Swissmedic. Any party eligible to become a member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers.

In August 2017, the ICH Assembly endorsed the draft guidance titled ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals'' and agreed that the guidance should be made available for public comment. The draft guidance is the product of the S5(R3) Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the S5(R3) Safety Expert Working Group.

The draft guidance replaces the existing guidance entitled ''S5(R2) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' The guidance has undergone major revisions to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.

To support using alternative assays, compounds that are either positive or negative in their ability to induce embryolethality or malformations are used in the process of qualifying the assays. Although a number of compounds have been identified in the draft guidance's Annex, section 11.3.4, Tables 9–6 and 9–7, with the type of information for the compounds, the list is not complete; therefore, FDA is requesting data in the form of public comments to the docket for additional positive and negative reference compounds for potential inclusion into the list. These compounds can be either pharmaceuticals or non-pharmaceuticals and should be commercially available. For additional guidance, please refer to Endnote 3 in the S5(R3) guidance. This is not a request for data for the compounds already listed in Table 9–6, nor is this a request for examples of assays that could be used.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24483 Filed 11–9–17; 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: Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration, OMB No. 0915–0212—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 must be received no later than January 12, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 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* 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, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Voluntary Partner Surveys to Implement Executive Order 12862 in the Health Resources and Services Administration OMB No. 0915–0212—Extension.

Abstract: In response to Executive Order 12862, HRSA is proposing to conduct voluntary customer surveys of its partners to assess strengths and weaknesses in program services and processes. HRSA partners are typically state or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting continued approval for a generic clearance from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees to measure satisfaction with the training experience. HRSA will use the results of these surveys to plan and redirect resources and efforts as needed to improve services and processes.

HRSA may also use focus groups to gain partner input into the design of mail and telephone surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred data collection methods.

A generic approval allows HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If this request receives continued approval, information on each individual partner survey will not be published in the **Federal Register**.

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
In-class evaluations	40,000	1	40,000	.05	2,000
Mail/Telephone surveys	12,000	1	12,000	.25	3,000
Focus groups	250	1	250	1.5	375
Total	52,250	.....	52,250	.....	5,375

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–24492 Filed 11–9–17; 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; Assessing Client Factors Associated With Detectable HIV Viral Loads; and Models of Care and the Ryan White HIV/AIDS Program

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 December 13, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *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* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing Client Factors Associated with Detectable HIV Viral Loads and Models of Care and the Ryan White HIV/AIDS Program.

OMB No.: 0906–xxxx—NEW.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), first authorized by the U.S. Congress in 1990, is administered by HRSA's HIV/AIDS Bureau (HAB). The RWHAP provides medical services, treatment, and/or support services to 533,036 clients in 2015; 97.0 percent of these clients were living with HIV. This information collection request covers two distinct evaluation studies with RWHAP provider sites that will share components of data collection instruments through shared variables. Sharing data collection instruments will minimize burden for RWHAP provider sites collecting this data and will increase the sample size for data analysis thus resulting in more robust data and greater generalizability of results.

The first evaluation study, *Assessing Client Factors Associated with Detectable HIV Viral Loads,* will explore individuals' specific facilitators and barriers to achieving and sustaining viral suppression. Early and effective treatment for HIV has been shown to greatly reduce associated morbidity and mortality, and prevents transmission of HIV. In spite of the known benefit of treatment, many individuals remain out of care or access care only intermittently; the CDC estimated that in 2013, approximately 45 percent of people living with HIV (PLWH) in the United States were not virally suppressed, indicating a significant gap in the percentage of PLWH who are being successfully engaged and retained in care. In spite of the increased attention on retention in care and the overarching goal of viral suppression, little data exist regarding the specific individual factors that are associated with sub-optimal viral suppression. Such information is valuable for targeting programs to reach populations that are currently not achieving HIV viral suppression.

The second evaluation study, *Models of Care and the Ryan White HIV/AIDS Program,* seeks to answer the critical questions of what individual and system-wide factors, including the models of care employed among RWHAP provider sites, contribute to better health outcomes for PLWH. While advances in treatment have improved survival in patients with HIV, longer lives are associated with increased prevalence of adverse effects of HIV infection and therapeutic complications, concurrent with medical conditions related to aging processes that would occur in the absence of HIV. These long-term complications amplify chronic disease management as a major issue for the HIV population and a challenge for the delivery of effective health care. Yet little is known about how the method of health services delivery (the ''model of care'') contributes to better health outcomes, including HIV-related outcomes. For example, does it make a difference if a patient receives HIV care from a primary care provider, a