

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard <sup>1</sup>	Reference No. and date
<b>S. Tissue Engineering</b>		
15–56 .....	Standard Test Method for Evaluating Growth of Engineered Cartilage Tissue using Magnetic Resonance Imaging.	ASTM F3224–17.

<sup>1</sup> All standard titles in this table conform to the style requirements of the respective organizations.

**IV. List of Recognized Standards**

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with list 52, FDA will no longer announce in the **Federal Register** updates to current recognized standards for reapproved or reaffirmed standards because reapproved or reaffirmed standards have not changed from the recognized standard. International and national standards developing organizations use the designations of reapproved or reaffirmed to indicate a standard has been reviewed but no changes were made to the standard at that time.

**V. Recommendation of Standards for Recognition by FDA**

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov). To be considered, such recommendations should contain, at a minimum, the following information available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123739.htm>.

Dated: March 8, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: 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 requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than May 13, 2019.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* HIV Quality Measures (HIVQM) 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 (PLWH). 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 PLWH—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 subrecipients 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 that recipients relate 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, (2) all ages, (3) adolescent/adult, (4) HIV-infected children, (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 4 times a year and then generate reports to assess their performance. Recipients may also compare their performance against other recipients regionally and nationally.

*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 recipients and sub-recipients participating in the Centers for Medicare & Medicaid Incentive Programs, such as the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System, the module is to qualify them for incentives and comply with the requirements to receive incentives from these programs.

For this revised information collection request, 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. 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.

**Likely Respondents:** HRSA Ryan White HIV/AIDS Program 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 Report .....	2,316	4	9,264	1	9,264
Total .....	2,316	.....	9,264	.....	9,264

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**John R. Womack,**

*Acting Deputy Director, Division of the Executive Secretariat.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Listening Session To Inform the Development of the National Youth Sports Strategy**

**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 Department of Health and Human Services (HHS) provides notice of a public listening session; invites the public to attend; and solicits request to provide oral remarks to inform the

development of the National Youth Sports Strategy.

**DATES:** The meeting for the public to provide oral remarks to HHS will be held on Thursday, April 4, 2019, from 9:00 a.m. to 5:00 p.m. E.D.T.

**ADDRESSES:** Those providing public oral remarks to HHS are required to attend the listening session in-person at the Hubert H. Humphrey Building, Auditorium, 200 Independence Ave. SW, Washington, DC 20201. Others wanting to attend can do so in-person or via webcast on the internet.

**FOR FURTHER INFORMATION CONTACT:** Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite LL-100; Rockville, MD 20852; Telephone: (240) 453-8280. Email: [odphpinfo@hhs.gov](mailto:odphpinfo@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Executive Order 13824 directs the development of a National Strategy on Youth Sports and outlines the key pillars that the strategy will address. The Office of Disease Prevention and Health Promotion, in collaboration with the President's Council on Sports, Fitness & Nutrition, Centers for Disease Control and Prevention, and National Institutes of Health, is leading the development of this strategy.

**Key Pillars of Youth Sports Strategy**

1. Increase awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition;
2. Promote private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition;
3. Develop metrics that gauge youth sports participation and physical activity to inform efforts that will improve participation in sports and regular physical activity among young Americans; and
4. Establish a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs.

**Agenda:** The agenda will include opportunity for the public to provide oral remarks to HHS and to hear an update about this project from HHS.

**Submitting a Request to Speak:** HHS requests applications from organizations to speak at the April 4, 2019 listening session. There are a limited number of speaking slots available. Length of presentation will be determined based on interest and is anticipated to be approximately 15 minutes per organization, including time for comments or questions. HHS is interested in hearing from organizations that have experience and expertise in