Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation.

Reclassification of this device from class III to class II for the intended use of routine collection of blood and blood components relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under part 814, subpart E (21 CFR part 814, subpart E), including the submission of periodic reports under § 814.84.

Collecting or transfusing facilities and manufacturers have certain responsibilities under Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b)). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility, or similar reports of adverse events collected, in addition to those required under the MDR regulation. The MedWatch medical device reporting code instructions (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm*) contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

In the **Federal Register** of January 29, 2015 (80 FR 4927), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report	4	1	4	5	20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. The estimated average burden per response is based on the time that the manufacturers will spend preparing and submitting the annual report.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 501(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Dated: June 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14889 Filed 6–16–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–new–30D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, 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 on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before July 17, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–new–30D for reference. Information Collection Request Title: Title X Sustainability Assessment Tool for Grantees and Service Sites.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health seeks to collect data from the Title X centers on efforts related to (1) assisting individuals in obtaining health insurance; (2) partnerships with primary care providers; (3) availability and use of electronic health records; (4) monitoring patient care quality; (5) factors affecting revenue sources; and (6) the way that sites conduct analyses to consider the cost of providing services.

Need and Proposed Use of the Information: The Title X Family Planning Program (''Title X program'' or ''program'') is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services (*e.g.,* screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus [HIV]). By law, priority is given to persons from low-income families (Section 1006[c] of Title X of the Public Health Service Act, 42 U.S.C. 300). The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

The American health care system is experiencing unprecedented levels of change as a result of the Patient Protection and Affordable Care Act (ACA). The exact impact of these health system changes to Title X centers needs to be assessed in order to ensure the

long term sustainability of the Title X network.

Data collected from this effort will be used to inform the work of the training centers so they can better support the Title X grantees. This data will help OPA better understand challenges affecting Title X centers in order to better work with HHS entities and national stakeholders to provide resources to Title X centers. Data will be collected through an online data collection tool directly from grantees and from Title X centers.

Likely Respondents: This annual reporting requirement is service sites that receive funding (either directly from OPA or through a sub recipient or grantee agency) for family planning services authorized and funded by the Title X Family Planning Program [''Population Research and Voluntary Family Planning Programs'' (91)], which was enacted in 1970 as Title X of the Public Health Service Act (Section 1001 of Title X of the Public Health Service Act, 42 United States Code [U.S.C.] 300).

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average annualized burden per response (hours)	Annual total burden (hours)
Grantees	Sustainability Assessment—Grantees	92	1	0.66	60.72
Service Sites	Sustainability Assessment—Sites	4,168	1	0.66	2750.88
Total		4,260			2,811.60

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–14850 Filed 6–16–15; 8:45 am]

BILLING CODE 4150–48–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Population Assessment of Tobacco and Health (PATH) Study—3rd Wave (NIDA)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 11, 2015, pages 7619–7620 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Drug Abuse (NIDA), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_Submission@omb.eop.gov* or by fax to (202) 395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443–8755 or Email your request, including your address to: *PATHprojectofficer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Population Assessment of Tobacco and Health (PATH) Study—Third Wave of Data Collection—0925–0664—Revision, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925–0664, expires 9/30/2016) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the third wave of data collection. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The Study conducts annual interviews and collects biospecimens from adults to assess within-person changes and between-person differences in tobacco-product use behaviors and related health conditions over time. Its longitudinal, population-based data will help to enhance the evidence base that informs FDA's regulatory actions under the Family Smoking Prevention and Control Act to protect the Nation's public health and reduce its burden of tobacco-related morbidity and mortality.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 54,434.

ESTIMATED ANNUALIZED BURDEN HOURS

Form or activity name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Adult Extended Interview	Adults	25,444	1	1	25,444
Consent for Adult Extended Interview	Adults	2,046	1	4/60	136