

conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB. PDF Help) relating to the listing and operation of PSOs. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs. AHRQ has accepted a notification from The Georgia Hospital Association Research and Education Foundation Patient Safety Organization (GHA-PSO), PSO number P0057, which is a component entity of the Georgia Hospital Association Research and Education Foundation, to voluntarily relinquish its status as a PSO. Accordingly, The Georgia Hospital Association Research and Education Foundation Patient Safety Organization (GHA-PSO) was delisted effective at 12:00 Midnight ET (2400) on December 6, 2011.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: December 14, 2011.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5048-N]

Medicare Program; Independence at Home Demonstration Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice creates a new demonstration program for chronically ill Medicare beneficiaries to test a payment incentive and service delivery system that utilizes physician and nurse practitioner directed home-based primary care teams aimed at improving health outcomes and reducing expenditures, beginning December 21, 2011.

DATES: *Effective Date:* This notice is effective on December 21, 2011.

Application Deadline: February 6, 2012 at 5 p.m., Eastern Standard Time (E.S.T.).

FOR FURTHER INFORMATION CONTACT:
Linda Colantino (410) 786-3343.
Jennifer Brown (410) 786-4036.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3024 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111-148, enacted on March 23, 2010), amends title XVIII of the Social Security Act (the Act) by establishing the Independence at Home (IAH) Demonstration.

The IAH Demonstration will test a service delivery model that utilizes physician and nurse practitioner directed primary care teams to provide services to high cost, chronically ill Medicare beneficiaries in their homes. Participating practices will be accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinate health care across all treatment settings. Participating practices may share in savings under the demonstration if specified quality measures and savings targets are achieved.

II. Provisions of the Notice

We are seeking interested practices that can provide home-based primary care to Medicare beneficiaries for purposes of this demonstration. We anticipate that a wide variety of interested practices may be eligible to apply to the IAH Demonstration. The participants in the Demonstration will be multidisciplinary teams composed of various members such as physicians, nurse practitioners, physician assistants, pharmacists, social workers, and other supporting staff. The practices must be led by physicians or nurse practitioners and must have experience providing home-based primary care to patients with multiple chronic illnesses. These practices will also be organized, at least in part, for the purpose of providing physician services. Qualifying practices may share in savings. Providers cannot be participating in section 1899 of the Act, the Medicare Shared Savings Program, or other Medicare shared savings programs at the time of the Demonstration.

Each participating practice must provide services to at least 200 applicable beneficiaries during each year of the demonstration. A practice's enrollment may vary over each year but must reach at least an average of 200 applicable beneficiaries during the first year and not drop below that average for the remainder of the demonstration. There are three options available for practices to apply for the

Demonstration. Practices may apply as a sole legal entity, consortium, or become a part of a national pool. These three options are for the purpose of establishing expenditure targets and determining incentive payments. Practices must enroll all existing patients meeting beneficiary eligibility criteria.

Participating practices will make in-home visits tailored to an individual patient's needs. Each practice must be available 24 hours per day, 7 days a week to carry out plans of care. Practices must use electronic health information systems, remote monitoring, and mobile diagnostic technology.

Applicable beneficiaries are defined as Medicare fee-for-service (FFS) patients, who have at least 2 chronic illnesses, need assistance with 2 or more functional dependencies requiring the assistance of another person, have had a nonelective hospital admission within the last 12 months, and have received acute or subacute rehabilitation services within the last 12 months. Beneficiaries to be included in the Demonstration must be entitled to Medicare part A and enrolled in Medicare part B, not enrolled in a Medicare Advantage plan or a Program for All-Inclusive Care for the Elderly, and cannot be enrolled in a practice that is part of the Medicare Shared Savings Program or other program that shares Medicare savings.

We will establish a practice-specific spending target derived from claims, based on expected Medicare FFS utilization for each of the beneficiaries in the practices in the absence of the Demonstration. Annual spending targets will be calculated for each participating practice at the end of each performance year. The spending target will be derived from a base expenditure amount equal to the average payments under Medicare Part A and Part B. Savings will be calculated as the difference between each practice's spending target and actual costs. Practices will also be required to meet quality performance standards in order to share in any savings. Under this 3-year demonstration, IAH providers will continue to bill and be paid standard Medicare FFS reimbursement.

Applicants must submit completed applications following the format outlined in the Demonstration application instructions in order to be considered for review by CMS. Applications not received in this format will not be considered for review.

For the Project Application and specific details regarding the IAH Demonstration, please refer to the CMS Web site at <http://www.cms.gov/>

DemoProjectsEvalRpts/downloads/IAH_FactSheet.pdf

Please refer to file code [CMS–5048–N] on the Application. Applicants must submit at least 1 electronic copy on CD–ROM of the Application and are required to submit a paper version of the Application with an original signature. Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission. Hard copies and electronic copies must be identical.

Applications for practices applying to the IAH Demonstration will be considered timely if they are received on or before 5 p.m., Eastern Standard Time (E.S.T.) on the date listed in the **DATES** section of this notice.

III. Collection of Information Requirements

Accordance to section 3024 of the Affordable Care Act this notice does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Authority: Section 3024 of the Affordable Care Act.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medicare—Supplementary Medical Insurance Program)

Dated: September 9, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–32568 Filed 12–20–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

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 publish notice in the **Federal Register**

concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on regulations requiring the distribution of patient labeling, called Medication Guides, for certain products that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication.

DATES: Submit either electronic or written comments on the collection of information by February 21, 2012.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–7651, juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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. “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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collections of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of

information, including the validity of the methodology and assumption used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control Number 0910–0393)—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug’s approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

- 21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

- 21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient’s agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

- 21 CFR 208.26 (a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

- 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

FDA estimates the burden of this collection of information as follows: