

UBRELVY is 2,883 days. Of this time, 2,520 days occurred during the testing phase of the regulatory review period, while 363 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* February 2, 2012. The applicant claims February 3, 2012, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 2, 2012, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 26, 2018. FDA has verified the applicant's claims that the new drug application (NDA) for UBRELVY (NDA 211765) was initially submitted on December 26, 2018.

3. *The date the application was approved:* December 23, 2019. FDA has verified the applicant's claim that NDA 211765 was approved on December 23, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 555 days or 774 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written

petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18753 Filed 8–30–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Advisory Council, September 19, 2022, 10:00 a.m. to 04:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Rooms 260 C, D, E and F, Bethesda, MD 20892, which was published in the **Federal Register** on August 24, 2022, FR Doc 2022–18262, 87 FR 52000.

This notice is being amended to remove the visitor testing requirement for entering NIH facilities due to CDC updates published August 11, 2022, regarding screening testing. The meeting is open to the public.

Information is also available on the Institute's/Center's home page: <https://public.csr.nih.gov/AboutCSR/Organization/CSRAdvisoryCouncil>, where an agenda and any additional information for the meeting will be posted when available.

The meeting will be videocast and can be accessed from the NIH Videocasting website (<https://videocast.nih.gov/watch=45767>).

Dated: August 25, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18785 Filed 8–30–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Request for Information: SAMHSA's Role in Possible Agency Actions Regarding Mental Health and Substance Use Wellbeing in the Context of Climate Change and Health Equity

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Notice of request for information.

SUMMARY: SAMHSA seeks input from members of the public about how it can best address the behavioral health impacts of climate change and health equity considerations. Behavioral health includes mental health conditions and substance use disorders. SAMHSA specifically seeks input on suggested priorities, resources, partners and collaborating agencies and organizations.

DATES: Comments on this notice must be received by October 31, 2022.

ADDRESSES: Please submit all responses via email to ClimateChange@SAMHSA.HHS.gov as a Word document, Portable Document Format (PDF) or in the body of an email. Please include "Request for Information: SAMHSA's Role in Climate Change" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Mitchell Berger, Public Health Advisor, Telephone: 240–276–1757, Email: Mitchell.Berger@SAMHSA.HHS.gov, or Maggie Jarry, Emergency Management Specialist, Email: Maggie.Jarry@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: In January 2021, President Biden signed Executive Order 14008, Tackling the Climate Crisis at Home and Abroad. Recognizing that "we face a climate crisis that threatens our people and communities, public health and economy, and, starkly, our ability to live on planet Earth," the Order called for a "government-wide approach" to climate change and development of agency action plans to "bolster adaptation and increase resilience to the impacts of climate change."¹

President Biden also in January 2021 signed Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which called upon Agencies to take steps to enhance

programs for underserved communities.²

In August 2021, HHS established the Office of Climate Change and Health Equity (OCCHE) as part of the Office of the Assistant Secretary for Health. OCCHE priorities include supporting efforts to reduce greenhouse gas emissions, partnering with other government agencies and the nonprofit and private sectors and supporting efforts to address health disparities.

Consistent with Administration priorities, HHS in 2021 developed a Climate Action Plan emphasizing the Department's proactive response to climate change.³

SAMHSA leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA accomplishes this mission by working closely with other federal partners, state, local, tribal, and territorial governments, health care providers, academic institutions, persons with lived experience and family members and caregivers to promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery. SAMHSA works closely with such partners as the Administration for Strategic Preparedness and Response, Health Resources and Services Administration, Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention and other agencies to expand access to behavioral health services, ensure compliance with the Mental Health Parity and Addiction Equity Act, and provide services to vulnerable populations.

SAMHSA also supports such programs as the Substance Abuse and Mental Health Block Grants, Disaster Technical Assistance Center, Projects for Assistance in Transition from Homelessness emphasizing services for vulnerable populations. Through these and other grants and activities supported by SAMHSA's Office of Behavioral Health Equity and Office of Tribal Affairs and Policy, SAMHSA, consistent with the Administration's January 2021 Executive Orders, works to ensure disadvantaged and underserved communities and individuals experiencing behavioral health conditions are supported.

Increasingly, climate change is impacting, directly and indirectly, clients, providers, caregivers, and communities, and in particular, persons with behavioral health conditions. For instance, climate change may increase the likelihood of extreme weather

events, such as heatwaves, that adversely impact persons with psychiatric conditions.⁴ Hurricanes may disrupt access to and participation in behavioral health treatment and recovery supports for people with substance use and/or mental disorders. For instance, hurricanes may disrupt access to medications or increase anxiety, depression, and substance use.^{5 6} Hurricanes may also disrupt access to the SAMHSA identified four major dimensions of recovery—health, home, purpose, and community. In addition, growing numbers of youth and others are experiencing heightened anxiety related to current and potential impacts of climate change. Climate emergencies, such as droughts, also may lead to loss of community cohesion, depopulation, loss of natural resources, and loss of economic opportunities.⁷ Under-resourced populations are among those most impacted by climate change because of their inadequate access to healthy foods, lack of stable housing and healthcare barriers.⁸

SAMHSA programs, along with those of other HHS and federal agencies, are working to address these impacts. For instance, SAMHSA participates in the National Integrated Heat Health Information System, which works to mitigate the health impacts of extreme heat and supports the recently launched website, Heat.gov. In collaboration with the Federal Emergency Management Agency, SAMHSA also supports the Crisis Counseling Assistance and Training Program, which provides outreach and psychosocial support following disasters.

Consistent with its mission and the Administration's focus on climate change and health equity, SAMHSA seeks input on how its programs, technical assistance and training, and other resources can support clients, providers, family members and communities in confronting the impacts of climate change. Specifically, SAMHSA seeks input on the following questions:

A. What should SAMHSA's top priorities be with respect to climate change and behavioral health? What are current strengths or gaps in SAMHSA's work in this area?

B. What should SAMHSA's top priorities be to ensure behavioral health equity with respect to climate change?

C. Which population(s) are most vulnerable to the behavioral health impact(s) of climate change? How can SAMHSA communicate with such population(s) and others to support their preparedness for the behavioral health impact(s) of climate change?

D. In thinking about behavioral health, what are the top lessons learned from past climate-related emergencies and natural disasters, such as recent or past hurricanes, heat waves, wildfires, or other events?

E. What peer-reviewed articles, papers, toolkits, listservs or other resources related to climate change should SAMHSA highlight in its work with states, local, tribal and territorial health authorities, behavioral health providers, grant recipients, national and local stakeholder organizations, and the general public?

F. Should SAMHSA programs highlight the importance of climate change to its grant recipients? If so, how?

G. What barriers exist in SAMHSA's programs or regulations that make it difficult to prepare for, mitigate, respond to or recover from the impacts of climate change on mental health or substance use disorders?

H. What steps should SAMHSA take to help states, local, tribal and territorial health authorities, grant recipients and stakeholders, behavioral health providers, national and local stakeholder organizations, and the general public address the impacts of climate change and the needs of underserved populations?

I. Can SAMHSA promote behavioral health equity by addressing intergenerational trauma resulting from climate change? If so, how?

J. How can SAMHSA support access to behavioral health and climate change resources and supports for future generations?

K. How can SAMHSA effectively collaborate with governmental and non-governmental partners to facilitate adaption to current and future climate change impacts?

L. What research should be prioritized to build the evidence base on how climate change affects mental health and substance use disorder outcomes?

Endnotes

¹ 86 FR 7619 (2021).

² 86 FR 7009 (2021).

³ HHS Climate Action Plan, Sept. 2021, <https://www.hhs.gov/sites/default/files/hhs-climate-action-plan-9-28-2021.pdf>.

⁴ See e.g., Disaster Behavioral Health in an Era of Climate Change, Dialogue, 2022; 17(3), <https://www.samhsa.gov/sites/default/files/dtac-dialogue-vol-17-issue-3.pdf>; Mental Health and Our Changing Climate, 2021 Edition, <https://ecoamerica.org/mental-health-and-our-changing-climate-2021-edition/>; N. Obradovich and K. Minor, Identifying and Preparing for the Mental Health Burden of Climate Change, JAMA Psychiatry 2022 Apr 1;79(4):285–286. doi: 10.1001/jamapsychiatry.2021.4280; R.

Thompson *et al.*, Associations between high ambient temperatures and heat waves with mental health outcomes: a systematic review. *Public Health*. 2018 Aug;161:171–191. doi: 10.1016/j.puhe.2018.06.008. Epub 2018 Jul 12. PMID: 30007545; D. Dodgen *et al.*, 2016: Ch. 8: Mental Health and Well-Being. *The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment*. U.S. Global Change Research Program, Washington, DC, 217–246. <http://dx.doi.org/10.7930/JOTX3C9H>.

⁵ K. Bevilacqua *et al.* Understanding Associations Between Hurricane Harvey Exposure and Mental Health Symptoms Among Greater Houston-Area Residents. *Disaster Med Public Health Prep*. 2020 Feb;14(1):103–110. doi: 10.1017/dmp.2019.141. PMID: 32019618; JM Shultz and S. Galea, Mitigating the Mental and Physical Health Consequences of Hurricane Harvey. *JAMA*. 2017;318(15):1437–1438. doi:10.1001/jama.2017.14618; E.A. Storch *et al.*, Psychiatric Diagnoses and Medications for Hurricane Harvey Sheltered Evacuees, *Community Mental Health Journal*, 2019; 55 (7): 1099–1102. doi: 10.1007/s10597-019-00378-9.

⁶ See *e.g.*, L. Elliott *et al.*, Disaster preparedness among opioid treatment programs: Policy recommendations from state opioid treatment authorities. *International Journal of Disaster Risk Reduction*, 2017; 23: 152–159. doi.org/10.1016/j.ijdr.2017.05.001; A.R. Griffin, *et al.*, A Crisis Within a Crisis: The Extended Closure of an Opioid Treatment Program After Hurricane Sandy. *Journal of Drug Issues*, 2018; 48(4), 536–545. doi.org/10.1177/0022042618779541; H. Matusow *et al.*, Challenges to Opioid Treatment Programs After Hurricane Sandy: Patient and Provider Perspectives on Preparation, Impact, and Recovery. *Substance Use & Misuse*, 2018; 53(2), 206–219. <https://doi.org/10.1080/10826084.2016.1267225>; PJ Joudrey *et al.*, Assessment of Community-Level Vulnerability and Access to Medications for Opioid Use Disorder, *JAMA Network Open*. 2022;5(4):e227028. doi:10.1001/jamanetworkopen.2022.7028.

⁷ H. Vins *et al.* The mental health outcomes of drought: a systematic review and causal process diagram. *Int J Environ Res Public Health*. 2015;12(10):13251–13275. doi: 10.3390/ijerph121013251. LA Palinkas and M. Wong, M. Global climate change and mental health. *Current Opinion in Psychology*, 2020; 32, 12–16. <https://doi.org/10.1016/j.copsyc.2019.06.023>.

⁸ See *e.g.*, Behavioral Health Equity. <https://www.samhsa.gov/behavioral-health-equity>.

How To Submit a Response

Responses will be accepted through October 31, 2022. Responses must be emailed to ClimateChange@SAMHSA.HHS.gov. Please include “Request for Information: SAMHSA’s Role in Climate Change” in the subject line.

Responders are free to address any or all the questions listed above. Please identify the question or question(s) to

which you are responding. Responses also may address concerns or issues not identified above.

The submitted information will be reviewed by SAMHSA and HHS staff. However, individual comments may not be acknowledged by SAMHSA due to the volume of comments received.

Responses to this RFI are entirely voluntary and may be submitted anonymously. Please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response.

SAMHSA will use the information submitted in response to this RFI at its discretion. SAMHSA reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), contract(s) or cooperative agreement(s), or in the development of future funding opportunity announcements.

This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–18834 Filed 8–30–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2022 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This is a notice of intent to award supplemental funding to the National Training and Technical Assistance Center for Certified Community Behavioral Health Clinics—Expansion Grant (TTA–CCBHC) recipient funded in FY 2021 under Funding Opportunity Announcement SM–21–015. This is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an

administrative supplement, which is consistent with the initial award, of up to \$150,000 for one-year to the TTA–CCBHC recipient, The National Council for Mental Wellbeing. This supplement will provide support to new Certified Community Behavioral Health (CCBHC) recipients that have opted to participate in the SAMHSA/NIH Evidence-Based Practices Implementation Science Pilot as noted in the Notice of Funding Opportunities (NOFOs) in FY 2022, CCBHC-Planning, Development, and Implementation (SM–22–002) and CCBHC-Improvement and Advancement (SM–22–012). The technical assistance will provide the following: (1) support to SAMHSA and CCBHC grant recipients to develop capacity and the ability to implement and sustain effective treatment and practices; (2) support delivery of evidence-based practices with fidelity; and (3) identification and/or development of resources that can be used by CCBHC recipients to augment the implementation of effective practices in alignment with the CCBHC certification criteria. This is not a formal request for application. Assistance will only be provided to the TTA–CCBHC recipient, The National Council for Mental Wellbeing, based on the receipt of a satisfactory application and associated budget. This recipient was funded in FY 2021 under Funding Opportunity Announcement SM–21–015 with a project end date of September 29, 2026.

FOR FURTHER INFORMATION CONTACT:

Mary Blake, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone (240) 276–1747; email: mary.blake@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2021 National Training and Technical Assistance Center for Certified Community Behavioral Health Clinics—Expansion Grant (SM–21–015).

Assistance Listing Number: 93.243.

Justification: Eligibility for this supplemental funding is limited to The National Council for Mental Wellbeing which was funded in FY 2021 under the National Training and Technical Assistance Center for Certified Community Behavioral Health Clinics—Expansion Grant. The National Council for Mental Wellbeing has special expertise in completing activities that support SAMHSA-funded CCBHC grant recipients and their ability to effectively implement evidence-based and effective practices in alignment with the CCBHC Certification Criteria.