether they choose to participate in the Medicare EHR Incentive Program or the Medicaid EHR Incentive Program. For eligible hospitals and CAHs, their CCN will also be included. For MA Organizations, their CMS contract number will be included. For providers participating in the Medicaid EHR Incentive Program, it will include the State in which they choose

to participate. Additionally, EPs, eligible hospitals and CAHs will have the option to provide an e-mail address for inclusion in the system. At this time, participation in the Medicare and Medicaid EHR Incentive Program is voluntary for EPs, eligible hospitals and CAHs.

II. Agency Policies, Procedures, and Restrictions On Routine Uses

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that 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 information collected in the NLR that can be associated with an individual EP as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Identifiable data may be disclosed under a routine use.

We will only disclose the minimum provider-level data necessary to achieve the purpose of the Medicare and Medicaid EHR Incentive Program. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. These policies do not apply to Routine Use No. 3 for this system. In general, disclosure of information from the system will be approved only for the minimum information necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, to collect, maintain, and process information promoting the nationwide health information technology infrastructure that allows for the electronic use and exchange of information.

2. Determines that:
 - a. The purpose of the disclosure can only be accomplished if the record is provided in an individually identifiable form;

- b. 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 provider that additional exposure of the record might bring; and

- c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:
 - a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all individually-identifiable information; and

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

4. 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

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the Medicare and Medicaid EHR Incentive Program 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. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors or consultants who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing a CMS function relating to purposes for this SOR.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To assist another Federal or state agency, agency of a state government, or an agency established by state law pursuant to agreements with CMS to:

a. Contribute to the accuracy of CMS's proper incentive payment to Medicare

and Medicaid EHR Incentive Program participants, and

b. Assist Federal/state Medicaid programs which may require Medicare and Medicaid EHR Incentive Program information for purposes related to this system.

c. Assist other Federal agencies that have the authority to perform collection of debts owed to the Federal government.

Other Federal or state agencies in their administration of a Federal health program may require EHR Incentive Program information in order to support evaluations and monitoring of various aspects of the Medicare and Medicaid EHR Incentive payments.

2. To assist in making the information for EPs, eligible hospitals and CAHs, and MA Organizations that receive Medicare EHR incentive payments through the new payment contractor, available through a public web site. If local websites are used by a local or regional collaborative, CMS would have links to these Web sites on its main Web site.

This information would be posted for the purpose of, and in a manner that would promote the use of EHRs by EPs, eligible hospitals and CAHs, and MA Organizations to Medicare and Medicaid beneficiaries.

3. To assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology.

We contemplate disclosing information under this routine use only in situations in which CMS may be asked to provide necessary information to ONC grantees, also referred to as Health Information Technology Regional Extension Centers (RECs) to assist in accomplishing an ONC function relating to support for "eligible professional" (EP) adoption of, meaningful use of certified EHR technology, and provider support.

4. To support 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, CMS determines that the records are both relevant and necessary to the

litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court, or adjudicatory body involved.

5. 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.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste or abuse.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract or grant and requiring the contractor or grantee to return or destroy all information.

6. To assist another Federal agency or to 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.

Other agencies may require Medicare and Medicaid EHR Incentive Program information for the purpose of

combating fraud, waste or abuse in such Federally-funded programs.

7. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and unnecessary for the assistance.

Other Federal agencies and contractors may require EHR Incentive Program information for the purpose of assisting in a respond to a suspected or confirmed breach of the security or confidentiality of information.

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the New System On the Rights of Individuals

CMS 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. We will only disclose the minimum personal data necessary to achieve the purpose of the data collection and the routine uses contained in this notice. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure. CMS has assigned a higher level of security clearance for the information maintained in this system in an effort to provide added security and protection of data in this system.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure 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. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

Dated: November 16, 2010.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM No. 09-70-0587

SYSTEM NAME:

"Medicare and Medicaid Electronic Health Record (EHR) Incentive Program National Level Repository" HHS/CMS/OESS.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244-1850 and at various contractor sites.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The National Level Repository (NLR) contains information on eligible professionals who receive Medicare incentives as meaningful users of certified EHR technology.

CATEGORIES OF RECORDS IN THE SYSTEM:

The NLR will contain provider name, National Provider Identifier (NPI), business address and phone number, Taxpayer Identification Number (TIN) to which the EP, eligible hospital or CAH, or MA Organization wants the incentive payment to be made, and, for EPs,

whether they choose to participate in the Medicare EHR Incentive Program or the Medicaid EHR Incentive Program. For eligible hospitals and CAHs, their CCN will also be included. For MA Organizations, their CMS contract number will be included. For providers participating in the Medicaid EHR Incentive Program, it will include the State in which they choose to participate. Additionally, EPs, eligible hospitals and CAHs will have the option to provide an e-mail address for inclusion in the system. At this time, participation in the Medicare and Medicaid EHR Incentive Program is voluntary for EPs, eligible hospitals and CAHs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for the collection, maintenance, and disclosures from this system is provided under §§ 1848(o), 1886(m), 1848(l), and 1853(m) of the Social Security Act which were added by the HITECH Act, respectively authorize incentive payments for EPs, eligible hospitals, CAHs and MA Organizations that successfully demonstrate meaningful use of certified EHR technology. Sections 1903(a)(3) and 1903(t) of the Social Security Act provides authority for the Medicaid EHR Incentive Program. These provisions are implemented by 75 FR 44314 and 42 CFR parts 412, 413, 422, collectively known as the Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system, called the National Level Repository or NLR, is to collect, maintain, and process information that is required for the Medicare and Medicaid EHR Incentive Program. Information in this system will also be disclosed to: (1) Support regulatory, incentive payments and policy functions such as evaluation and reporting, whether performed by the Agency or by an Agency contractor or consultant; (2) assist another Federal and/or state agency, agency of a state government, or an agency established by state law; (3) assist in making the individual physician-level participation data available through an Agency website and by various other means of data dissemination; (4) assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology; (5) support litigation involving the Agency; (6) combat fraud, waste, and abuse in certain health

benefits programs, and (7) assist in a response to a suspected or confirmed breach of the security or confidentiality of information.

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

A. ENTITIES WHO MAY RECEIVE DISCLOSURES UNDER ROUTINE USE

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the EHRI 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. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, or CMS grantees who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

2. To assist another Federal or state agency, agency of a state government, or an agency established by state law pursuant to agreements with CMS to:

a. Contribute to the accuracy of CMS's proper incentive payment to Medicare and Medicaid EHR Incentive Program participants, and

b. Assist Federal/state Medicaid programs which may require Medicare and Medicaid EHR Incentive Program information for purposes related to this system.

c. Assist other Federal agencies that have the authority to perform collection of debts owed to the Federal government.

3. To assist in making the information for EPs, eligible hospitals and critical access hospitals (CAHs), who receive EHR incentive payments through the new payment contractor, available through a public website. If local Web sites are used by a local or regional collaborative, CMS would have links to these websites on its main website.

4. To assist the Department's Office of the National Coordinator of Health Information Technology's (ONC's) grantees for the purpose of supporting "eligible professional" (EP) adoption and meaningful use of certified EHR technology.

5. To support 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, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To assist a CMS contractor (including, but not limited to 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.

7. To assist another Federal agency or to 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.

8. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for the assistance.

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

STORAGE:

Records are stored on both tape cartridges (magnetic storage media) and

in a DB2 relational database management environment (DASD data storage media).

RETRIEVABILITY:

Information is most frequently retrieved by provider number (facility, physician, IDs), service dates, and prescriber identification number.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 10 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Office of E-Health Standards and Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Mail-stop: S2-26-17, Baltimore, MD 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name, and the retrieval selection criteria (e.g., Provider number, SSN, etc.).

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:

Information in the National Level Repository will be populated from other CMS systems of records, including the

Provider Enrollment, Chain, and Ownership System (PECOS) and the National Plan & Provider Enumeration System (NPPES).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.
[FR Doc. 2010-29952 Filed 11-26-10; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Evaluation of Pregnancy Prevention Approaches and Teen Pregnancy Prevention Evaluation.
OMB No.: 0970-0360.
Description: The Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Office of the Assistant Secretary for Health (ASH), 13.5. Department of Health and Human Services (HHS), are proposing a data collection activity to be undertaken by two related studies—the Evaluation

of Pregnancy Prevention Approaches study and the Teen Pregnancy Prevention Evaluation. Both studies are sponsored by ASH and will use the same data collection instruments; ACF is facilitating the Evaluation of Pregnancy Prevention Approaches, while ASPE is facilitating the Teen Pregnancy Prevention Evaluation.

These two studies will assess the effectiveness of a range of programs designed to prevent or reduce sexual risk behavior and pregnancy among older adolescents. Knowing what types of programs are effective will enhance programmatic decisions by policymakers and practitioners.

The proposed activity involves the collection of information from observations of program activities and interviews with a range of experts and persons involved with programs about various aspects of existing prevention programs and topics the experts view as important to address through evaluation. These data will be used to help enhance decisions about the types of programs to be evaluated in the studies.

Respondents: Researchers and policy experts, program directors, program staff, or school administrators.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Discussion Guide for Use with Researchers and Policy Experts	30	1	1	30
Discussion Guide for Use with Program Directors	30	2	2	120
Discussion Guide for Use with Program Staff	60	1	2	120
Focus Group Discussion Guide for Use with Program Participants	300	1	1.5	450
Discussion Guide for Use with School Administrators	200	1	1	200

Estimated Total Annual Burden Hours: 920.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed

collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 22, 2010.
Steven Hanmer,
OPRE Reports Clearance Officer.
[FR Doc. 2010-29917 Filed 11-26-10; 8:45 am]
BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0601]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to