

order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Paragraph III, for three years, requires RFV to notify the Commission before it enters into any arrangements to act as a messenger or an agent on behalf of any physicians, with payers regarding contracts. Paragraph IV sets out the information necessary to make the notification complete.

Paragraph V, for three years, requires RFV to notify the Commission before participating in contracting with health plans on behalf of either a qualified risk-sharing or a qualified clinically-integrated joint arrangement. Paragraph VI sets out the information necessary to satisfy the notification requirement.

Paragraph VII imposes other notification obligations on RFV and requires the termination of certain contracts that were entered into illegally. Paragraph VII.A requires RFV to distribute the complaint and order to (1) physicians who have participated in RFV since 2001; (2) to various past and current personnel of RFV; and (3) to payers with whom RFV has dealt since 2001. Paragraph VII.B requires RFV, at any payer's request and without penalty, to terminate its existing contracts with the payer for the provision of physician services. Paragraph VII.B allows certain contracts currently in effect to be extended at the written request of the payer no longer than one year from the date that the order becomes final. Paragraph VII.C requires RFV to distribute payer requests for contract termination to physicians who participate in the contract. Paragraph VII.D requires RFV for three years, to provide new members, personnel, and payers not previously receiving a copy, a copy of the Order and the Complaint. Paragraph VII.D also requires RFV to publish annually a copy of the Order and the Complaint in its newsletter.

Paragraphs VIII, IX, and X impose various obligations on RFV to report or provide access to information to the

Commission to facilitate the monitoring of compliance with the order. Finally, Paragraph XI provides that the order will expire in 20 years.

By direction of the Commission.

**Donald S. Clark**

*Secretary.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**[Document Identifier: OS-0990-New]**

### **Agency Information Collection Request; 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [Sherette.funncoleman@hhs.gov](mailto:Sherette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

*Proposed Project:* Evaluation of Medicare Personal Health Records Choice Pilot—OMB No. 0990-NEW—Office of the Assistant Secretary for Planning and Evaluation.

*Abstract:* Since 2003, HHS has worked toward the goal of establishing electronic, longitudinal health records for Americans that can be accessed safely, across the Internet, and anytime and anywhere by patients, doctors, and other health care providers. In addition to electronic health records (EHRs), where health information is created, stored and accessed mainly by health care organizations and practitioners, personal health records (PHRs), electronic, patient-centered applications and services, are gaining increasing recognition and momentum. Current PHR business models represent broad and varied uses, from disease management to health promotion, with sponsors consisting of commercial vendors, health plans, employers, and health care providers. We know very little about why consumers, and specifically Medicare beneficiaries, elect to use PHRs and what functionality they want from a PHR. Understanding these needs will be critical if HHS and the Centers for Medicare & Medicaid Services (CMS) are to pursue PHRs as a tool to empower consumers to manage their health and have the capability to link to their provider's EHR.

In January 2009, CMS launched a new program in Arizona and Utah, the *Medicare PHR Choice Pilot* (PHRC). This pilot encourages Medicare fee-for-service (FFS) beneficiaries to take advantage of the newer, more robust Internet-based tools for tracking their health and health care services. This is the first pilot to offer a choice of PHRs to Medicare FFS beneficiaries, including PHRs with additional functionality and direct data linkages for the consumers. Pilot participants can choose among GoogleHealth™, NoMoreClipboard™, PassportMD™, and HealthTrio™, competitors in the open PHR market.

HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) has contracted with Mathematica Policy Research to conduct an evaluation of this pilot program, including a PHR enrollee user satisfaction survey to assess barriers, facilitators, and satisfaction with the PHRs. A self-administered paper-and-pencil instrument will be the primary data collection mode for the PHRC user satisfaction survey, with telephone followup for mail nonrespondents. The one-time data collection field period is expected to be 12 weeks in Fall 2010.

## ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-administered questionnaire .....	Medicare beneficiaries .....	500	1	25/60	208
Total .....		500	.....	.....	208

**Seleda Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0074]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

**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 the proposed extension of an existing collection of information pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and to listing of ingredients in tobacco products under the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

**DATES:** Submit written or electronic comments on the collection of information by April 19, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the 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:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, [Jonnalynn.Capezzuto@fda.hhs.gov](mailto:Jonnalynn.Capezzuto@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 collection 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 these topics: (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 assumptions 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.

#### Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910-0650)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(b) of the act (21 U.S.C. 395(b)), as amended by the Tobacco Control Act, requires that "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products \* \* \*" register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(i)(1) of the act, as amended by the Tobacco Control Act, requires that all registrants "shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit "a listing of all ingredients, including tobacco, substances, compounds, and additives that are \* \* \* added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand." Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22,