

issued a letter to Swedish Match North America Inc. that denied the MRTPAs, in part, and outlined deficiencies in the remaining portions of the MRTPAs that the applicant could address by submitting an amendment to the applications. FDA recently received an amendment to Swedish Match North America Inc.'s MRTPAs and is making the amendment available (except for matters in the amendment that are trade secrets or otherwise confidential commercial information) for public comment. FDA is reopening the period for public comment so that the public has the opportunity to review and comment on the amendment.

FDA is required by section 911(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k(e)) to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

FDA has posted the application amendment for public comment, which has been redacted in accordance with applicable laws. FDA intends to establish a closing date for the comment period that is at least 30 days after the final documents from the application are made available for public comment and will announce the closing date at least 30 days in advance. FDA will notify the public about the availability of additional application documents, if any, and the closing date for the comment period via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. FDA does not intend to issue additional notices in the **Federal Register** regarding amendments or the comment period for these MRTPAs. To receive email alerts, visit FDA's email subscription service management website (<http://go.fda.gov/subscriptionmanagement>), provide an email address, scroll down to the "Tobacco" heading, select "Modified Risk Tobacco Product Application Updates", and click "Submit". To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted

MRTPAs that are the subject of this notice available electronically (see section II).

## II. Electronic Access

Persons with access to the internet may obtain the documents at either <https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533454.htm> or <https://www.regulations.gov>.

Dated: October 23, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## 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; Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906-xxxx-NEW

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

**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 November 28, 2018.

**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:* Client-Level Data Reporting System.  
*OMB No. 0906-xxxx-NEW.*

*Abstract:* The Ryan White HIV/AIDS Program's (RWHAP) client-level data

reporting system, entitled the RWHAP Services Report or the Ryan White Services Report (RSR), is designed to collect information from grant recipients, as well as their subrecipients, funded under Parts A, B, C, and D of the RWHAP statute. The RWHAP, authorized under Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, is administered by HRSA HIV/AIDS Bureau (HAB). The HRSA 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).

*Need and Proposed Use of the Information:* The RWHAP statute requires HRSA to monitor the administration of grant funds, allocation of funding, service utilization, and client demographic and HIV health outcome data (e.g., viral suppression). The RSR collects data on the characteristics of RWHAP-funded recipients, subrecipients, and the patients or clients served. The RSR system consists of two online data forms: the Recipient Report and the Service Provider Report; and the Client Report, which is a data file containing the client-level data elements. Data are submitted annually. The RWHAP statute specifies the importance of recipient accountability and linking performance to budget. The RSR is used to ensure recipient compliance with the statute, including evaluating the effectiveness of programs, monitoring recipient and subrecipient performance, and informing annual reports to Congress. Information collected through the RSR is critical for HRSA, state/local grant recipients, and individual service providers to understand existing HIV-related service delivery systems and the clients served. Information in the RSR is used to assess trends in service utilization and HIV health outcomes for clients served. Data from the RSR is analyzed to identify disparities and gaps within the service delivery systems. The 60-day notice published on November 27, 2017 (Vol. 82, No. 226).

This new ICR is being developed to replace the existing ICR (OMB control number 0915-0323), for which HRSA has collected RSR data since 2009. As more recipients fully fund services using other RWHAP-related funding streams, such as pharmacy rebate dollars, HRSA HAB receives less information on RWHAP eligible clients, which reduces HRSA HAB's ability to measure the investment and impact of all RWHAP-related expenditures at state

and local levels. Revisions in this new package will account for the funding decisions made by recipients and will now include reporting of eligible clients who receive HRSA RWHAP allowable services using RWHAP-related funding (e.g., program income and pharmacy rebates) starting with the 2019 RSR, submitted in March 2020. The proposed change may require recipients to collect additional data, either on clients or outcome measures. To decrease burden in collecting these additional data, HRSA HAB proposes a phased approach to allow time for recipients to expand their systems to collect the data. HRSA HAB expects that some recipients already receive this information from subrecipients for monitoring purposes. However, with respect to those subrecipients who are not collecting these data, such subrecipients would be required to collect additional client level information.

In an effort to increase HRSA HAB's ability to understand coverage areas for RWHAP provider sites and the population that provider sites serve, this new ICR will ask recipients to provide

zip codes for RWHAP clients receiving outpatient ambulatory health services, in addition to asking them to list the number of unduplicated clients residing in each zip code.

Additional modifications will be made to several variables within the client report to reduce burden, improve data quality, and align data collection efforts with Policy Clarification Notice Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds (PCN 16-02). These modifications will include the removal of 14 variables in the Client, Service Provider, and Recipient Reports. HRSA will continue to collect and report the client-level data elements supplied by the existing ICR through 2019. In 2019, HRSA will discontinue use of the existing ICR and will collect and report on the data elements defined in the new ICR. While there will be no overlap in the data collected and reported between the existing and new ICR, HRSA is submitting this new ICR in tandem with the existing ICR to allow recipients the ability to make modifications to their RSR systems

between the two reporting periods. This will allow recipients to continue collecting and reporting on both the old and new variables without interruption.

**Likely Respondents:** RWHAP Part A, Part B, Part C, and Part D recipients and their subrecipients.

**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 (1) review instructions; (2) 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; (3) train personnel and respond to a collection of information; (4) search data sources; (5) complete and review the collection of information; and (6) 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

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
RWHAP Parts A, B, C, and D Grant recipients.	Recipient Report ..	475	1	475	11	5,225
	Service Provider Report.	2,079	1	2,079	13	27,027
	Client Report .....	1,607	1	1,607	113	181,591
Total .....	.....	4,161	.....	4,161	.....	213,843

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0302]

#### Agency Information Collection Request. 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the

following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before December 28, 2018.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

#### FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-0302-60D and project title for reference, to [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), or call the Reports Clearance Officer at 202-795-7714.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

**Title of the Collection:** Medical Reserve Corps Unit Profile and Reports.

**Type of Collection:** Revision.

**OMB No.** 0990-0302.

**Abstract:** Medical Reserve Corps Units are currently located in 889 communities across the United States and represent a resource of 188,229 volunteers. In order to continue to support MRC units detailed information about the MRC units, including unit demographics, contact information (regular and emergency), volunteer numbers and information about unit activities is needed by the MRC