



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on the Proposed Measures and 2020 Targets for the National Action Plan for Adverse Drug Event Prevention: Inpatient and Outpatient Measures for Reduction of Adverse Drug Events from Anticoagulants, Diabetes Agents, and Opioid Analgesics.

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

ACTION: Notice.

SUMMARY: The Office of Disease Prevention and Health Promotion (ODPHP), on behalf of the U.S. Department of Health and Human Services (HHS) Federal Interagency Steering Committee for Adverse Drug Events, proposes new measures and targets for adverse drug events (ADEs) from anticoagulants, diabetes agents, and opioid analgesics for the *National Action Plan for Adverse Drug Event Prevention (ADE Action Plan)*. Based on input from the Federal Interagency Workgroups for Adverse Drug Events, six national measures and targets for the reduction of ADEs are being proposed. Each drug class highlighted in the *ADE Action Plan* (anticoagulants, diabetes agents, and opioid analgesics) includes a proposed inpatient and outpatient measure to track national progress in reduction of ADEs from these drug classes. The proposed targets will reflect improvement efforts over a four to six year period since the release of the *ADE Action Plan* in August 2014. As such, HHS is proposing a baseline year of 2014 for five of the measures and 2016 for one measure. All targets are to be achieved by 2020.

HHS invites interested public and private professionals, organizations, and consumer representatives to submit written comments on the proposed 2020 ADE targets, found at <https://health.gov/hcq/ade-measures.asp>.

DATES: Comments on the proposed ADE 2020 measures and targets must be received no later than 5 p.m. on **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]**

ADDRESSES: Interested persons or organizations are invited to submit written comments by any of the following methods:

- *E-mail:* OHQ@hhs.gov (please indicate in the subject line: Proposed ADE Measures and Targets)
- *Mail/Courier:* Office of Disease Prevention and Health Promotion, Attn: Division of Health Care Quality, Department of Health and Human Services, 1101 Wootton Parkway, Suite LL100, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Anna Gribble, Health Policy Fellow, Office of Disease Prevention and Health Promotion, via e-mail at anna.gribble@hhs.gov.

SUPPLEMENTARY INFORMATION

In September 2012, in response to heightened awareness of the contribution of ADEs to the burden of health care-related harm and costs, the Office of the Assistant Secretary for Health (OASH) marshaled the wide-ranging and diverse resources of federal partners to form an extensive interagency partnership, the Federal Interagency Steering Committee

and Workgroups for Adverse Drug Events, whose goals would be to develop the *ADE Action Plan*, as well as identify measures to track national progress in reducing ADEs and targets to meet based on those measures.

ODPHP, in conjunction with the Federal Interagency Steering Committee and three Federal Interagency Workgroups, developed and released the final *ADE Action Plan* in 2014. The *ADE Action Plan* seeks to engage all stakeholders in a coordinated, aligned, and multi-sector effort to reduce ADEs that are clinically significant, account for the greatest number of measurable harms as identified by existing surveillance systems, and are largely preventable; these were identified as ADEs resulting from inpatient and outpatient use of anticoagulants, diabetes agents, and opioid analgesics (with specific focus on ADEs from therapeutic use of opioids). The *ADE Action Plan* identifies the federal government's highest priority strategies and opportunities for advancement, which will have the greatest impact on reducing ADEs. Implementation of these strategies is expected to result in safer and higher quality health care services, reduced health care costs, informed and engaged consumers and ultimately, improved health outcomes. The reduction of ADEs subsequent to implementation of these strategies will be tracked by the proposed measures and will aim to meet the targeted reduction rate by 2020.

The six proposed measures use data from the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). The inpatient and outpatient measures for anticoagulants and diabetes agents and the outpatient measure for opioids will set baseline rates using data from 2014 and establish targets to be achieved by 2020. The inpatient opioids measure will have a 2016 baseline and a 2020 target year. The inpatient opioids measure will use

data from AHRQ's Quality Safety Review System (QSRS) which will begin collecting data in 2016. The inpatient measures for anticoagulants and diabetes agents will use AHRQ's Medicare Patient Monitoring System (MPSMS) for 2015 and QSRS for 2016-2020 and data will be adjusted accordingly. MPSMS did not include an opioids specific measure and QSRS now allows AHRQ to now track inpatient opioids adverse drug events.

Descriptions of the surveillance systems, measures, and targets can be found here:

<https://health.gov/hcq/ade-measures.asp>.

Interested persons or organizations are invited to submit written comments in response to the proposed measures and targets. Written comments should not exceed more than two pages per ADE measure. The comments should reference the specific measure or target to which feedback refers. To be considered, the person or representative from an organization must self-identify and submit the written comments by close of business on **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]**

DATE: September 30, 2016

Don Wright, MD, MPH
Deputy Assistant Secretary for Health
Director, Office of Disease Prevention and Health Promotion
Office of the Assistant Secretary for Health
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