

Fiscal Year (FY) 2023 Omnibus Appropriations Package

Telehealth and Related Provisions

On December 20, 2022, House and Senate Appropriators released the text of the <u>FY2023 Omnibus</u> <u>Appropriations bill</u>, which includes \$1.7 trillion in appropriations for fiscal year 2023 and several key health care extenders and new authorizations.

The Alliance for Connected was thrilled to see the inclusion of several critical telehealth provisions included in this package. Along with the <u>appropriations bill</u>, the accompanying <u>Joint Explanatory Statement</u> and House Committee on Appropriations <u>Report</u> for the Departments of Labor, Health and Human Services, and Education, and Related Agencies for Fiscal Year 2023 Appropriations included specific instructions with respect to the appropriated amounts.

Below we have pulled notable provisions related to telehealth that were included as part of this package.

Provisions From the FY2023 Omnibus Appropriations Bill

<u>DIVISION A - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND</u> <u>RELATED AGENCIES APPROPRIATIONS ACT, 2023</u>

TITLE I - AGRICULTURAL PROGRAMS

- **Distance Learning, Telemedicine, And Broadband Program -** Grants for telemedicine and distance learning services in rural areas, \$64,991,000, to remain available until expended, of which up to \$4,991,000 shall be for the purposes, and in the amounts, specified for this account in the table titled "Community Project Funding/Congressionally Directed Spending"

<u>DIVISION H—DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND</u> RELATED AGENCIES APPROPRIATIONS ACT, 2023

Title II—Department of Health and Human Services

- Health Resources & Services Administration (HRSA)
 - Rural Health \$352,407,000, of which \$64,277,000 from general revenues shall be available for carrying out the Medicare rural hospital flexibility grants program. Of the funds made available for such grants, up to \$1,000,000 shall be available to carry out the Providing Mental Health Services and Other Health Services to Veterans and Other Residents of Rural Areas (section 1820(g)(6) of the Social Security Act), with funds available for the purchase and implementation of telehealth services and other efforts to improve health care coordination for rural veterans between rural providers and the Department of Veterans Affairs.
 - HRSA-Wide Activities and Program Support \$1,735,769,000, of which \$38,050,000 shall be for expenses necessary for the Office for the Advancement of Telehealth, including grants, contracts, and cooperative agreements for the advancement of telehealth activities.



<u>DIVISION U—JOSEPH MAXWELL CLELAND AND ROBERT JOSEPH DOLE MEMORIAL VETERANS BENEFITS</u> <u>AND HEALTH CARE IMPROVEMENT ACT OF 2022</u>

Title I – Health Care Matters, Chapter 4 – Administration of Non-Department Care

- Subtitle D—Improvement of Rural Health and Telehealth
 - Sec. 151. Establishment of strategic plan requirement for Office of Connected Care of Department of Veterans Affairs. The Secretary of Veterans Affairs, acting through the Office of Connected Care of the Department of Veterans Affairs, shall develop a strategic plan to ensure the effectiveness of the telehealth technologies and modalities delivered by the Department to veterans who are enrolled in the patient enrollment system. The strategic plan will be updated no less than once every three years following the development of the plan. The Secretary shall submit a report to Congress within 180 days after the development of the strategic plan outlining the completed strategic plan or update, and identifying areas of improvement by the Department in the delivery of telehealth and virtual care services to veterans enrolled in patient enrollment systems, with a timeline of improvements to be implemented.
 - O Sec. 153. Comptroller General report on telehealth services of the Department of Veterans Affairs GAO shall submit a report to Congress no later than 18 months of enactment on telehealth services provided by the Department of Veterans Affairs. The report will include the telehealth and virtual health care programs of the VA, including VA Video Connect; challenges faced by the VA in delivering telehealth and virtual care to veterans who reside in rural and highly rural areas due to lack of connectivity in many rural areas; mitigation strategies used to overcome connectivity barriers; partnerships entered into by the Office of Connected Care in an effort to bolster telehealth services; extent to which the VA has examined the effectiveness of health care services provided to veterans through telehealth in comparison to in-person treatment; Satisfaction of veterans with respect to the telehealth services; and other areas deemed appropriate.

DIVISION FF—HEALTH AND HUMAN SERVICES

TITLE III—FOOD AND DRUG ADMINISTRATION

- Subtitle F—Cross-Cutting Provisions, CHAPTER 1—CLINICAL TRIAL DIVERSITY AND MODERNIZATION
 - Sec. 3606 Decentralized clinical studies No later than one year after enactment, the Secretary shall issue or revise draft guidance that includes recommendations to clarify and advance the use of decentralized clinical studies to support the development of drugs and devices, including recommendations for how to advance the use of flexible and novel clinical trial designs and to help improve trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population, including with respect to race, ethnicity, age, sex, and geographic location, when appropriate. The guidance shall be finalized no later than one year after closing the comment period on such draft guidance. Guidance will include areas such as:
 - Recommendations related to digital health technology or other assessment options, such as telehealth, local laboratories, local health care providers, or other options for remote data collection, could support decentralized clinical



studies, including guidance on considerations for selecting technological platforms and mediums, data collection and use, data integrity and security, and communication to study participants through digital technology.

- Recommendations for subject recruitment, retention, and engagement, including considerations for sponsors to minimize or reduce burdens for clinical study participants through the use of digital health technology, telehealth, local health care providers and laboratories, health care provider home visits, direct-toparticipant engagement, electronic informed consent, or other means, as appropriate.
- Recommendations for methods of remote data collection, including clinical trial participant experience data, through the use of digital health technologies, telemedicine, local laboratories, local health care providers, or other options for data collection.
- Considerations for sponsors to minimize or reduce burdens for clinical trial participants associated with participating in a clinical trial, such as the use of digital technologies, telemedicine, local laboratories, local health care providers, or other data collection or assessment options, health care provider home visits, direct-to-participant shipping of investigational drugs and devices, and electronic informed consent, as appropriate.
- Recommendations regarding conducting decentralized clinical trials to facilitate and encourage meaningful diversity among clinical trial participants, including with respect to race, ethnicity, age, sex, and geographic location, as appropriate.
- Recommendations for strategies and methods for recruiting, retaining, and engaging with clinical trial participants, including communication regarding the role of clinical trial participants and community partners to facilitate clinical trial recruitment and engagement, including with respect to diverse and underrepresented populations, as appropriate.
- Recommendations related to digital health technology and other remote assessment tools that may support decentralized clinical trials, including guidance on appropriate technological platforms and tools, data collection and use, data integrity, and communication to clinical trial participants through such technology.
- Sec. 3607 Modernizing clinical trials To clarify the use of digital health technologies in clinical trials, the Secretary shall issue or revise draft guidance regarding the appropriate use of digital health technologies in clinical trials to help improve recruitment for, retention in, participation in, and data collection during, clinical trials, and provide for novel clinical trial designs utilizing such technology for purposes of supporting the development of, and review of applications for, drugs and devices. Guidance can touch on areas such as:
 - Recommendations for data collection methodologies by which sponsors may incorporate the use of digital health technologies in clinical trials to collect data remotely from trial participants.



- Considerations on data collection methods to help increase recruitment of clinical trial participants and the level of participation of such participants, reduce burden on clinical trial participants, and optimize data quality.
- Recommendations regarding the data and information needed to demonstrate that a digital health technology is fit-for-purpose for a clinical trial, and a description of how the Secretary will evaluate such data and information.
- Recommendations for increasing access to, and the use of, digital health technologies in clinical trials to facilitate the inclusion of diverse and underrepresented populations, as appropriate, including considerations for access to, and the use of, digital health technologies in clinical trials by people with disabilities and pediatric populations.

TITLE IV—MEDICARE PROVISIONS

- Subtitle B—Other Expiring Medicare Provisions
 - Sec. 4113 Advancing telehealth Beyond COVID–19. This section provides a two-year extension of the following Medicare telehealth flexibilities through December 31, 2024:
 - Removing Geographic Requirements and Expanding Originating Sites for Telehealth Services - This section would amend the current originating site definition and expand it to mean any site in the United States at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system (without geographic restriction). Additionally, there is no facility fee.
 - Expanding Practitioners Eligible to Furnish Telehealth Services This section temporarily adds qualified physical therapist, qualified speech-language pathologist, and qualified audiologist as eligible providers to provide telehealth services.
 - Expanding Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics - This section would extend the CARES Act telehealth payment structure for federally qualified health centers and rural health clinics.
 - Delaying the In-Person Requirements Under Medicare for Mental Health Services Furnished Through Telehealth and Telecommunications Technology -This section delays in-person requirements for mental health services until on or after January 1, 2025 (or if later, the first day after the end of the PHE). In-person requirements for rural health clinics and federally qualified health centers shall not apply prior to January 1, 2025 (or if later, the first day after the end of the PHE).
 - Allowing for the Furnishing of Audio-Only Telehealth Services This section requires the HHS Secretary to continue providing coverage and payment for audio-only telehealth services as of the date of enactment through December 31, 2024.
 - Use of Telehealth to Conduct Face-to-Face Encounter Prior to Recertification of Eligibility for Hospice Care During Emergency Period - This section continues the CARES Act provision which allows virtual recertification of hospice care, through December 31, 2024.



- Study on Telehealth and Medicare Program Integrity This section requires the Secretary to conduct a study using medical record review (of a sample of claims for telehealth services from January 1, 2022 through December 31, 2024) on program integrity related to telehealth services under Medicare Part B. The study will review and analyze the duration, type and impact of telehealth services furnished on future utilization of health care services by Medicare beneficiaries.
 - Interim report to Congress would be due on October 1, 2024, and final report due no later than April 1, 2026.
 - \$10M appropriated to CMS Program Management Account for FY2023.

Subtitle D—Other Medicare Provisions

Sec. 4140 – Extending Acute Hospital Care At Home Waivers and Flexibilities – This section extends the Acute Hospital Care at Home initiative, as currently authorized under CMS waivers and flexibilities, through December 31, 2024. This includes the waiver of telehealth requirements under the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, Strengthening Public Health Act of 2022, such that an originating site shall include the home or temporary residence of the individual.

Subtitle E—Health Care Tax Provisions

Sec. 4151 – Extension of Safe Harbor for Absence of Deductible For Telehealth (pg. 3805)

 This section provides a two-year extension of the flexibility allowing employers/plans to provide coverage for telehealth services pre-deductible for individuals with a high-deductible health plan coupled with a health savings account (HDHP-HSA) through December 31, 2024.

TITLE V—MEDICAID AND CHIP PROVISIONS

- Subtitle C—Medicaid and CHIP Mental Health
 - Sec. 5123 Requiring Accurate, Updated, and Searchable Provider Directories. Requires managed care organizations, prepaid ambulatory health plans, and when appropriate, primary care case management entities with a contract with a state to enroll individuals who are eligible for medical assistance under the state plan or under a waiver of such plan, to publish on a public website a searchable directory of network providers, which includes with respect to such providers whether the provider offers covered services via telehealth, among other areas.
 - Sec. 5124 Supporting Access to a Continuum of Crisis Response Services Under Medicaid and CHIP. The Secretary, in coordination with CMS Administrator and Assistant Secretary for Mental Health and Substance Use, shall issue guidance to states regarding Medicaid and CHIP that includes strategies to facilitate timely provision of crisis response services, such as the use of telehealth to deliver crisis response services (among other areas).

<u>Provisions from Accompanying Joint Explanatory Statement and House Report Language</u>

Health Resources and Services Administration (HRSA)

• **Telehealth Centers of Excellence (COE).-** The agreement includes \$8,500,000 for the Telehealth COE awarded sites.



- **Provider Bridge.-** The agreement includes \$500,000 to continue the development of the Provider Bridge as part of the Licensure Portability Grant Program.
- Rural Telehealth Initiative. —The Committee supports the Memorandum of Understanding entered into on August 31, 2020, establishing a Rural Telehealth Initiative among HHS, the Federal Communications Commission, and the Department of Agriculture. Together, this important initiative can leverage expertise of each respective agency and improve collaboration amongst entities tasked with addressing rural telehealth access. This initiative recognizes the unique problems facing rural Americans that need access to critical care services through telehealth platforms. The Committee encourages agencies involved in this initiative to prioritize opportunities to continue the expansion of telehealth services, close the digital divide, and not leave rural communities behind.

National Institutes of Health

National Institute on Aging - Clinical Trials.- The agreement directs NIA to work with ADRCs and other organizations to promote participation in clinical trials within underrepresented populations and, to the maximum scientifically-feasible extent, reduce the burden of participating. These efforts should include expanding community engagement and outreach to these populations, incentivizing trial locations in areas of unmet need, encouraging the diversity of clinical trial staff, allowing appropriate flexibility in trial design and inclusion and exclusion criteria, and utilizing technology like remote patient monitoring, where appropriate, to facilitate clinical trial participation and retention. Further, the agreement urges NIA to provide an assessment of the data and metrics it collects related to the planning, recruitment, and retention of clinical trial participants from underrepresented communities and, when possible, how those data have been or plan to be used in grant-making decisions. The assessment should also address how NIA plans to provide more timely data to the Committees and greater transparency to the public about the planning, engagement, and recruitment efforts of its extramural grantees, including a focus on addressing barriers to inclusive and representative enrollment such as eligibility criteria, language accessibility, and adequate planning for diverse enrollment among grantees. The agreement requests that NIA provide this assessment within 180 days of enactment of this Act. In addition, with various treatments for Alzheimer's disease in the pipeline, the agreement encourages NIA to support a wide range of trials, including those with a patient-based national registry of regulatory grade, longitudinal evidence for patients receiving any FDAapproved disease modifying therapies for Alzheimer's disease in real-world clinical practice.

Substance Abuse and Mental Health Services Administration (SAMHSA)

Opioid Use in Rural Communities .- The agreement encourages SAMHSA to support initiatives to
advance opioid use prevention, treatment, and recovery objectives, including by improving access
through telehealth. SAMHSA is encouraged to focus on addressing the needs of individuals with
substance use disorders in rural and medically underserved areas. In addition, the agreement
encourages SAMHSA to consider early interventions, such as co-prescription of overdose
medications with opioids, as a way to reduce overdose deaths in rural areas.



Centers for Medicare & Medicaid Services (CMS)

- **Telehealth and Health Care Access**. —The Committee requests a report in the fiscal year 2024 Congressional Budget Justification on the impact of telehealth on health care access, utilization, cost, and outcomes, broken down by race, ethnicity, sex, age, disability status, and zip code under the Medicaid program and CHIP.
- Evaluation and Management Services (E/M).- The agreement requests an update in the fiscal year 2024 Congressional Justification on a process to evaluate E/M services more regularly and comprehensively
- Transitional Coverage for Emerging Technologies.- The agreement requests an update in the fiscal year 2024 Congressional Justification on this program and related CMS resources.
- **Health Care Fraud and Abuse Control Senior Medicare Patrol.-** Within the amount provided for CMS, the agreement includes \$35,000,000 for this program.

HHS Office of the Secretary

- Broadband Deployment Locations Map.- The agreement directs the Department to submit a
 report to the Committees not less than 120 days after the date of enactment of this Act detailing
 the steps it has taken to coordinate with the Federal Communications Commission and carry out
 its responsibilities to implement the Deployment Locations Map pursuant to Section 60 I 05 of the
 Infrastructure Investment and Jobs Act (P.L. 117-58).
- Telehealth Data. —The Committee recognizes that demand for telemedicine increased in 2020 in response to the COVID—19 pandemic. In addition, the Committee notes disparities in telehealth exist between and within racial and ethnic groups, rural and urban locations, and geographic regions as detailed in a December 2021 report by the Assistant Secretary for Planning and Evaluation. The Committee urges the Secretary, working with CMS and HRSA, to categorize telehealth usage data, including for audio-only services, by Health Professional Shortage Areas. The Committee further urges the Secretary to work across agencies to ensure that improvements to broadband availability are prioritized in those areas with lowest telehealth usage, highest audio-only usage, and a known health professional shortage. The Committee requests an update within 120 days of the date of enactment of this Act on this categorization and broadband availability.

Administration for Strategic Preparedness and Response (ASPR)

• National Emergency Tele-critical Care Network (NETCCN).- The agreement includes \$6,500,000 to continue clinical deployments for the NETCCN, which has helped health systems respond to the COVID-19 public health emergency by accessing skilled telehealth providers, and directs ASPR to make NETCCN partners available to respond to other public health emergencies and disaster response efforts on an as-needed basis. The agreement directs ASPR to submit a spend plan and report to the Committees within 60 days of enactment of this Act on its plans for fully assuming and maintaining operations of the NETCCN from the U.S. Medical Research and Development Command Telemedicine and Advance Technology Research Center.



Drug Enforcement Agency (DEA)

• Special Registration for Telemedicine.—In October 2018, Congress took necessary steps in passing the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (P.L. 115–271) to combat the worsening opioid overdose epidemic. Section 3232 of the Act amends the Controlled Substance Act (CSA) Section 311(h)(2) to require that no later than one year after enactment, the Attorney General, in consultation with the Secretary of Health & Human Services (HHS), propagate final regulations specifying a Special Registration for the use of telemedicine to prescribe controlled substances under the Ryan Haight Act. More than three full years have elapsed since the SUPPORT Act was signed into law with no appreciable progress in moving forward a rulemaking process to implement this key telemedicine provision. The Committee supports efforts by the DEA to enable health care providers to safely prescribe controlled substances remotely and to provide mechanisms that can be used to prevent illegal online drug sales and drug diversion. The Committee directs the DEA to promulgate final regulations specifying the circumstances in which a Special Registration for telemedicine may be issued and the procedure for obtaining the registration.