TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2012, THROUGH DECEMBER 31, 2012

PMA No., Docket No.	Applicant	Trade name	Approval date
P110038, FDA–2012–M–1012	Bolton Medical Inc	Relay® Thoracic Stent-Graft with Plus Delivery System.	September 21, 2012.
P110042, FDA–2012–M–1048	Cameron Health, Inc	Subcutaneous Implantable Defibrillator (S–ICD®) System.	September 28, 2012.
P100003, FDA–2012–M–1039	Globus Medical, Inc	Secure-C Artificial Cervical Disc	September 28, 2012.
P120005, FDA–2012–M–1049	Dexcom, Inc	Dexcom G4 PLATINUM Continuous Glucose Monitoring System.	October 5, 2012.
P120006, FDA–2012–M–1110	TriVascular, Inc	Ovation Abdominal Stent Graft System	October 5, 2012.
P120007, FDA–2012–M–1066	Gen-Probe, Inc	APTIMA® HPV 16 18/45 Genotype Assay.	October 12, 2012.
P110008, FDA–2012–M–1085	Paradigm Spine, LLC	coflex® Interlaminar Technology	October 17, 2012.
P110039, FDA–2012–M–1084	InSightec, Inc	InSightec ExAblate® System	October 18, 2012.
P110021, FDA–2012–M–1088	Edwards Lifesciences, LLC	Edwards SAPIEN™ Transcatheter Heart Valve.	October 19, 2012.
P100040/S008, FDA–2012–M–1109	Medtronic Vascular	Valiant® Thoracic Stent Graft with the Captivia Delivery System.	October 26, 2012.
P100012, FDA–2012–M–1111	NuVasive, Inc	PCM® Cervical Disc System	October 26, 2012.
P120002, FDA–2012–M–1183	Cordis Corporation	S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems..	November 7, 2012
P100022, FDA–2012–M–1146	Cook, Inc	Zilver PTX Drug-Eluting Peripheral Stent.	November 14, 2012.
P100047, FDA–2012–M–1184	HeartWare, Inc	HeartWare® Ventricular Assist System	November 20, 2012.
P120008, FDA–2012–M–1176	Abbott Laboratories	ARCHITECT AFP Assay, ARCHITECT AFP Calibrators and ARCHITECT AFP Controls.	November 28, 2012.

II. Electronic Access

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

Dated: March 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06429 Filed 3–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. 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 the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially 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.

Information Collection Request Title: Ryan White HIV/AIDS Treatment Extension Act of 2009, Part A Minority AIDS Initiative Report (the *Part A MAI Report*): (OMB No. 0915–0304)—EXTENSION

Abstract: HRSA's HIV/AIDS Bureau (HAB) administers the Ryan White HIV/AIDS Part A Program authorized under Title XXVI of the Public Health Service Act (Ryan White HIV/AIDS Treatment Extension Act of 2009). Part A provides emergency relief for areas with substantial need for HIV/AIDS care and support services that are most severely affected by the HIV/AIDS epidemic, including eligible metropolitan areas (EMAs) and Transitional Grant Areas (TGAs). As a component of Part A, the purpose of the Minority AIDS Initiative (MAI) Supplement is to improve access to high quality HIV care, services, and outcomes for individuals in disproportionately impacted communities of color who are living with HIV disease, including African Americans, Latinos, Native Americans, Asian Americans, Native Hawaiians, and Pacific Islanders (Section 2693(b)(2)(A) of the Public Health Service (PHS) Act). Since the purpose of the Part A MAI is to expand access to medical, health, and social support services for disproportionately impacted racial/ethnic minority populations living with HIV/AIDS, it is important that HRSA is able to report on minorities served by the Part A MAI.

The *Part A MAI Report* is a data collection instrument in which grantees report on the number and characteristics of clients served and services provided. The *Part A MAI Report,* first approved for use in March 2006, is designed to collect performance data from Part A grantees. The report has two parts: (1) A web-based data entry application that collects standardized quantitative and qualitative information and (2) an accompanying narrative report. Grantees

submit two *Part A MAI Reports* annually: The *Part A MAI Plan* (*Plan*) and the *Part A MAI Year-End Annual Report* (*Annual Report*). The *Plan* and *Annual Report* components of the report are linked to minimize the reporting burden and include drop-down menu responses; fields for reporting budget, expenditure, and aggregated client level data; and open-ended responses for describing client or service-level outcomes. Together, the *Plan* and *Annual Report* components collect information from grantees on MAI-funded services, expenditure patterns, the number and demographics of clients served, and client-level outcomes.

The MAI *Plan* Narrative that accompanies the *Plan* web forms provides: (1) An explanation of the data submitted in the *Plan* web forms; (2) a summary of the *Plan,* including the plan and timeline for disbursing funds, monitoring service delivery, and implementing any service-related capacity development or technical assistance activities; and (3) the plan and timeline for documenting client-level outcome measures. In addition, if the EMA/TGA revised any planned services, allocation amounts, or target communities after their grant application was submitted, the changes must be highlighted and explained. The accompanying MAI *Annual Report* Narrative describes: (1) Progress towards achieving specific goals and objectives identified in the grantee's approved MAI Plan for that fiscal year and in linking MAI services/activities to Part A and other Ryan White Program services; (2) achievements in relation to client-level health outcomes; (3) summary of challenges or barriers at the provider or grantee levels, the strategies and/or action steps implemented to address them, and lessons learned; and (4) discussion of MAI technical assistance needs identified by the EMA/TGA.

This information is needed to monitor and assess: (1) Changes in the type and amount of HIV/AIDS health care and related services being provided to each disproportionately impacted community of color; (2) the aggregate number of persons receiving HIV/AIDS services within each racial and ethnic community; and (3) the impact of Part A MAI-funded services in terms of client-level and service-level health outcomes. This information also is used to plan new technical assistance and capacity development activities, and influence the HRSA policy and program management functions. The data provided to HRSA does not contain individual or personally identifiable information. No changes have been made to the *Part A MAI Report.*

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 Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Part A MAI Report	53	2	106	5	530

Note: Data collection system enhancements have resulted in a shortened response burden (from 6 to 5 total hours per response) for respondents since the previous OMB approval request.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: March 14, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–06528 Filed 3–20–13; 8:45 am]

BILLING CODE 4165–15–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

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). 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. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

Information Collection Request Title: Organ and Tissue Donor and Recipient Life Stories Form (OMB No. 0915–xxxx)—NEW

Abstract: HRSA's Division of Transplantation (DoT) is the primary entity in the Department of Health and Human Services (HHS) responsible for the Organ Transplant Program established under the National Organ Transplant Act (Pub. L. 98–507, codified at sections 371–377D of the Public Health Service (PHS) Act). Section 377A of the PHS Act authorizes the Secretary of HHS to establish a public education program to increase awareness about organ donation and the need to provide for an adequate rate of such donations. In brief, DoT's responsibilities are two-fold: (1) To provide oversight and guidance to the national organ transplant system in the U.S. including monitoring the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients, and (2) to implement a program of public and professional education and outreach aimed at increasing the number of organ donors