

provide the initial IM within 2 calendar days of admission. A follow-up copy of the signed IM is given no more than 2 calendar days before discharge. The follow-up copy is not required if the first IM is provided within 2 calendar days of discharge. In accordance with 42 CFR 405.1206 for Original Medicare and 422.622 for Medicare health plans, if a beneficiary/enrollee appeals the discharge decision, the beneficiary/enrollee and the QIO must receive a detailed explanation of the reasons services should end. This detailed explanation is provided to the beneficiary/enrollee using the DND, the second notice included in this renewal package. *Form Number:* CMS-10065/10066 (OMB control number: 0938-1019); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 6,123; *Total Annual Responses:* 17,742,803; *Total Annual Hours:* 2,990,720. (For policy questions regarding this collection contact Janet Miller at [Janet.Miller@cms.hhs.gov](mailto:Janet.Miller@cms.hhs.gov).)

Dated: August 20, 2019.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: HIV Quality Measures (HIVQM) Module, OMB No. 0906-0022—Revision**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than September 25, 2019.

**ADDRESSES:** Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* HIV Quality Measures Module, OMB No. 0906-0022—Revision.

*Abstract:* HRSA Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people living with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people living with HIV—more than 50 percent of all people living with diagnosed HIV in the United States.

All parts of the RWHAP must follow the legislative requirements for the establishment of clinical quality management programs to assess their HIV services according to the most recent HHS guidelines and to develop strategies to improve access to quality HIV services. The HIVQM Module supports recipients and sub recipients in their clinical quality management, performance measurement, service delivery, and monitoring of client health outcomes; and supports the requirement imposed by the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards that recipients relate financial data to performance accomplishments of their federal awards. 45 CFR 75.301. The module is accessible via the Ryan White Services Report, an existing online portal that RWHAP recipients already use for required data collection of their services. While the use of the module is voluntary for RWHAP recipients, its use is strongly encouraged.

The HRSA performance measures are comprised of the following categories: (1) Core medical services, (2) all ages, (3) adolescent/adult, (4) children with

HIV, (5) HIV-exposed children, (6) medical case management, (7) oral health, (8) AIDS Drug Assistance Program, and (9) systems level performance measures. Recipients can choose the performance measures they want to monitor and may enter data on their measures into the module up to four times a year and then generate reports to assess their performance. Recipients may also compare their performance against other recipients regionally and nationally.

A 60-day notice was published in the **Federal Register** on March 14, 2019, vol. 84, No. 50; pp. 9362-63. There were four public comments.

*Need and Proposed Use of the Information:* The HIVQM Module provides recipients an easy-to-use and structured platform to voluntarily and continually monitor their performance. The main purpose for the module is to help recipients set goals and monitor performance measures and quality improvement projects. For this revised ICR, HRSA is proposing to allow recipients the option to enter data for specific populations for a subset of performance measures based on age, gender, race, ethnicity, and specific risk factors, which will allow for target services and quality improvement activities to people most at need. In addition, recipients will be able to generate reports of performance measures, review them stratified by the recipients or their service providers, and compare to results at the state, regional, and national levels. HRSA is proposing these enhancements to increase the functionality and overall usability of the HIVQM Module.

The HIVQM Module was piloted for this revision request in June 2019. Recipients or sub recipients, who submitted data for more than two reporting periods in the last year and represented the use of various data systems, submitted feedback on the new data stratification feature. Their feedback included questions about: (1) How the data stratification feature in the HIVQM Module would differ from and integrate with CAREWare (CW) reporting; and (2) the availability of the template for the data stratification feature. HRSA's responses included describing the interface between CW and the HIVQM Module, explaining how reports will be produced and further explaining why the HIVQM Module will be a useful tool in comparing state, regional, and national performance measure data among recipients/sub recipients who use the HIVQM Module.

*Likely Respondents:* HRSA RWHAP Part A, Part B, Part C, and Part D

recipients and their service providers and the AIDS Drug Assistance Program recipients.

*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 table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
HIVQM Module .....	2,316	4	9,264	6	55,584
Total .....	2,316	.....	9,264	.....	55,584

**Maria G. Button,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443-6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**." Set forth below is a list of petitions received by HRSA on July 1, 2019, through July 31, 2019. This list provides the name of petitioner, city

and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction. Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

a. "[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by" one of the vaccines referred to in the Table, or

b. "[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading "For Further Information Contact"), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau,