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
Delta States Rural Development Network Program Performance Improvement Measurement System	12	1	12	1.66	*20
Total	12		12		20

*Number is rounded to the nearest whole number.

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.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–18425 Filed 8–26–19; 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; Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx—NEW

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

ACTION: Notice.

SUMMARY: In compliance with of 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 September 26, 2019.

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: Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx—NEW.

Abstract: This ICR is for a new approval of measures for the Federal Office of Rural Health Policy's Office of Advancement of Telehealth programs. Specifically, grants administered in accordance with the following legislative statute (ii) Section 711(b) of the Social Security Act (42 U.S.C. 912(b)), as amended. The purpose of these programs are to provide grants that demonstrate how telehealth programs and networks can improve access to quality health care services in rural, frontier, and underserved communities. These grants will work to: (a) Expand access to, coordinate, and improve the quality of health care services; (b) improve and expand the training of health care providers; and (c) expand and improve the quality of health information available to health care providers and patients and their families for decision-making. In addition, these grants will help HRSA assess the effectiveness of evidence based practices with the use of telehealth for patients, providers, and payers.

A 60-day notice was published in the **Federal Register** on April 08, 2019, vol. 84, No. 67; pp. 13936. There were no public comments.

Need and Proposed Use of the Information: The measures will enable HRSA and HRSA to capture awardee-level and aggregate data that illustrate the impact and scope of federal funding along with assessing these efforts. The measures cover the principal topic areas of interest to HRSA including: (a) Population demographics; (b) access to health care; (c) cost savings and cost-effectiveness; and (d) clinical outcomes.

Likely Respondents: Award recipients of the Evidence Based Telehealth Network Program.

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
Evidence-Based Telehealth Network Program Report	50	12	600	14	8,400
Telehealth Performance Measurement Report	50	1	50	5	250

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
	*50	.....	650	.....	8,650

*There are 50 unique respondents. All respondents will be responding to the two forms.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–18388 Filed 8–26–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: Regarding Revisions to the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information; notice.

SUMMARY: The Office of the Assistant Secretary for Health in the Department of Health and Human Services (HHS) seeks public comment regarding proposed revisions to the 2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation.

DATES: To be assured consideration, comments must be received at the address provided below no later than 5:00 p.m. ET on September 26, 2019.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to *ACBTSA@hhs.gov.* Written responses should be addressed to: U.S. Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Room L001, Washington, DC 20024 Attn: ACBTSA—RFI.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Official, Office of Infectious Disease and HIV/AIDS Policy, (202) 795–7608.

SUPPLEMENTARY INFORMATION:

I. Background

Since implementation of the Guideline in 2014,[1] the organ donation and transplantation community monitored the impact of the recommendations on provider and patient perceptions, organ utilization, and clinical outcomes. HHS conducted analyses to inform efforts to revise the Guideline recommendations. In April 2019, the Assistant Secretary for Health of the Department of Health and Human Services (HHS) received input from the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) regarding revisions to the Guideline recommendations to reflect recent epidemiologic trends in clinical characteristics of deceased organ donors and scientific advances and improvements in testing for and treatment of HIV, HBV, and HCV infections.

HHS is asking respondents to review the proposed revisions to the current Guideline and provide assessments on updating the Guideline, whether these changes are achievable in the clinical setting, or if there are potential barriers to implementation. In addition, impact on organ allocation and utilization should be considered. Other comments pertinent to these proposed revisions are welcome.

Since the emergence of the human immunodeficiency virus (HIV) epidemic, the U.S. Public Health Service (PHS) has made recommendations to reduce the risk of HIV transmission associated with organ transplantation.[2] [3] Historically, recommendations included identifying risk factors among organ donors associated with HIV infection to minimize risk of potential transmission to recipients. Recommendations also included laboratory screening of donors using anti-HIV antibody testing, with additional testing recommendations added as technologies such as nucleic acid testing (NAT) were developed. In 2013, based on donor-derived transmission events and reports of poor recipient outcome from hepatitis B (HBV) and C (HCV) transmission, the PHS released a revised guideline. The 2013 Guideline added organ donor screening recommendations for HBV (hepatitis B surface antigen (HBsAg) and total antibody to hepatitis B core antigen (anti-HBc)) and HCV (antibody to hepatitis C (anti-HCV) and NAT), in addition to HIV, to reduce the risk of unintended transmission through transplantation. This revised Guideline was enhanced by recommending specific recipient informed consent and post-transplant recipient monitoring for evidence of possible disease transmission.

Per the 1994 guideline, donors with risk factors for HIV infection and transmission to recipients were designated ''Centers for Disease Control and Prevention (CDC) High Risk'' donors. The 2013 Guideline changed this terminology to ''Increased Risk Donor (IRD)'' and recommended HCV nucleic acid testing (NAT) for all donors and HIV NAT or p24 antigen testing for IRD. For living donors, testing was recommended to be performed as close as possible to the date of the organ recovery but at least within 28 days prior to surgery. For deceased donors, specimens for testing were to be obtained before procurement but with no specific recommendation on the timing of collection relative to organ recovery. The term ''Increased Risk'' was adopted over ''High Risk'' to convey the continued but small possibility of donor-derived disease transmission from donors with risk factors, even with use of the more sensitive NAT screening tests.

The 2013 Guideline specifically outlines 12 medical or social history criteria resulting in IRD designation if these risk factors occurred within the 12 months prior to organ recovery. The 12 criteria are:

1. Sex with a person known or suspected to have HIV, HBV, or HCV infection.

[1] Seem DL, Lee I, Umscheid CA, Kuehnert MJ. PHS guideline for reducing human immunodeficiency virus, hepatitis B virus, and hepatitis C virus transmission through organ transplantation. Public health reports (Washington, DC: 1974). 2013;128(4):247–343.

[2] CDC. Guidelines for preventing transmission of human immunodeficiency virus through transplantation of human tissue and organs. Centers for Disease Control and Prevention. MMWR Recommendations and reports: Morbidity and mortality weekly report Recommendations and reports/Centers for Disease Control. 1994;43(RR–8):1–17.

[3] CDC. Testing donors of organs, tissues, and semen for antibody to human T-lymphotropic virus type III/lymphadenopathy-associated virus. MMWR Morbidity and mortality weekly report. 1985;34(20):294.