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

before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

Dated: August 28, 2013.

Don Wright,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2013–21434 Filed 9–3–13; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting Standards Subcommittee

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards

Time and Date: September 18, 2013 8:30 p.m.—5:00 p.m. EDT.

Place: Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium B & C, Hyattsville, Maryland 20782, (301) 458–4524.

Status: Open

Purpose: The health care industry is experiencing major transformative changes as a result of the confluence of various national, regional and local initiatives, including: the Affordable Care Act, the adoption of electronic health records and the Meaningful Use program, implementation of national messaging and vocabulary standards for clinical exchanges, the establishment of regional health information exchanges, and adoption of new administrative standards, including new versions of HIPAA transactions, operating rules, ICD–10 and Health Plan ID. In light of these many pressing demands and requirements, the NCVHS Standards Sub-Committee is interested in developing a roadmap of key healthcare mandates and their impact on health IT standards that identify and map: (1) The various upcoming health care compliance requirements and deadlines that relate to health IT standards, in a multi-year timeline; (2) the milestones needed to successfully achieve these compliance requirements, including the development and testing of standards; (3) the underlying standards needed to achieve those milestones and requirements; (4) the interdependencies of the various compliance requirements, milestones and standards development processes; (5) the gaps, overlaps and issues with these requirements; and, (6) opportunities for better alignment, synergistic coordination, and most effective, appropriate sequencing of requirements, milestones and standards development.

To discuss these issues, this meeting will bring together subject-matter experts and representatives from various stakeholders to discuss questions related to each of the six items identified above in a facilitated exchange format. Topics to be covered include, but will not be limited to: (1) Administrative Transactions, Codes, Identifiers, and Operating Rules; (2) ACA-related health information exchange requirements; (3) Meaningful Use; (4) Quality and Patient Safety; and, (5) Privacy and Security.

Contact Person for More Information: Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245 or Denise Buenning, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland, 21244, telephone (410) 786–6711. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: http://www.ncvhs.hhs.gov/, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: August 26, 2013.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2013–21433 Filed 9–3–13; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting Full Committee

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS); Full Committee Meeting.

Time and Date:

September 16, 2013 9:00 a.m.–2:45 p.m. EDT.

September 17, 2013 9:00 a.m.–12:00 p.m. EDT. 1:00 p.m.–5:00 p.m. EDT, Working Group on Data Access and Use.

Place: U.S. Department of Health and Human Services, Hubert Humphrey Building, 200 Independence Avenue SW., Room 800, Washington, DC 20201.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day, the Committee will hear updates from the Department (HHS), the Centers for Medicare and Medicaid Services (CMS), the Office of the National Coordinator (ONC), and the Office for Civil Rights (OCR). The Committee will also review and discuss a recommendation letter from the Standards Subcommittee on the status of Implementation of HIPAA and the ACA.

Following the lunch break, Subcommittee Co-chairs will update the Committee on the hearing organized by several subcommittees to explore aspects of the Community as a Learning Health System. Also, the Committee will review the proposed outline and plans for the upcoming HIPAA Report to Congress and the NCHS Acting Director will give an update on the Center. Finally, the Committee will receive a briefing about healthcare initiatives at the Federal Communications Commission.

On the morning of the second day, the Committee will discuss and consider for approval a draft recommendation letter and hear from the Standards Subcommittee Co-Chairs about plans for the September 18 roundtable on a standards roadmap. In addition, the Committee chair will discuss elements of convergence, after which, an update will be given regarding HHS Data Working Group activities. Finally, co-chairs will give reports on plans, and the Committee chair will give final remarks and receive feedback from the membership regarding NCVHS strategic implementation. Once the full Committee adjourns, the NCVHS's Working Group on HHS Data Access & Use will convene to discuss best practices and suggestions for release of open HHS data, and summarize future plans of the Working Group. Further information will be provided on the NCVHS Web site at *http://www.ncvhs.hhs.gov/.*

The times shown above are for the full Committee meeting. Subcommittee breakout sessions are scheduled for late in the afternoon on the first day and early morning the second day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: August 26, 2013.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2013–21432 Filed 9–3–13; 8:45 am]

BILLING CODE 4151–05–P