

5. Capital Market and L Fund
6. 2017 Proposed Internal Audit Schedule
7. Blended Retirement Update

*Closed Session*

Information covered under 5 U.S.C. 552b(c)(4), c(6), and (c)(9)(B).

*Adjourn*

**CONTACT PERSON FOR MORE INFORMATION:**

Kimberly Weaver, Director, Office of External Affairs, (202) 942-1640.

Dated: November 16, 2016.

**Megan Grumbine,**

*General Counsel, Federal Retirement Thrift Investment Board.*

[FR Doc. 2016-27980 Filed 11-16-16; 4:15 pm]

**BILLING CODE 6760-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*Pharmacy Survey on Patient Safety Culture Comparative Database.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by January 17, 2017.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:**

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Pharmacy Survey on Patient Safety Culture Comparative Database*

In 1999, the Institute of Medicine called for health care organizations to develop a “culture of safety” such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health System). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Pharmacy Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0183; Approved 08/12/2011). The survey is designed to enable pharmacies to assess staff opinions about patient and medication safety and quality-assurance issues and includes 36 items that measure 11 dimensions of patient safety culture. AHRQ made the survey publicly available along with a Survey User’s Guide and other toolkit materials in October 2012 on the AHRQ Web site.

The AHRQ Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) Comparative Database consists of data from the AHRQ Pharmacy Survey on Patient Safety Culture. Pharmacies in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Pharmacy SOPS Database is modeled after three other SOPS databases: Hospital SOPS [OMB NO. 0935-0162; Approved 05/04/2010]; Medical Office SOPS [OMB NO. 0935-0196; Approved 06/12/12]; and Nursing Home SOPS [OMB NO. 0935-0195; Approved 06/12/12] that were originally developed by AHRQ in response to requests from hospitals, medical offices, and nursing homes interested in knowing how their patient safety culture survey results compare to those of other similar health care organizations.

Rationale for the information collection. The Pharmacy SOPS survey and the Pharmacy SOPS Comparative Database will support AHRQ’s goals of promoting improvements in the quality and safety of health care in pharmacy settings. The survey, toolkit materials, and comparative database results are all made publicly available on AHRQ’s Web site. Technical assistance is provided by AHRQ through its contractor at no charge to pharmacies, to facilitate the use of these materials for pharmacy patient safety and quality improvement.

Request for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove, under the

Paperwork Reduction Act of 1995, AHRQ’s collection of information for the AHRQ Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) Comparative Database; OMB NO. 0935-0218, last approved on June 12, 2014.

This database will:

- (1) Allow pharmacies to compare their patient safety culture survey results with those of other pharmacies,
- (2) provide data to pharmacies to facilitate internal assessment and learning in the patient safety improvement process, and
- (3) provide supplemental information to help pharmacies identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ’s statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services; quality measure and development, and database development. 42 U.S.C. 299a(a)(1), (2), and 8.

**Method of Collection**

To achieve the goal of this project the following activities and data collections will be implemented:

(1) Pharmacy Eligibility and Registration Form—The point of contact (POC), often the pharmacy manager of a participating organization, completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the pharmacy and initiate the registration process.

(2) Data Use Agreement—The purpose of the data use agreement, completed by the pharmacy POC, is to state how data submitted by pharmacies will be used and provides confidentiality assurances.

(3) Pharmacy Site Information Form—The purpose of this form, completed by the pharmacy POC, is to collect background characteristics of the pharmacy. This information will be used to analyze data collected with the Pharmacy SOPS survey.

(4) Data Files Submission—POCs upload their data file(s), using the community pharmacy or hospital pharmacy data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted.

The number of submissions to the database is likely to vary each year because pharmacies do not administer

the survey and submit data every year. Data submission is typically handled by one POC who is either a pharmacy manager or a survey vendor who contracts with a pharmacy to collect and submit its data. POCs submit data on behalf of 3 pharmacies, on average, because many pharmacies are part of a multi-pharmacy system, or the POC is a vendor that is submitting data for multiple pharmacies.

Survey data from the AHRQ Pharmacy Survey on Patient Safety Culture are used to produce three types of products: (1) A Pharmacy SOPS Comparative Database Report that is made publicly available on the AHRQ Web site (see <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/pharmacy/pharm-reports.html>), (2) Individual Pharmacy Survey Feedback Reports that are confidential, customized reports produced for each pharmacy that submits data to the database (the number of reports produced is based on the number of pharmacies submitting each year); and (3) Research data sets of individual-level and pharmacy-level de-

identified data to enable researchers to conduct analyses. Pharmacies are asked to voluntarily submit their Pharmacy SOPS survey data to the comparative database. The data are then cleaned and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 36 items and 11 patient safety culture dimensions, as well as displaying these results by pharmacy characteristics (pharmacy type, number of locations, average number of prescriptions dispensed per week, etc.) and respondent characteristics (staff position, tenure, and hours worked per week).

Data submitted by pharmacies are also used to give each pharmacy its own customized survey feedback report that presents the pharmacy's results compared to the latest comparative database results. If a pharmacy submits data more than once, its survey feedback report also presents trend data, comparing its previous and most recent data.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 100 POCs from community pharmacies and 50 POCs from hospital pharmacies, each representing an average of 3 individual pharmacies, will complete the database submission steps and forms. Completing the eligibility and registration form will take about 5 minutes. The Pharmacy Site Information Form is completed by all POCs for each of their pharmacies (150 x 3 = 450 forms in total) and is estimated to take 5 minutes to complete. Each POC will complete a data use agreement which takes 3 minutes to complete and submitting the data will take an hour on average. The total burden is estimated to be 209 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$11,222 annually.

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility and Registration Form .....	150	1	5/60	13
Data Use Agreement .....	150	1	3/60	8
Pharmacy Site Information Form .....	150	3	5/60	38
Data Files Submission .....	150	1	1	150
<b>Total .....</b>	<b>NA</b>	<b>NA</b>	<b>NA</b>	<b>209</b>

**EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN**

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility and Registration Form .....	150	13	\$53.69	\$698
Data Use Agreement .....	150	8	53.69	430
Pharmacy Site Information Form .....	150	38	53.69	2,040
Data Files Submission .....	150	150	53.69	8,054
<b>Total .....</b>	<b>NA</b>	<b>209</b>	<b>NA</b>	<b>11,222</b>

\* Based on the weighted average hourly wage in community pharmacies for 100 General and Operations Managers (11-1021; \$49.26) and 50 General and Operations Managers (11-1021; \$62.56) obtained from the May 2015 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 446110—Pharmacies and Drug Stores (located at [http://www.bls.gov/oes/current/naics5\\_446110.htm](http://www.bls.gov/oes/current/naics5_446110.htm)) and NAICS 622000—Hospitals (located at [http://www.bls.gov/oes/current/naics3\\_622000.htm](http://www.bls.gov/oes/current/naics3_622000.htm)).

**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information

dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the

respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All

comments will become a matter of public record.

**Sharon B. Arnold,**  
Deputy Director.

[FR Doc. 2016-27705 Filed 11-17-16; 8:45 am]

**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-244]

#### 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 January 17, 2017.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. 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 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](mailto: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-R-244** Programs for All-Inclusive Care of the Elderly (PACE) and Supporting Regulations in 42 CFR Part 460

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:* Revision of a currently approved collection; *Title of*

*Information Collection:* Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations in 42 CFR part 460; *Use:* This information collection addresses all operational components of the PACE program (as defined in 42 CFR part 460) with the exception of the application process (§ 460.12). In this iteration the application is removed from this control number and moved under a new information collection request with a new CMS identification number (CMS-10631). An OMB control number specific to the application process is pending.

The CMS-10631 information collection request was submitted to OMB on October 6, 2016, under ICR Reference No: 201610-0938-001. When approved, the control number can be found on [www.reginfo.gov/public/](http://www.reginfo.gov/public/).

We are removing the application requirements and burden since this CMS-R-244 package is lengthy and we recognize that it can be somewhat time consuming to review. We believe the change will help streamline the public and OMB's review of the application as well as the remaining requirements and burden under this CMS-R-244 package. *Form Number:* CMS-R-244 (OMB control number: 0938-0790); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 130; *Total Annual Responses:* 145,455; *Total Annual Hours:* 61,350. (For policy questions regarding this collection contact Debbie Van Hoven at 410-786-6625).

Dated: November 15, 2016.

**William N. Parham, III,**  
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016-27836 Filed 11-17-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0804]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the