TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS AND SAFETY AND PROBABLE BENEFIT SUMMARIES FOR APPROVED HDES MADE AVAILABLE FROM JANUARY 1, 2021, THROUGH FEBRUARY 14, 2022—Continued

PMA No., docket No.	Applicant	Trade name	Approval date
P190012, FDA–2021–M–1119	Spatz FGIA Inc	Spatz3 Adjustable Balloon System	10/15/2021
P160046/S010, FDA–2021–M–0532.	Ventana Medical Systems, Inc	VENTANA PD–L1 (SP263) Assay	10/15/2021
P150031/S040, FDA–2021–M–1176.	Boston Scientific Corporation	Vercise PC, Vercise Gevia and Vercise Genus DBS Systems.	10/20/2021
P150038/S014, FDA–2021–M–1182.	INSIGHTEC, Inc	Exablate Model 4000 Type 1.0 and 1.1 System (''Exablate Neuro'').	10/29/21
P130026/S070, FDA–2021–M–1207.	Abbott Medical	TactiCath Contact Force Ablation Catheter, Sensor Enabled (Uni-Directional); TactiCath Contact Force Ablation Catheter, Sensor Enabled (Bi-Directional); TactiSys Quartz Equipment; Ampere RF Generator and Cool Point Irrigation Pump.	11/4/21
P210020, FDA–2021–M–1284	Urotronic, Inc	Optilume® Urethral Drug Coated Balloon	12/3/21
P190022, FDA–2021–M–1271	OPKO Health, Inc	4Kscore® Test	12/7/21
P200035, FDA–2021–M–1317	OrganOx Limited	OrganOx metra® System	12/9/21
P210014, FDA–2021–M–1321	Svelte Medical Systems, Inc	SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System and DIRECT Sirolimus-Eluting Coronary Stent Rapid Exchange Delivery System.	12/13/21
P200041, FDA–2021–M–1316	OrbusNeich Medical (Shenzhen) Co., Ltd.	Scoreflex NC Scoring PTCA Catheter	12/21/21
P200015/S011, FDA–2021–M–1325.	Edwards Lifesciences LLC	Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent.	12/16/21
P200040, FDA–2021–M–1352	Delphinus Medical Technologies, Inc.	SoftVue Automated Whole Breast Ultrasound System with Sequr Breast Interface Assembly.	10/6/21
P170002/S012, FDA–2022–M–0029.	TEOXANE S.A	RHA® Redensity™	12/22/21
P970051/S205, FDA–2022–M–0071.	Cochlear Americas	Nucleus 24 Cochlear Implant System	1/10/22
P130022/S042, FDA–2022–M–0087.	Nevro Corporation	Senza® Spinal Cord Stimulation (SCS) System	1/18/22
P840001/S469, FDA–2022–M–089.	Medtronic Neuromodulation	Restore, Itrel, Synergy, Intellis, and Vanta Spinal Cord Stimulation Systems, Pisces, Specify and Vectris Spinal Cord Stimulation Leads.	1/21/22
P080012/S068, FDA–2022–M–0090.	Flowonix Medical, Inc	Prometra® Programmable Infusion Pump System	1/12/22
P160048/S016, FDA–2022–M–0171.	Senseonics, Incorporated	Eversense® E3 Continuous Glucose Monitoring System	2/10/22

II. Electronic Access

Persons with access to the internet may obtain the documents at *https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: June 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12371 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: HRSA Ryan White HIV/AIDS Program HIV Quality Measures Module, OMB No. 0906–0022—Extension

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, 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 should be received no later than August 8, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 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* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

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

Information Collection Request Title: HIV Quality Measures (HIVQM) Module OMB No. 0906–0022—Extension.

Abstract: The 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 with HIV. 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 with HIV—more than 50 percent of all people diagnosed with HIV in the United States. Nearly two-thirds of clients live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities.[1]

RWHAP Parts A, B, C, and D recipients and sub recipients must follow legislative requirements for the establishment of clinical quality management programs to assess the extent to which their HIV services are consistent with the most recent Department of Health and Human Services Clinical Treatment guidelines. In support of these requirements, HRSA created the HIV Quality Measures (HIVQM) Module as an online tool to assist recipients in meeting the clinical quality management program requirement by allowing recipients to input data for the HRSA performance measures. HRSA maintains over 40 performance measures across 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. The HIVQM Module also supports the requirement imposed by the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Health and Human Service Award (45 CFR 75.301) that recipients relate financial data to performance accomplishments of their federal awards. The HIVQM Module helps recipients set goals and monitor performance measures and quality improvement projects. The use of the HIVQM Module is voluntary for RWHAP recipients but strongly encouraged.

Need and Proposed Use of the Information: The HIVQM Module supports recipients and sub-recipients in their clinical quality management programs, performance measurement, service delivery, and monitoring of client health outcomes and quality HIV services. The HIVQM Module is accessible via the RWHAP Services Report, an existing online portal that RWHAP recipients use for required data collection of their services. Recipients may enter performance measures data into the HIVQM Module four times a year and then generate reports to assess their performance. Recipients have the option to enter data for specific populations for a subset of performance measures based on age, gender, race/ethnicity, and risk factor. Recipients may also compare their performance against other recipients in their state, region, and nationally. Additionally, recipients can choose the performance measures they want to monitor and enter data accordingly. 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 HIVQM Module may be used to monitor the HRSA measures that qualify and comply with the requirements to receive incentives from these programs.

Likely Respondents: RWHAP Part A, Part B, Part C, and Part D recipients and their sub-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	2,063	4	8,252	1	8,252
	2,063		8,252		8,252

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–12287 Filed 6–7–22; 8:45 am]

BILLING CODE 4165–15–P

[1] HRSA. Ryan White HIV/AIDS Program Data Report, 2020.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD)

AGENCY: National Institutes of Health.

ACTION: Notice.