The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910–0284 and 0910–0291. While FDA does not charge for the use of the ESG, the Agency requires respondents to obtain a public key infrastructure certificate to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Our estimated burden for the information collection reflects an overall increase of 688,547 hours and a corresponding increase of 1,145,763 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: November 26, 2018.

Leslie Kux,
Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Program Analyst, Division of Injury Compensation Programs (DICP), HRSA, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857; 301–443–6593; or aberzhog@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service (PHS) Act (42 U.S.C. 300aa–19), as enacted by Public Law (Pub. L.) 99–660, and as subsequently amended, and advises the Secretary of HHS (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP). During the December 6, 2018, meeting, agenda items will include, but are not limited to, updates from the DICP, Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate. Refer to the ACCV website listed above for any updated information concerning the meeting to include a draft agenda and additional meeting materials that will be posted before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACCV should be sent to Annie Herzog using the contact information above by Wednesday, December 5, 2018.

Individuals who need special assistance or another reasonable accommodation should notify Annie Herzog at the address and phone number listed above at least 3 business days before the meeting.

Amy P. McNulty,
Acting Director, Division of the Executive Secretariat.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); Correction

ACTION: Notice of public meetings; correction.

SUMMARY: The Department of Health and Human Services published a document in the Federal Register of February 5, 2018 detailing the 2018 PTAC meeting dates and the link that connects to the meeting registration website. The December meeting date has been shortened to a one day meeting and the registration link has been updated.


SUPPLEMENTARY INFORMATION: Correction

In the Federal Register of February 5, 2018, in FR Doc. 2018–02211, on page 5109, in the first column, correct the “Dates” caption to read:

DATES: The 2018 PTAC meetings will occur on the following dates:
- Monday–Tuesday, March 26–27, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, June 14–15, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Thursday–Friday, September 6–7, 2018, from 9:00 a.m. to 5:00 p.m. ET
- Monday, December 10, 2018, from 12:30 p.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

Correction

In the Federal Register of February 5, 2018, in FR Doc. 2018–02211, on page 5109, in the second column, correct the “Meeting Registration” caption to read:

Meeting Registration:
The public may attend the meetings in-person or participate by phone via...