a private citizen and one from an executive branch ethics official.

The private citizen suggested several changes to the form including requiring filers to indicate whether or not a reported asset in Part I was over $15,000 and changing OGE's underlying regulation to require filers to report the value of any assets. OGE does not believe that making either change is necessary or desirable because reporting specific asset values will not provide the ethics official with sufficient information for making the conflicts analysis. This commenter also suggested that OGE create a customized version of the OGE Form 450 for special Government employee (SGE) filers. OGE does not see the need for an additional form for use throughout the executive branch because agencies already have available an alternative procedure process at 5 CFR 2634.905(a) to collect the information necessary to perform the conflicts analysis tailored for its SGE filers.

The comment from an executive branch ethics official suggested modifying the instructions for Part III of the OGE Form 450 by adding more examples. OGE has decided not to make this change to the form because this type of information is best conveyed to filers in reference materials that can easily be updated. OGE will consider creating reference materials containing additional descriptions of reportable positions to those provided in the broad language of 5 CFR 2634.907(e)(1).

Request for Comments: Agency and public comment is again invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of OMB paperwork approval. The comments will also become a matter of public record.

Approved: August 27, 2013.

Walter M. Shaub, Jr.,

Director, Office of Government Ethics.

[FR Doc. 2013–21392 Filed 9–3–13; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–20296–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for revision of the approved information collection assigned OMB control number 0945–0003 scheduled to expire on 12/31/2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before October 4, 2013.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0945–0003 and document identifier HHS–OS–20296–30D for reference.

Information Collection Request Title: Standards for Privacy of Individually Identifiable Health Information, Security Standards for the Protection of Electronic Protected Health Information, and Supporting Regulations Contained in 45 CFR Parts 160 and 164

OMB No.: 0945–0003.

Abstract: The Office for Civil Rights (OCR) is notifying the public of revisions to a previously approved OCR data collection. The revisions reflect certain regulatory modifications to the HIPAA Privacy and Security Rules, pursuant to the Health Information for Economic and Clinical Health (HITECH) Act and the Genetic Information Nondiscrimination Act (GINA), that were finalized in the Omnibus HIPAA Final Rule published on January 25, 2013 (78 FR 5566). These modifications strengthen privacy and security protections for individually identifiable health information used or disclosed by business associates and enhance the rights of individuals with respect to their identifiable health information.

Need and Proposed Use of the Information: The information collection addresses HIPAA requirements related to the use, disclosure, and safeguarding of individually identifiable health information by covered entities affected by the HIPAA Rules. The information is routinely used by covered entities and business associates for treatment, payment, and health care operations. In addition, the information is used for specified public policy purposes, including research, public health, and as required by other laws. The Privacy Rule also ensures that the individuals are able to exercise certain rights with respect to their information, including the rights to access and seek amendments to their health records and to receive a Notice of Privacy Practices (NPP) from their direct treatment providers and health plans.

Likely Respondents: Respondents include HIPAA covered entities and their business associates, as well as members of the public.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the tables below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Section	Type of respondent	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
New Burdens Associated With the Final Rule					
164.316	Documentation of Security Rule Policies and Procedures and Administrative Safeguards (business associates).	300,000	1	70/60	350,000
164.504	Business Associates Needing to Establish or Modify Business Associate Agreements with Subcontractors.	375,000	1	20/60	125,000
164.520	Revision of Notice of Privacy Practices for Protected Health Information (drafting revised language) (health plans).	1,500	1	.111	167
164.520	Dissemination of Notice of Privacy Practices for Protected Health Information (health plans).	20,000,000	1	.00333335	66,667
164.520	Revision of Notice of Privacy Practices (providers).	697,000	1	.11111	77,444
Total					619,278
Ongoing Annual Burdens of Compliance with the Rules					
160.204	Process for Requesting Exception Determinations (states or persons).	1	1	16	16
164.504	Uses and Disclosures—Organizational Requirements.	700,000	1	5/60	58,333
164.508	Uses and Disclosures for Which Individual authorization is required.	700,000	1	1	700,000
164.512	Uses and Disclosures for Research Purposes.	113,524	1	5/60	9,460
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by paper mail).	100,000,000	1	0.25	416,667
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by electronic mail).	100,000,000	1	0.167	278,333
164.520	Notice of Privacy Practices for Protected Health Information (health care providers—dissemination and acknowledgement).	613,000,000	1	3/60	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information.	150,000	1	3/60	7,500
164.524	Access of Individuals to Protected Health Information (disclosures).	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (requests).	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (denials).	50,000	1	3/60	2,500
164.528	Accounting for Disclosures of Protected Health Information.	70,000	1	3/60	5,833
Total					32,143,642
TOTAL HOURS					
32,762,920					

Keith A. Tucker,

Information Collection Clearance Officer.

[FR Doc. 2013–21398 Filed 9–3–13; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on Draft National Action Plan for Adverse Drug Event Prevention

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Disease Prevention and Health Promotion is soliciting public comment on the draft National Action Plan for Adverse Drug Event Prevention.

DATES: Comments on the draft National Action Plan for Adverse Drug Event Prevention must be received no later than 5 p.m. on October 4, 2013. This document provides an overview of current federal efforts to support surveillance, prevention, research, and the use of policy levers to reduce adverse drug events across the United States. The draft Action Plan reflects the work of many offices across the Department of Health and Human Services, Department of Defense, Department of Justice, and Department of Veterans Affairs. The draft Action Plan also reflects input from national experts.

ADDRESSES: The draft National Action Plan for the Prevention of Adverse Drug Events is available at: *http://www.hhs.gov/ash/initiatives/ade/ade-action-plan.pdf.* Comments are preferred electronically and may be addressed to *ADE@hhs.gov*. Please use the title ''Draft National ADE Action Plan'' when sending comments electronically. Written responses should be addressed to the Department of Health and Human Services, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite LL100, Rockville MD 20852, Attention: Draft National ADE Action Plan.

FOR FURTHER INFORMATION CONTACT: Yael Harris, Director, Division of Health Care Quality, Office of Disease Prevention and Health Promotion, 240–453–8206, *yael.harris@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Adverse drug events (ADEs) have been defined by the Institute of Medicine as ''an injury resulting from medical intervention related to a drug.'' This broad term encompasses harms that occur during medical care that are directly caused by the drug and can include, but are not limited to, medication errors, adverse drug reactions, allergic reactions, and overdoses. ADEs can occur in any health care setting, including both inpatient and outpatient settings and even more likely to occur during patient transitions from one health care setting to another. ADEs are the single largest contributor to hospital-related complications within hospitals and account for over 3.5 million physician office visits, approximately 1 million emergency department (ED) visits, and an estimated 125,000 hospital admissions every year.

For these reasons, the reduction of ADEs is a top priority for the Department of Health and Human Services (HHS). Multiple Operating and Staff Divisions within HHS have been working to reduce the incidence and prevalence of adverse drug events for years. To further these efforts, in 2012, a Cross-Federal Steering Committee for Adverse Drug Event Prevention was established. The Steering Committee was charged with developing a comprehensive strategy to significantly reduce adverse drug events within the three drug classes which account for a significant proportion of all ADEs: anticoagulants, diabetes agents, and opioids. The draft Action Plan focuses on four main opportunities for federal engagement: surveillance, prevention, incentives and oversight, and research.

The draft Action Plan identifies current federal activity across both inpatient and outpatient settings, as well as transitions of care, that are related to these four opportunities, with a focus on the three drug classes associated with high levels of harm. It also highlights opportunities to advance these efforts through cross-federal partnerships and coordinated resources.

The release of the plan is only the beginning of a coordinated process that will result in stakeholders who are more engaged, aware, and knowledgeable of issues regarding the safe use of prescribed medications to prevent ADEs. Although the initial phase of the Action Plan reflects primarily the efforts and resources of federal agencies, the draft Action Plan was developed with the expectation and understanding that outlining ADE prevention goals and, more importantly, actually achieving ADE reductions and improving patient safety can be considered neither complete nor feasible without further engagement of professional organizations representing medical, nursing, pharmacy, and other allied health professionals, academia, patient and consumer representatives, and other private sector stakeholders. For this reason, every opportunity to ensure that feedback of and engagement with these entities will be sought through the public release of the draft Action Plan. Through coordinated federal partnerships, as well as public and private sector collaborations and aligned approaches, we can improve the quality and safety of health care, reduce health care costs, and improve the health and quality of life of millions of people in the United States.

II. Information Request

The Office of Disease Prevention and Health Promotion, on behalf of the HHS Steering Committee for Adverse Drug Event Prevention, requests input on the revised draft National Action Plan for Adverse Drug Event Prevention.

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in reducing adverse drug events. Some examples of these organizations include, but are not limited to the following:

- Caregivers or health system providers (e.g., physicians, physician assistants, nurses, pharmacists)
- Collaboratives and consortia
- Foundations
- Health care, professional, and educational organizations/societies
- Insurers and business groups
- Medicaid- and Medicare-related organizations
- Patients and their advocates
- Pharmaceutical Industry
- Prescription drug monitoring programs
- Public health organizations
- State and local public health agencies.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written materials submitted for consideration should not exceed 10 pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses, however, we request that comments are identified by section, subsection, and page number so they may be addressed accordingly. All comments received