

to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

Follow-Up 3

We estimate that we will retain 80 percent of the sample from FU2 and collect data from 4,800 respondents at FU3. We do not intend to replenish the sample at FU3. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

Supplemental Data Collection

In addition to the main data collection, we intend to collect data from subpopulations shown to be at higher risk of initiating use of cigarettes and ENDS products, such as youth who identify as LGBTQ+ and youth who have a mental health disorder. Data collection will consist of online self-administered surveys of participants recruited through social media advertisements. The recruitment sample for this data collection will be youth ages 14 to 20 who meet the subpopulation criteria. We intend to collect data at baseline from 1,500 respondents. We anticipate that we will need to screen 5,000 respondents (5 minutes per response) to obtain a baseline sample of 1,500 respondents who meet the subpopulation criteria. At baseline, we plan to collect data from approximately 1,500 respondents identified as eligible through screening. These 1,500 youth respondents are estimated to provide assent (5 minutes per response) and complete the survey (30 minutes per response). We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave; therefore, estimating 1,200 respondents at FU1, 960 respondents at FU2, and 768 respondents at FU3. For the FU samples, youth will provide assent (5 minutes per response) and complete the survey (30 minutes per response).

We made several minor edits from the 60-day **Federal Register** notice to the 30-day **Federal Register** notice. These edits consisted of (a) minor revisions for clarity (e.g., indicating that self-report exposure is a measure of awareness rather than a unique outcome); (b) removing text alluding to using multiple methods to understand the campaign

impact (because the proposed study is just one method); and (c) removing bullets on two outcomes related to perceived norms of tobacco use, as the ads that will be on air at the time of data collection are not attempting to change those particular outcomes so they are not relevant to assess in the study.

Dated: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0008]

Advisory Committee; Cellular, Tissue, and Gene Therapies Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Cellular, Tissue, and Gene Therapies Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cellular, Tissue, and Gene Therapies Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 28, 2024, expiration date.

DATES: Authority for the Cellular, Tissue, and Gene Therapies Advisory Committee will expire on October 28, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993-0002, 240-402-8054, Christina.Vert@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice

to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program that provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine, and various medical specialties, including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics). Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to

exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/cellular-tissue-and-gene-therapies-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: February 1, 2023.

Lauren K. Roth,

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; Optimizing Virtual Care Grant Program Performance Measures, OMB No. 0906-0075—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 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 March 9, 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, email Samantha Miller, the acting HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Optimizing Virtual Care Grant Program Performance Measures OMB No. 0915-0075—NEW.

Abstract: The Health Center Program and supplemental awards for health centers are authorized by section 330 of the Public Health Service Act (42 U.S.C. 254b). HRSA is authorized to make supplemental awards for health centers to "implement evidence-based models for increasing access to high-quality primary care services, which may include models related to expanding the use of telehealth and technology-enabled collaborative learning and

capacity building models." 42 U.S.C. 254b(d)(1)(E). Under the Optimizing Virtual Care (OVC) grant program, 29 high-performing health centers received 2-year supplemental awards to increase health care access and quality for underserved populations through virtual care such as telehealth, remote patient monitoring, digital patient tools, and health information technology platforms. Specifically, award recipients will use OVC funding to develop and implement innovative evidence-based strategies with the potential to be adapted, leveraged, and scaled across the Health Center Program to increase access to care and improve clinical quality by optimizing the use of virtual care with a specific focus on underserved communities and vulnerable populations.

The goal of the OVC grant program is to continue to support innovation that began during the COVID-19 pandemic, when health centers quickly expanded their use of virtual care to maintain access to essential primary care services for underserved communities. HRSA-funded health centers serve special and vulnerable populations facing barriers to virtual care access, such as low digital literacy, low connectivity capabilities, or limited technology access. The OVC grant recipients will serve as a model for how to increase equitable virtual care, generating and refining strategies that can be adapted and scaled across the Health Center Program.

A 60-day notice published in the **Federal Register**, 87 FR 37874-37875 (June 24, 2022). HRSA received comments from OVC grant recipients during this public comment period. A 30-day notice published in the **Federal Register**, 87 FR 64066-64067 (October 21, 2022). HRSA did not receive comments on the 30-day notice. However, HRSA is republishing the 30-day notice with the correct information collection instrument.

Need and Proposed Use of the Information: The information collected on OVC grant recipient activities and performance will help HRSA demonstrate, adapt, assess, and disseminate promising practices, strategies, and novel models of virtual care across the nation's health centers. The information will support an assessment that yields:

- Increased evidence of how to optimize the use of virtual care in the Health Center Program to enhance access to care and improve clinical quality for underserved communities and special and vulnerable populations.
- Maximized impact of the new OVC grant program, as a model to be adapted,