

- Do facilitators and barriers that impact use vary by health care settings and systems?

- Do facilitators and barriers that impact use vary by IT system characteristics?

KQ 8: What factors influence sustainability of HIE?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Setting)

Populations

Any individual or group of health care providers, patients, managers, health care institutions, or regional organizations.

Intervention

Health Information Exchange (HIE). HIE is defined as the electronic sharing of clinical information among users such as health care providers, patients, administrators or policy makers across the boundaries of health care institutions, health data repositories, States and others, typically not within a single organization or among affiliated providers, while protecting the integrity, privacy, and security of the information.

Comparators

- Time period prior to HIE implementation
- Locations (geographic or organizational without HIE)
- Situations in which HIE is not available, akin to “usual care” in a clinical study
- Comparisons across types of HIE
- Comparisons of the characteristics of the different settings, health care system, and IT systems in which HIE is used

Outcomes (specified for each Key Question)

KQ 1: Effectiveness is defined in terms of clinical outcomes (e.g., mortality and morbidity), economic outcomes (e.g., costs and resource use, the value proposition for HIE) and population outcomes (e.g., syndromic surveillance for the identification of trends or clusters).

KQ 2: Harms include unintended negative consequence or adverse events experienced by individuals, institutions, or organizations. Harms from HIE may include negative outcomes or the risk of negative outcomes resulting from information that is wrong, not provided in a timely manner, or in formats that inhibit its identification, comprehension, and use. Harms also may result from too much information as well as lack of information. Harms can also include negative impacts on

attitudes (e.g., patients not trusting the privacy will be protected, clinicians’ concerns about legal liability).

KQ 3: Intermediate outcomes include outcomes such as provider and patient experience and perceptions; changes in provider behavior and health care processes; and changes in the availability, completeness, or accuracy of information.

KQ 4: Level of use is the rate of HIE use by individuals, health care institutions, or regional organizations.

KQ 5: Usability focuses on the function of the HIE in terms of the interaction between users and HIE and their ability to navigate and accomplish tasks.

KQ 6: Implementation of HIE is defined as the realization of an HIE project such that the exchange of data is operational.

KQ 7: Use is the incorporation of the HIE into the workflow and decisions of patients, providers or organizations.

KQ 8: Sustainability is long-term maintenance, and improvement or expansion of HIE, after the implementation period.

Timing

No minimum duration of time lapsed from implementation of HIE to the measurement of outcomes.

Settings

Any aspect of the setting in which health information is exchanged for the purpose of improving health or health care decisions that is hypothesized to impact effectiveness, use, usability or sustainability. This may include the type(s) of clinical environments (e.g., ambulatory care, hospital, nursing home, etc.), payment/reimbursement model(s) (e.g., fee-for-service, managed care setting, risk/value-based model such as an accountable care organization, etc.), and legislative requirements (e.g., participation in HIE required to participate in Medicaid).

Dated: August 20, 2014.

Richard Kronick,

AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10147, CMS–2540–10, CMS–265–11, CMS–10106 and CMS–10537]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *September 29, 2014*.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Coverage and Your Rights; *Use:* Through the delivery of this standardized notice, Part D plan sponsors’ network pharmacies are in the best position to inform enrollees (at the point of sale) about how to contact their Part D plan if their prescription cannot be filled and how to request an exception to the Part D plan’s formulary. The notice restates certain rights and protections related to the enrollees Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered.

Form Number: CMS-10147 (OMB control number: 0938-0975); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 56,000; *Total Annual Responses:* 37,620,000; *Total Annual Hours:* 626,749. (For policy questions regarding this collection contact Kathryn M. Smith at 410-786-7623).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Skilled Nursing

Facility and Skilled Nursing Facility Health Care Complex Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 USC 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. Form CMS-2540-10 is used by Skilled Nursing Facilities (SNFs) and Skilled Nursing Facility Complexes participating in the Medicare program to report health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries.

Form Number: CMS-2540-10 (OMB control number: 0938-0463); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 14,185; *Total Annual Responses:* 14,185; *Total Annual Hours:* 2,865,370. (For policy questions regarding this collection contact Amelia Citerone at 410-786-3901.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Independent Renal Dialysis Facility Cost Report and Supporting Regulations; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS-265-11 cost report is needed to determine a provider’s reasonable costs incurred in furnishing medical services to Medicare beneficiaries.

Form Number: CMS-265-11 (OMB control number: 0938-0263); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 5,677; *Total Annual Responses:* 5,677; *Total Annual Hours:* 369,005. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278.)

4. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Authorization to Disclose Personal Health Information; *Use:* Unless permitted or required by law, the

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits Medicare (a HIPAA covered entity) from disclosing an individual’s protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS-10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. *Form Number:* CMS-10106 (OMB control number: 0938-0930); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,298,329; *Total Annual Responses:* 1,298,329; *Total Annual Hours:* 324,582. (For policy questions regarding this collection contact Sam Jenkins at 410-786-3261.)

5. *Type of Information Collection Request:* New collection (Request for a new control number); *Title of Information Collection:* National Implementation of the Hospice Experience of Care Survey (CAHPs Hospice Survey); *Use:* We are requesting a three-year clearance from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 to implement the Hospice Experience of Care Survey (HECS), also called the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey, and to conduct an assessment of the effects of survey administration mode. Under Contract Number HHSM-500-2014-00350G, the project team will implement and analyze a hospice experience of care survey for primary caregivers (i.e., bereaved family members or close friends) of patients who died while receiving hospice care (“decedents”). Specifically, we will: (1) Implement a survey to collect data on experiences of hospice care, and (2) conduct an experiment to examine effects of survey mode (i.e., mail-only, telephone-only, and mail with telephone follow-up).

This survey supports the National Quality Strategy developed by the U.S. Department of Health and Human Services (HHS) that was called for under the Affordable Care Act to create national aims and priorities to guide local, state, and national efforts to

improve the quality of health care. This strategy has established six priorities that support a three-part aim focusing on better care, better health, and lower costs through improvement. The six priorities include: Making care safer by reducing harm caused by the delivery of care; ensuring that each person and family are engaged as partners in their care; promoting effective communication and coordination of care; promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; working with communities to promote wide use of best practices to enable healthy living; and making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models. Because the hospice survey focuses on experiences of care, implementation of the survey supports the following national priorities for improving care: Engaging patients and families in care and promoting effective communication and coordination. In addition, national implementation and public reporting of hospice survey results will provide data on experiences with hospice care that enable consumers to make meaningful comparisons between hospices across the nation.

Form Number: CMS-10537 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 561,026; *Total Annual Responses:* 561,026; *Total Annual Hours:* 98,179.55. (For policy questions regarding this collection contact Lori Teichman at 410-786-6684.)

Dated: August 26, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10536]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 28, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10536 Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (request for a new OMB Control Number); *Title of Information Collection:* Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use:* To assess the appropriateness of states' requests for enhanced federal financial participation for expenditures related to Medicaid eligibility determination systems, we will review the submitted information and documentation to make an approval determination for the advanced planning document.

Form Number: CMS-10536 (OMB control number: 0938-New); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 1,344. (For policy questions regarding this collection contact Christine Gerhardt at 410-786-0693).