could serve as educators and resources to assist Medicare beneficiaries and others to detect and report error, fraud, and abuse.

This tool provides ACL an opportunity to assess the success and impact of the training provided to the SHIP and SMP grantees by ACL along with determining the future training needs of the program grantees. Section 301 of the Public Health Service Act (42 U.S.C. 241) is the authorizing law for data collections within the Department of Health and Human Services (HHS). Specifically, agencies within HHS should ''collect and make available through publications and other appropriate means . . . research and other activities.''

The March 3, 1998, White House Memorandum, ''Conducting Conversations with America to Further Improve Customer Service,'' directs agencies ''to track customer service measurements, then take necessary actions to change or improve how the agency operates, as appropriate. Integrate what your agency learns from its customers with your agency's strategic plans, operating plans, and performance measures required by the Government Performance and Results Act of 1993, reporting on financial and program performance under the Chief Financial Officers Act of 1990, and the Government Management Reform Act of 1994.'' The information collected in this survey is necessary to ensure that ACL is meeting the technical assistance needs of the attendees and to capture valuable feedback to be used for future training meetings. By gathering feedback on the quality of the training and content provided, we can ensure attendee satisfaction and gather information for future planning. ACL administers a contract to develop and provide the training conference evaluation tool for ACL's approval. The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

ACL will collect data once following the Annual SMP/SHIP/MIPPA National Training Conference. This evaluation will be sent to all event attendees, which is estimated to include maximum 486 participants, each survey is estimated at .25 hours to complete. This time estimate is based on research performed by ACL with the existing survey instrument and in consideration of previous survey content and length. The target number 486 is a result of 54 states/territories, each sending up to 9 conference participants who may be eligible to complete a survey (54 * 9 = 486). Factoring in an additional 40 non-grantee, non-federal partner event participants (486 + 40 = 526). 526 respondents taking 15 minutes to complete for a total of 131.5 annual burden hours.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Number of respondents	Responses per respondent	Average burden hours per response (minutes)	Total burden hours
526	1	15	131.5

Dated: May 8, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–10120 Filed 5–11–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1211]

Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions To Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry.'' The guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection. FDA is also recommending that these blood establishments make corresponding revisions to donor educational materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures. The guidance announced in this notice finalizes the draft guidance of the same title issued January 2023. This guidance also supersedes the guidance entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry'' dated April 2020 and updated August 2020.

DATES: The announcement of this guidance is published in the **Federal Register** on May 12, 2023.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–1211 for ''Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance document to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Andrew Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry.'' This guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting HIV infection. FDA is also recommending that these blood establishments make corresponding revisions to donor educational materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures.

In this guidance, based on FDA's review of the available science, FDA recommends eliminating the screening questions specific to men who have sex with men (MSM) and women who have sex with MSM. Instead, FDA recommends assessing donor eligibility using the same individual risk-based questions relevant to HIV risk for every donor regardless of sex or gender. In addition, FDA recommends deferral of any individual taking medications to treat or prevent HIV infection. FDA does not expect that implementation of these revised recommendations will be associated with any adverse effect on the safety or availability of the blood supply.

In the **Federal Register** of January 30, 2023 (88 FR 5894), FDA announced the availability of the draft guidance of the same title. FDA considered comments received on this draft guidance as the guidance was being finalized and revised the guidance as appropriate in response to the comments. For instance, we clarified that all donors, regardless of their sex or gender, will be asked the same screening questions with respect to HIV risk. We have provided additional information to explain why undetectable does not equal untransmissible for blood transfusion regarding medication used to treat or prevent HIV infection, and we added a recommendation that individuals should not stop taking their prescribed medication, including PrEP or PEP, in order to donate blood. In response to questions about deferral recommendations for anal sex, we clarified that scientific data demonstrate the risk of HIV infection is significantly greater for anal sex when compared to other sexual exposures. In response to comments requesting clarification on a screening question, we included examples of who a ''new partner'' may include. Additionally, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2023 and supersedes the guidance entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry'' dated April 2020 and updated August 2020.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on evaluating donor eligibility using individual risk-based questions to reduce the risk of HIV transmission by blood and blood products. 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.121 and parts 610 and 630 have been approved under OMB control number 0910–0116; and the collections of information for consignee notification have been approved under OMB control number 0910–0681.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10252 Filed 5–11–23; 8:45 am]

BILLING CODE 4164–01–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; Enhancing HIV Care of Women, Infants, Children and Youth Building Capacity Through Communities of Practice

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 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 12, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enhancing HIV Care of Women, Infants, Children and Youth Building Capacity through Communities of Practice, OMB No. 0915–xxxx—New.

Abstract: HRSA aims to increase delivery of evidence-based interventions that enhance client outcomes, increase the skill level of the HIV workforce providing care and treatment to Women, Infants, Children and Youth, and involve partnerships for dissemination of best practices to Ryan White HIV/AIDS Program (RWHAP) Part D participants. To that end, HRSA seeks to implement a Communities of Practice (CoP) platform for RWHAP Part D recipients. A CoP engages recipient teams in improvement learning sessions using subject matter experts along with application experts who help recipient teams select, test, and implement changes on the front line of care. Through organizational self-assessments, didactic learning on specific care topics, goals setting, and work plan development, each team can strategically benefit their organization. CoPs afford participants the opportunity to work in a group to solve a recognized challenge related to a CoP domain and support dialogue among participants and the consultant/subject matter experts. Recipient teams commit to working over a period of 12 months, alternating between Learning Sessions in which teams come together to learn about the chosen topic and to plan changes, and Action Periods in which the teams return to their respective organizations and test those changes in their clinic settings. The domains for the proposed CoPs are trauma informed care, pre-conception counseling, and youth transitioning into adult HIV care services.

A 60-day notice published in the **Federal Register** on February 27, 2023, vol. 88, No. 38; pp. 12386–12387. The one comment received was outside the scope of the ICR, and therefore no changes to the information collection were made as a result of this comment.

Need and Proposed Use of the Information: Process and outcome evaluations are a critical part of ensuring that CoP initiatives were implemented as planned and met their intended outcome. Evaluation of technical assistance (TA) depends on establishing clear goals and plans from the beginning of the process. This includes specifying the intended impact of the TA with concrete, measurable objectives. To judge performance against goals, HRSA will administer TA evaluation surveys following TA and training, webinars, teleconferences, and meetings. Findings will drive quality improvement activities and reports.

The evaluation plan focuses on process and impact evaluation of all CoP Teams (Pre-Conception Counseling and Sexual Health, Trauma-Informed Care, and Transitioning Adolescents to Adult Care) over the duration of the 4-year period of performance. The evaluation plan components will be operationalized to include TA satisfaction measures (reaction), change in knowledge after the TA (learning), and change in behavior or practice after the introduction of evidence-based interventions (behavior). More specifically, the evaluation plan includes (1) post TA satisfaction measures, (2) pre-post measures of CoP staff knowledge about effective practices, (3) retrospective measures to gather measures of CoP staff knowledge for the first community of practice only, and (4) measures of TA usefulness and impact on CoP performance.

Likely Respondents: Up to 90 RWHAP Part D Women, Infants, Children and Youth recipients will participate in the CoPs. Each recipient may have up to six staff members who may complete the survey.

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