TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total responses</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delta States Rural Development Network Program Performance Improvement Measurement System</td>
<td>12</td>
<td>1</td>
<td>12</td>
<td>1.66</td>
<td>* 20</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td></td>
<td>12</td>
<td></td>
<td>20</td>
</tr>
</tbody>
</table>

* 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]

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

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.

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</thead>
<tbody>
<tr>
<td>Evidence-Based Telehealth Network Program Report ................................</td>
<td>50</td>
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<td>600</td>
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<tr>
<td>Telehealth Performance Measurement Report ........................................</td>
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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 ACBTSAG@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: ACBTSAG-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 (ACBTSAG) 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.

Maria G. Button, Director, Division of the Executive Secretariat.

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

