Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of States. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Notice

The Medicare statute requires the publication of the monthly actuarial rates and the Part B premium amounts in September. We ordinarily use general notices, rather than notice and comment rulemaking procedures, to make such announcements. In doing so, we note that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. The statute establishes the time period for which the premium rates will apply, and delaying publication of the Part B premium rate such that it would not be published before that time would be contrary to the public interest. Moreover, we find that notice and comment are unnecessary because the formulas used to calculate the Part B premiums are statutorily directed. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 9, 2015.

Sylvia M. Burwell,

Secretary. Department of Health and Human Services.

[FR Doc. 2015–29181 Filed 11–10–15; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3972]

Eighth Annual Sentinel Initiative; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Eighth Annual Sentinel Initiative Public Workshop.'' Convened by the Center for Health Policy at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an update on the state of FDA's Sentinel Initiative, including an overview of the transition from the Mini-Sentinel pilot to the full Sentinel System, and key activities and uses of the Sentinel System accomplished in 2015. In addition, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel projects.

DATES: The public workshop will be held on February 3, 2016, from 9 a.m. to 4 p.m., Eastern Standard Time (EST).

Location: The public workshop will be held at the Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Ave. NW., Washington, DC 20037. For additional travel and hotel information, please refer to *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3972 for ''Eighth Annual Sentinel Initiative; Public Workshop.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR MORE INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–3714, FAX: 301–796–9832, email: *SentinelInitiative@fda.hhs.gov.*

Registration: To attend the public workshop, you must register before February 3, 2016, by visiting *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.* You may also register for the live webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (see **FOR MORE INFORMATION CONTACT**). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Renaissance Washington, DC Dupont Circle Hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (phone: 813–586–1201, email: *jklatzman@brookings.edu*) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast (archived video footage will be available following the workshop). Persons interested in viewing the live webcast must register online by February 2, 2016, at 5 p.m. EST. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

Meeting Materials: All event materials will be available to registered attendees via email before the workshop at the Eventbrite Web site at *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.*

Transcripts: Please be advised that transcripts will not be available.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28851 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0986]

Center for Devices and Radiological Health: Experiential Learning Program; General Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH or Center) is announcing the 2015 Experiential Learning Program (ELP) General Training Program. This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to request to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP General Training Program.

DATES: Submit either an electronic or written request for participation in the ELP General Training Program by December 16, 2015.

ADDRESSES: Submit either electronic requests to *http://www.regulations.gov* or written requests to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify proposals with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5232, Silver Spring, MD 20993–0002, 301–796–6965, FAX: 301–827–3079, *Latonya.powell@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for helping to ensure the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711).

CDRH is committed to advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP General Training Program component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. This component is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

These formal training visits are not intended for FDA to inspect, assess,