# Documents for the Record

## Subcommittee on Health Markup

## May 16, 2024

**Majority:**

- May 15, 2024 – Statement submitted by the Advanced Care at Home Coalition
- May 15, 2024 – Statement submitted by the American Telemedicine Association
- May 15, 2024 – Statement submitted by the Association of University Centers on Disabilities and Autism Society
- May 15, 2024 – Statement submitted by the Association of University Centers on Disabilities on H.R. 7213
- May 15, 2024 – Statement submitted by the EveryLife Foundation
- May 15, 2024 – Statement submitted by Laurie Fenton Ambrose, President & CEO, GO2 for Lung Cancer
- May 16, 2024 - Statement submitted by Autism Speaks
- May 16, 2024 - Statement submitted by the American Association for Respiratory Care
- May 16, 2024 - Statement submitted by the American Physical Therapy Association
- May 16, 2024 - Statement submitted by the American Speech-Language-Hearing Association
- May 16, 2024 - Statement submitted by The Association for Behavioral Health and Wellness
- May 16, 2024 - Statement submitted by the Children's Hospital Association
- May 16, 2024 - Statement submitted by the Muscular Dystrophy Association

**Minority:**

- April 7, 2022 – CMS Memorandum, "Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers"
- May 7, 2024 – Coalition letter in support of H.R. 6664
- May 15, 2024 – Statement submitted by the AFSCME
- May 15, 2024 – Statement submitted by the SEIU
- May 15, 2024 – Coalition letter in opposition to H.R. 468 and H.R. 3227
- May 16, 2024 – Statement submitted by the Cystic Fibrosis Foundation
- May 16, 2024 – Statement submitted by the Federation of American Hospitals

May 15, 2024

The Honorable Cathy McMorris Rodgers
Chair
House Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Buddy Carter
U.S. House of Representatives
Washington, DC 20515

The Honorable Lisa Blunt Rochester
U.S. House of Representatives
Washington, DC 20515

Dear Chair Rodgers, Ranking Member Pallone, Representative Carter and Representative Blunt Rochester:

The Advanced Care at Home Coalition (the ACH Coalition), a group of like-minded stakeholders focused on creating a pathway to permanent coverage for advanced care at home services, writes to thank you for your leadership in supporting the continuation of the hospital at home waiver program. We greatly appreciate the inclusion of a five-year extension of the waiver program in the amendment in the nature of a substitute (AINS) to H.R. 7623, the "Telehealth Modernization Act", which the Subcommittee on Health at the House Energy and Commerce Committee is marking up on Thursday, May 16.

This critically important provision would extend the Centers for Medicare & Medicaid Services (CMS) Acute Hospital Care at Home (AHCaH) waiver flexibilities through 2029. The ACH Coalition applauds the five-year waiver extension contained in this amendment, which demonstrates an ongoing commitment to increasing access to care in the home through hospital at home programs.

Today, according to CMS, 327 hospitals across 134 systems in 37 states are approved for the AHCaH waiver program. This program provides an important pathway to safe, high-quality care for Medicare patients in the comfort of their homes. Without Congressional action, this vital program will expire at the end of 2024.

Notably, the five-year waiver extension included in the AINS to H.R. 7623, the "Telehealth Modernization Act", will provide the stability and predictability necessary for providers and plans to scale nascent programs to sustainable levels, while also allowing for increased provider and patient participation, enhanced data collection, continued spreading of best practices, and improved access to underserved populations.

The ACH Coalition remains committed to the development of a permanent pathway for advanced care at home programs that is accessible, safe, high-quality, equitable, and innovative, but we understand that policymakers seek more data and experience to fully analyze the value and outcomes of

the program. The five-year extension of the waiver program included in this amendment will allow for robust data collection and an opportunity for more patients to have access to this model of care. Thank you again for your leadership and we look forward to being a resource to you and your staff throughout the legislative process.

Sincerely,

Advanced Care at Home Coalition
(www.achcoalition.org)

cc:
The Honorable Brett Guthrie, Chair, Subcommittee on Health
The Honorable Anna Eshoo, Ranking Member, Subcommittee on Health

May 15, 2024

The Honorable Brett Guthrie
Chair of House Energy and Commerce Health Subcommittee
2125 Rayburn Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member of House Energy and Commerce Health Subcommittee
2125 Rayburn Office Building
Washington, DC 20515

**Re: ATA Action Statement for the Record for House Energy and Commerce Health Subcommittee Markup**

On behalf of ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, thank you for your continued support of telehealth and holding this markup on important legislation that would extend many of the Medicare telehealth flexibilities, without inappropriate guardrails such as in-person requirements, ensuring access to lifesaving and effective care well after December 31, 2024. We also appreciate the Committee's tenacity to act on telehealth earlier this year rather than later to provide certainty for patients and providers across the country and provide U.S. healthcare systems enough time to implement appropriate virtual tools, technologies, programs, and processes moving forward.

ATA Action is supportive of the following bipartisan legislation up for consideration at the markup:

- **Amendment in Nature of a Substitute for Telehealth Modernization Act** (HR 7623) This legislation would extend many Medicare telehealth flexibilities through the end of CY2026 including audio-only coverage, waiving the originating and geographic site restrictions, allowing Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to bill as distant site providers and be reimbursed at a fair rate, and allowing physical therapists, occupational therapists, speech-language pathologists, and audiologists to be covered for rendering telehealth services. The amendment would also further postpone the arbitrary in-person requirement for telemental health services. Reinstating this requirement could disrupt the 80% of Medicare beneficiaries who have chosen to see their providers virtually without an in-person visit. This is crucial, particularly at a time when our behavioral health providers are in short supply, and our communities are grappling with ongoing mental health challenges. Lastly, the innovative and critical Acute Hospital Care at Home Program would be extended for five more years. Although ATA Action would prefer to make these provisions permanent, we understand the current dynamics and support a two-year extension. We hope that as this bill progresses, the full committee will take a close look at the guardrails proposed, such

as the incident to modifier, to ensure they are feasible and will not lead to unintended consequences.

- **Amendment in Nature of a Substitute for PREVENT DIABETES Act** (HR 7856) would allow all CDC-recognized delivery modalities, including virtual diabetes prevention platforms and suppliers, to participate in the Medicare Diabetes Prevention Program through the end of CY2026. Although ATA Action prefers the original legislative text, we do support this amended version. Enacting this legislation is imperative to help address the ongoing diabetes crisis in the United States which impacts 1 in 5 Medicare beneficiaries.

- **Expanding Remote Monitoring Access Act** (HR 5394) A major hurdle for the remote monitoring industry over the past few years, specifically since the Public Health Emergency (PHE) ended on May 11, 2023, has been the 16-day data collection requirement over a 30-day period for remote patient monitoring and remote therapeutic monitoring technologies. During the PHE, CMS waived the 16-day requirement, lowering it to two days of data collection, which was found to be effective and cost-saving in many use cases. This legislation would extend the remote monitoring two-day data collection minimum over a 30-day period for two years. The remote monitoring industry is already on thin margins; therefore, we strongly urge the Committee to take the lead and advance this bill.

- **Amendment in Nature of a Substitute for Sustainable Cardiopulmonary Rehabilitation (CR) Service in the Home Act** (HR 1406) would restore access to virtual cardiac and pulmonary rehabilitation services for hundreds of thousands of Medicare beneficiaries through CY2026. When many of the Medicare telehealth flexibilities were extended through the end of CY2024, this policy was unfortunately left behind, creating a tremendous gap in care. This flexibility allowed patients to complete cardiac and pulmonary rehabilitation programs from home rather than having to travel to a hospital, rehab center, or physician's office. Since its expiration at the end of the PHE on May 11, 2023, many of these virtual CR programs shut down. Unless Congress takes immediate action, these virtual CR programs will remain closed.

- **Supporting Patient Education and Knowledge (SPEAK) Act of 2023** (HR 6033) would require the HHS Secretary to publish guidance and best practices on services furnished via telehealth to individuals with limited English proficiency.

We urge immediate action to advance these bills out of the subcommittee and full committee to be considered on the House floor as soon as possible.

**A few other ATA Action legislative priorities that have advanced and await House floor consideration include the:**

- Preserving Telehealth, Hospital, and Ambulance Act (HR 8261) – unanimously passed out of the Ways and Means Committee last week. See ATA Action's statement of support here.
- Telehealth Expansion Act (S.1001, HR 1843) – would permanently allow individuals with HDHP-HSAs to receive telehealth coverage prior to meeting a deducible.
- Medicare Telehealth Privacy Act of 2023 (HR 6364) – would ensure all providers home addresses remain private.
- Telehealth Benefit Expansion for Workers Act of 2023 (HR 824) – would permanently allow telehealth to be an excepted benefit.

**An additional telehealth priority supported by ATA Action that hasn't been acted on to date and we believe if left omitted would lead to a tremendous gap in care is the remote prescribing of controlled substances:**

- Before the pandemic, the Ryan Haight Act mandated an in-person visit before prescribing controlled substances via telehealth. This requirement was waived during the pandemic and is set to expire at the end of 2024. This has significantly increased access to essential treatments for millions of patients. The DEA is supposed to release proposed rules this year outlining a special registration process for telehealth prescriptions of controlled substances. This process could verify providers' credentials and history to protect against misuse, allowing qualified providers to receive DEA approval for virtual prescribing. We kindly request that Congress continues to urge DEA to maintain these critical and lifesaving flexibilities by either publishing a special registration proposed rule soon or extending the current flexibility post-2024.

As Congress continues to contemplate telehealth policy post CY2024, we wanted to provide the Committee with key studies and research that dispel myths that telehealth leads to increased health care costs, overutilization, and is more suspectable to fraud, waste, and abuse than in-person care. For example:

- **Telehealth is Cost Effective:** Telehealth has been proven to reduce costs for hospitals and provider organizations, as well as for consumers. Several recent studies have shown that a telehealth consultation is as good as, and in some instances better than, in-person care. Telehealth also enables consumers to receive care sooner, hence reducing disease progression and costs of care.[1,2,3]

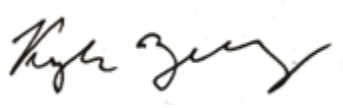
[1] Li, KY, Kim, PS, Thariath, J, Wong, ES, Barkham, J, & Kocher, KE. (2023). Standard nurse phone triage versus tele–emergency care pilot on Veteran use of in-person acute care: An instrumental variable analysis. *Acad Emerg Med*.;*30*: 310-320.
[2] Ascension. (n.d.). Task Force on Telehealth Policy. https://connectwithcare.org/wp-content/uploads/2020/08/Ascension-Telehealth-Data.pdf
[3] National Committee for Quality Assurance. (n.d.). Findings and Recommendations: Telehealth Effect on Total Cost of Care. https://www.ncqa.org/programs/data-and-information-technology/telehealth/taskforce-on-telehealth-policy/taskforce-on-telehealth-policy-findings-and-recommendations-telehealth-effect-on-total-cost-of-care/

- **Telehealth Does Not Lead to Overutilization:** Telehealth has proven to reach vulnerable and underserved patients who otherwise would never have received care in the first place due to limited transportation, childcare, time off of work, etc. Many studies have proven that utilization of telehealth has decreased and leveled off since the midst of the pandemic.[4]

- **Telehealth is Not More Vulnerable to Fraud, Waste, and Abuse (FWA):** Telehealth is not more susceptible to FWA than in-person services. The Office of Inspector General (OIG) recently released a report that found Medicare telehealth did not increase fraud, waste, and abuse. Specifically, during the first nine months of the PHE -- March 2020 to November 2020 -- Medicare practitioners correctly billed for telehealth evaluation and management services in 95% of cases. There have been a few recent OIG and Department of Justice (DOJ) Medicare cases that have been mislabeled as "telefraud" when it is traditional telemarketing scams which have been around for decades. ATA Action does appreciate and understand this valid concern but there are ample safeguards in place at the federal and state level that ensure program integrity and protect against fraud, waste, and abuse – see list of state and federal regulatory frameworks here.[5]

ATA Action is here as a resource and looks forward to continuing to work with the Committee to ensure that the appropriate telehealth policies are implemented in a timely manner without arbitrary and unnecessary barriers to care such as in-person, brick-and-mortar, or geographic requirements. Thank you for all your historic and current work on telehealth. Please reach out to [redacted] if you have any questions.

Kind regards,



Kyle Zebley
Executive Director
ATA Action

[4] Patients-Providers-and-Plans-Increase-Utilization-of-Telehealth-Recent-Stats-2.18-2.pdf (americantelemed.org)
[5] Telehealth-Integrity.pdf (americantelemed.org)

# Background and Recommendations for Reauthorization of the CARES Act in 2024

The **Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act** (P.L. 116-60) was first signed into law by President George W. Bush in 2006 (P.L. 109-416). The purpose of the law is to create a coordinated response and increase investments across the U.S. Department of Health and Human Services (HHS) to address the dramatically rising numbers of children and adults diagnosed with autism.

According to the Centers for Disease Control and Prevention (CDC), approximately 1 in 36 children have been diagnosed with autism – an increase of approximately 300 percent since 2006.[1]. Autism Spectrum Disorder (ASD), hereafter referred to as autism, is defined by a certain set of behaviors and is often referred to as a "spectrum condition". The cause of autism is unknown and is a complex, lifelong developmental condition that typically appears during early childhood and can impact a person's social skills, communication, relationships, and behavior. Autism impacts each person differently and to varying degrees.

The law was reauthorized in 2019 (P.L. 116-60). The bipartisan bill was passed unanimously in the House of Representatives and in the Senate. The law must be reauthorized by September 30, 2024. Following is a summary of authorized activities under the CARES Act.

***Interagency Committee in the U.S. Department of Health and Human Services***

The Interagency Autism Coordinating Committee (IACC) is a Federal advisory committee that coordinates Federal efforts and provides advice to the Secretary of HHS. The IACC is required to (1) develop and annually update a strategic plan for autism research, (2) develop and annually update a summary of advances in autism research, and (3) monitor Federal activities related to autism. Through its inclusion of both Federal and public members, the IACC helps to ensure that a wide range of ideas and perspectives are represented and discussed in a public forum.

***Programs in the National Institutes of Health***

The National Institutes of Health (NIH) is the largest biomedical research agency in the world and houses the Office of Autism Research Coordination (OARC), which assists the IACC by communicating information about autism/developmental disability research activities to Congress, government agencies and the public.

The Autism CARES Act supports NIH-funded research including Centers for Excellence that conduct basic and clinical research into autism. This research includes investigations into the causes, diagnosis, early and ongoing detection, prevention, and treatment of autism across the lifespan in the fields of developmental neurobiology, genetics, genomics, psychopharmacology, developmental psychology, behavioral psychology, and clinical psychology.

[1] "Data and Statistics on Autism Spectrum Disorder". Centers for Disease Control and Prevention. April 4, 2023. https://www.cdc.gov/ncbddd/autism/data.html

The Eunice Kennedy Shriver National Institute of Child Health and Human Development supports research on the individual and combined effects of evidence-based interventions in real world settings. The National Institute of Mental Health supports research aimed at developing and testing service system interventions that can be broadly implemented and rapidly engage young children with autism in evidence-based treatment and services early in life.

***Programs in the Centers for Disease Control and Prevention***

The Centers for Disease Control and Prevention (CDC) support the Autism and Developmental Disabilities Monitoring Network, a group of programs that estimate the number of children with autism and other developmental disabilities living in different areas of the United States. The CDC has also established the Centers for Autism and Developmental Disabilities Research and Epidemiology Network. These regional centers of excellence are working, in part to, help identify factors that may put children at risk for autism and other developmental disabilities. Learn The Signs. Act Early encourages parents of children ages birth to 5 years and providers who care for them to learn the signs of healthy development (developmental milestones), monitor every child's early development, and act early on possible developmental concerns. A dedicated cohort of 63 Act Early Ambassadors, spanning 49 states and Washington DC, as well as 4 territories and 3 American Indian and Alaskan Native tribal organizations, diligently deliver these resources to their communities through training, community meetings, and widespread resource distribution.

***Programs in the Health Resources and Services Administration***

There is a tremendous national shortage of personnel trained to screen, diagnose, and treat individuals with autism and other developmental disabilities. On average, most children are not identified and diagnosed until after age four, even though diagnosis as early as age two is possible.[2] The Maternal and Child Health Bureau of the Health Resources and Services Administration works to increase efforts to provide training to health and other professionals to screen for and diagnose (or rule out) autism and other neurodevelopmental disabilities, and to increase evidence-based interventions for children and adults with autism and other neurodevelopmental disabilities.

The Leadership Education in Neurodevelopmental and Related Disabilities programs and the Developmental Behavioral Pediatrics (DBP) Training programs provide interdisciplinary training to address the needs of children and adults with autism and other neurodevelopmental disabilities. In Fiscal Year 2021, LEND and DBP programs provided diagnostic services to over 137,000 children; provided training to over 22,000 trainees in pediatrics, other health professions and people with lived experience.

Research programs support four research networks to develop an interdisciplinary, multicenter research forum for scientific collaboration and infrastructure building, and provides leadership in research to advance the evidence base on effective interventions for children, adolescents, and adults with autism and other neurodevelopmental disabilities across the lifespan including two Single Investigator Innovation Programs to support focused research on priority, emerging and underdeveloped research areas in autism and other developmental disabilities; one Autism Field-Initiated Research Studies program to support innovative intervention studies; and one Autism Secondary Data Analysis Research Study to conduct secondary analysis of existing databases to determine evidence-based practices for interventions.

In Fiscal Year 2021, research programs conducted 95 studies on physical and behavioral health issues, screening and diagnostic measures, early intervention, and transition to adulthood. The

[2] "Report to Congress on Activities Related to Autism Spectrum Disorder and Other Developmental Disabilities". Interagency Autism Coordinating Committee. March 2019. https://iacc.hhs.gov/publications/report-to-congress/2018/diagnosis.shtml

Autism Intervention Research Network on Physical Health conducts research on effective interventions for children and adolescents with autism and neurodevelopmental disabilities with a focus on addressing the physical health and well-being across the lifespan.

***Conclusion and Recommendations for the Reauthorization of the Autism CARES Act***

The Autism CARES Act is the most comprehensive federal law addressing the urgent needs of children, adolescents and adults with autism. Over its 17-year history, this law has resulted in a significant increase in our understanding of autism and related neurodevelopmental disabilities.

However, with one in 36 individuals diagnosed with autism in the United States, the urgency to continue the work in research, surveillance, professional training, and the development of effective interventions and supports must continue and be increased. There is still much more work to be done to improve the quality of lives of individuals with autism across the lifespan and to support their families.

AUCD
Association of University Centers On Disabilities



May 15, 2024

Dear Chairman Guthrie, Ranking Member Eshoo, and Members of the Subcommittee on Health,

We are writing to you today to thank you for including the Autism CARES Act of 2024, H.R. 7213, in tomorrow's Energy and Commerce Subcommittee on Health mark-up. The Association of University Centers on Disabilities (AUCD) fully supports H.R. 7213 as amended. This piece of legislation is crucial to maintaining and improving the monitoring, training, and research programs throughout the U.S. Department of Health and Human Ser[redacted]als with autism, other neurodevelopmental disabilities, and their families.

AUCD is the national non-profit membership organization that supports and promotes a national network of 143 university-based interdisciplinary programs, including the University Centers for Excellence in Developmental Disabilities, Leadership Education in Neurodevelopmental Disabilities programs, and Eunice Kennedy Shriver Intellectual and Developmental Disability Research Centers. AUCD members conduct research, create innovative programs, provide training, and disseminate information about best practices in the service delivery system that support people with disabilities and their families in every state and territory. The programs serve as a bridge between the university and the community, bringing together the resources of both to achieve meaningful change.
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The CARES Act was first signed into law by President George W. Bush in 2006 (P.L. 109-416). The purpose of the CARES Act is to create a coordinated response and increase investments across the U.S. Department of Health and Human Services to address the dramatically rising numbers of children and adults diagnosed with autism. According to the Centers for Disease Control and Prevention (CDC), approximately 1 in 36 children have been diagnosed with autism – an increase of approximately 300 percent since 2006.

To improve the diagnosis, treatment and health and well-being of children and adults with autism and other neurodevelopmental disabilities, two important training programs are included in the CARES Act. The Leadership Education in Neurodevelopmental and Related Disabilities (LEND) programs and the Developmental Behavioral Pediatric (DBP) programs support the training of future professionals in a range of professional disciplines that diagnose and manage the health of individuals with autism and other neurodevelopmental disabilities. In Fiscal Year 2021, LEND and DBP programs provided diagnostic services to over 137,000 children; and provided training to over 22,000 trainees in pediatrics, other health professions, and people with lived experience.

The LEND and DBP programs, in addition to the other training, research, and monitoring included in the CARES Act, are working to effectively address the

AUCD
Association of University Centers On Disabilities

rising number of children and adults diagnosed with autism and other neurodevelopmental disabilities to ensure they have the best opportunity to receive the care and treatment they need so they can live inclusive lives in their communities. The proposed amendments to the CARES Act will ensure the CARES Act can continue to effectively coordinate programs across the U.S. Department of Health and Human Services to improve the health and well-being of children and adults with autism and other neurodevelopmental disabilities.

Thank you for considering our views. If you have any questions, please to do hesitate to contact Cindy Smith, Director of Public Policy at [redacted]. We have also attached to this email, a brief written about the CARES Act that maybe helpful to your office.

Regards,

John Tschida
Executive Director, Association of University Centers on Disabilities

cc: Chair McMorris Rogers, Ranking Member Pallone, Representative Smith, and Representative Cuellar

**Statement from EveryLife Foundation for Rare Diseases**
**House Energy & Commerce Subcommittee on Health Markup:**
**May 15, 2024**

Chairs Rodgers and Guthrie and Members of the Subcommittee,

On behalf of the EveryLife Foundation for Rare Diseases, we thank you for convening this week's hearing to review bipartisan legislation that will help to support the needs of people and families impacted by rare diseases and disorders. Rare diseases impact more than 30 million Americans and costing our nation $1 trillion or more each year when accounting for medical, non-medical, and indirect costs[1].

The EveryLife Foundation for Rare Diseases is a 501 (c)(3) nonprofit, nonpartisan organization dedicated to empowering the rare disease patient community to advocate for impactful, science-driven legislation and policy that advances the equitable development of and access to lifesaving diagnoses, treatments, and cures. EveryLife's establishment of the Community Congress, a diverse coalition comprised of patient advocacy organizations, industry leaders, coalition groups, and other relevant stakeholders guides our policy efforts and provides advice and insight on important policy issues impacting the rare disease community.

Several bills included in the markup are priorities of the EveryLife Foundation and represent critical steps forward in our collective effort to accelerate the development and availability of therapies for rare diseases. We urge the Committee to vote in support of the below bills. Individually and collectively, they represent important progress to bring therapies for the 95 percent of rare diseases without a FDA-approved therapy.

**H.R. 7384, the Creating Hope Reauthorization Act of 2024**
Without Congressional action, the Rare Pediatric Priority Review Voucher (PRV) Program will expire on September 30, 2024, leaving one less tool to bring treatments to a rare disease community in which only five percent of diseases have an FDA-approved treatment. It is imperative that we continue to advance solutions to treat these devastating diseases. Allowing the Rare Pediatric PRV program to expire would eliminate a powerful incentive for the development of treatments for the 70 percent of rare diseases that start in childhood[2]. PRVs

[1] Yang G, Cintina I, Pariser A, Oehlrlein E, Sullivan J, Kennedy A. The national economic burden of rare disease in the United States in 2019. Orphanet J Rare Dis. 2022;17:163
[2] Nguengang Wakap S, Lambert DM, Olry A, Rodwell C, Gueydan C, Lanneau V, et al. Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database. Eur J Hum Genet. 2020;28(2):165–73.

have been associated with an increased rate of progress throughout the clinical trial process, leading to product approvals to treat multiple rare diseases such as Progeria syndrome, Spinal Muscular Atrophy, Sickle Cell Disease, Rett syndrome, and other conditions that previously lacked any FDA-approved treatments. The Creating Hope Reauthorization Act supports that an important piece of the rare disease development incentive puzzle remains intact for another four years.

**H.R. 4758, the Accelerating Kids Access to Care Act:**
Many within the rare community are required to travel out of state to receive the healthcare they need. An EveryLife Foundation study found that the average number of out-of-state trips for rare disease patients just to obtain a diagnosis was 2.4[3]. For kids with Medicaid or CHIP coverage, the long delays associated with obtaining approval to see specialists located outside of their home state can result in irreversible adverse health outcomes. One aspect of this approval, the process to screen and enroll out-of-state physicians as eligible providers in the children's home state, can be improved through the simple changes proposed in the Accelerating Kids Access to Care Act. This legislation will allow pediatric providers to enroll more efficiently in multiple state Medicaid programs for a five-year period, enabling faster access to specialized rare disease care not available in a patient's home state. Streamlining this process for children with rare diseases will help to ensure timely and appropriate treatment for our youngest patients.

**H.R. 7383, the Retaining Access and Restoring Exclusivity (RARE) Act:**
A 2021 court ruling determined that orphan drug exclusivity under the Orphan Drug Act grants a manufacturer exclusivity across an entire disease or condition, even if it has only had a drug approved for one population or indication. This was contrary to how the FDA has interpreted the Orphan Drug Act over the last several decades. This legislation would specify that the seven-year market exclusivity period for drugs for rare diseases or conditions (i.e., orphan drug exclusivity period) prohibits the approval of other drugs for the same approved use or indication with respect to the disease or condition rather than applying to all uses within the disease or condition. The proposal would ensure that the FDA can continue to approve a drug that aims to serve different patient populations such as pediatric approval for a drug that has exclusivity based on an adult approval.

**Conclusion**
Thank you for your long history of supporting the rare disease community. This week's markup signifies important progress for the rare disease community and we look forward to supporting your efforts to shepherd these bills into law. We stand ready to assist the committee as you continue your consideration of these and other polices relevant to all impacted by rare diseases.

[3] Yang G, Cintina I, Pariser A, Oehlrlein E, Sullivan J, Kennedy A. The national economic burden of rare disease in the United States in 2019. Orphanet J Rare Dis. 2022;17:163

**Statement by Laurie Fenton Ambrose, President & CEO, GO2 for Lung Cancer on H.R. 4534, Women and Lung Cancer Research and Preventive Services Act of 2023 as part of the Legislative Proposals to Support Patients and Caregivers Hearing.**

**Wednesday, February 14, 2024**

**Submitted for the record to the House Energy and Commerce Committee and Subcommittee on Health**

Thank you Committee Chair McMorris Rodgers and Subcommittee Chair Guthrie distinguished members and all who have contributed to the discussions that led to holding today's important hearing that includes H.R. 4535, The Women and Lung Cancer Research & Preventive Services Act of 2023, introduced in the House by Congressman Brendan Boyle (D-PA) and Brian Fitzpatrick (R-PA), on legislative proposals to support patients and caregivers.

On behalf of GO2 for Lung Cancer, the leading national lung cancer organization founded by patients, survivors, and caregivers, we are proud to provide for the record our strongest endorsement of H.R. 4535 and to offer additional comments on the importance of advancing this vital legislation – now – for the tens of thousands of women who are at risk for or have been diagnosed with lung cancer.

Most people are not aware that lung cancer is the leading cause of cancer death in women – more than breast and cervical cancers combined. It is now estimated that every day 162 women die from the disease – one woman every 8.9 minutes. It is also estimated that 234,580 new cases of lung cancer are expected this year, and an estimated 125,070 lives will be lost to the disease. This "hidden" women's cancer is the least funded cancer, in terms of research dollars per death, of all the major cancers and one of the only cancers where patients are routinely blamed as responsible for their condition.

Reports continue to document how lung cancer develops differently in women and men within many facets of the disease including risk factors, clinical characteristics, progression, and length of survival.

For example, several years ago, a significant study by the National Cancer Institute (NCI) and the American Cancer Society (ACS) published in the New England Journal of Medicine on May 24, 2018, indicated that the incidence rates of lung cancer among White and Hispanic women born after 1965 are now higher than among their male counterparts, a reversal not correlated to changes in their smoking rates. The lung cancer incidence rates among young African American and Asian women were closer but do not yet exceed those

of their male counterparts. This NCI-ACS study concluded by calling for more research into this disturbing precedent.

GO2 has witnessed lung cancer's unique and devastating impact on women. We placed an early spotlight on the need for increased research into women and lung cancer. Beginning in 2010, GO2 partnered with The Connors Center for Women's Health and Gender Biology at Brigham and Women's Hospital (BWH) after they released a study, "Out of the Shadows," which highlights the gaps in current knowledge about lung cancer's lethality, summarizes existing research on sex and gender differences in lung cancer, identifies shortcomings in current research funding that would provide better understanding of these biological differences, and recommends steps to reduce the burden of this disease in women and men.

In 2016, BWH released an updated report, Lung Cancer: A Women's Health Imperative, as a follow-up to bring lung cancer in women "Out of the Shadows." This report brought even greater awareness of the need for a national strategy to address the study of sex- and gender-specific aspects of the disease. The report was released at a Congressional briefing on Women and Lung Cancer hosted by the Lung Cancer Alliance (now known as GO2 for Lung Cancer) in coordination with the Congressional Lung Cancer Caucus and ultimately became the basis of the bi-partisan, bi-cameral Women and Lung Cancer Research and Preventive Services Act, first introduced in 2016 and re-introduced in 2023.

It is our hope through H.R. 4534, the Women and Lung Cancer Research and Preventive Services Act of 2023, we will gain a better understanding of the roles that genetic, hormonal, behavioral, and environmental factors play in this lethal disease, uncover differences in incidence, prevalence, and survivability to identify treatment responses between men and women.

Increasing basic and clinical research knowledge of the disease will make the public aware of the vital need to create a national strategy that accelerates implementing lung cancer screening for women and bridge the gaps in lung cancer innovations.

Thank you for the opportunity to submit written testimony in support of people living with lung cancer. We share the obligation to serve the public and we stand ready to assist the committee and our bill sponsors to advance this legislation to passage, in this session of the 118th Congress.

Laurie Fenton Ambrose
President & CEO
GO2 for Lung Cancer

**Autism Speaks** *Support of the Autism CARES Act of 2024 (H.R. 7213)*

**House Committee on Energy and Commerce**

**Subcommittee on Health, Markup of 23 Bills**

*May 16, 2024 at 10:00am – Rayburn 2123*

Autism Speaks is a national, non-profit organization dedicated to creating an inclusive world for all individuals with autism throughout their span. We do this through advocacy, services, supports, research and innovation, and advances in care for autistic individuals and their families. We are grateful for this committee's leadership, and particularly Chair Guthrie, Ranking Member Eshoo, Chair McMorris Rodgers, and Ranking Member Pallone for convening this markup and recognizing the urgent need to invest in autism research and training programs to ensure better care and well-being for autistic people through the *Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2024 (H.R. 7213)*. We are also grateful to the co-chairs of the Autism Caucus, Reps. Chris Smith and Henry Cuellar, for introducing this important bill.

The Autism CARES Act exemplifies how bipartisan collaboration has fundamentally transformed our understanding of autism over the past two decades and can continue to shape the landscape of services and support for the **1 in 36 children and 1 in 45 adults on the autism spectrum in the United States**.[1][2] As autism prevalence has increased, our understanding and acceptance of the unique strengths and challenges of autistic individuals has fundamentally changed, and because of investments made as result of the Autism CARES Act, we are poised to take the next steps for each autistic person to live their best life.

The Autism CARES Act of 2024 builds on progress that has been made through previous iterations of the law and will help propel forward critical research and training programs that benefit people with autism and their families. But for these initiatives to continue, **the Autism CARES Act must be renewed before September 30, 2024**, when significant provisions of the current law, the Autism CARES Act of 2019, sunset.

Since first passing as a standalone bill in 2006, the legislation now known as the Autism CARES Act has been the **single most important driver of federal investment in autism research and training programs.** Initiatives by the National Center on Birth Defects and Developmental Disabilities, including the Autism and Developmental Disabilities Monitoring (ADDM) Network, have led to improvements in early intervention services, a lower average diagnosis age, and a better

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[1] Maenner MJ, Warren Z, Williams AR, et al. Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 8 Years — Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2020. MMWR Surveill Summ 2023;72(No. SS-2):1–14. DOI: http://dx.doi.org/10.15585/mmwr.ss7202a1.

[2] Dietz PM, Rose CE, McArthur D, Maenner M. National and State Estimates of Adults with Autism Spectrum Disorder. J Autism Dev Disord. 2020;50(12):4258-4266. doi:10.1007/s10803-020-04494-4

understanding of the prevalence of autism. In large part due to the research that the Autism CARES Act has funded, through programs like the National Institutes of Health's Autism Centers of Excellence, we also have a much clearer picture of the significant disparities that autistic people experience in terms of access to quality health care, daily life supports and services, and employment opportunities. For example, we know that autism people experience co-occurring physical and mental health conditions at much higher rates, with about three-quarters of autistic children having one or more mental health conditions.[3]

Through support of clinical and community-focused programs, the Autism CARES Act also ensures this knowledge reaches practitioners and families. Thanks to the Autism CARES Act, professionals are better equipped to meet the ever-changing and diverse needs of autistic people and other people with developmental disabilities. The Leadership Education in Neurodevelopmental and Other Related Disabilities (LEND) sites and Developmental Behavioral Pediatric Training Programs authorized by the Autism CARES Act prepare future leaders and professionals to deliver high-quality care and services to autistic individuals by promoting the use of evidence-based interventions, training professionals to use valid screening tools, and improving the understanding and awareness of autism. These programs are responsible for thousands of future health professionals being trained in how to provide better health care services for autistic people and other individuals with developmental disabilities.

As far as we have come in terms of our understanding of autism and acceptance of autistic people, there is so much work to do to ensure that every autistic person can access the personalized health care and services and supports that meet their needs. **The Autism CARES Act of 2024 offers the opportunity to help close the gap between what has been recommended for autism research investments and ensure that every autistic person is able to reach their full potential.** This includes investing more in research focused on the daily life challenges of autistic adults and improving our understanding of autism and aging. It includes furthering research on how to reduce disparities in autism diagnoses and access to services. It includes ensuring that we are researching how to best support autistic people who are non-speaking or may need additional communication supports, most notably through the addition of an Autism Intervention Research Network for Communication Needs (AIR-C). It includes investing in more research to how we can best meet the health care and safety needs for autistic people who require 24-hour care and may struggle with harmful or self-injurious behaviors. And it includes intentional efforts to be more inclusive in research activities to ensure that people across the spectrum are represented and we move closer to meeting the entire autism community's outstanding needs.

We are grateful for the subcommittee's review of the Autism CARES Act of 2024 and look forward to working with the Energy and Commerce Committee as the bill moves forward. This committee's leadership is key to ensuring that this strong foundation of federal investment in autism research is fortified and built upon so that federal autism programs meet the current and future needs of autistic individuals and their families.

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[3] Rast, Jessica E., Garfield, Tamara, Roux, Anne M., Koer Miller, Kaitlin H., Hund, Lisa M., Tao, Sha, Kerns, Connor M., Rosenau, Kashia A., Hotez, Emily, Anderson, Kristy A., Shattuck, Paul T., and Shea, Lindsay L. National Autism Indicators Report: Mental Health. Philadelphia, PA: Life Course Outcomes Program, A.J. Drexel Autism Institute, Drexel University, August 2021.

American Association
for Respiratory Care
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Statement from the American Association for Respiratory Care
In response to the
Energy & Commerce Health Subcommittee Mark-up on
May 16, 2024

The American Association for Respiratory Care (AARC) commends Chair Guthrie, Ranking Member Eshoo, and members of the Energy & Commerce Subcommittee on Health for holding today's mark-up and including H.R. 1406, the Sustainable Cardiopulmonary Rehabilitation Services in the Home Act. H.R. 1406 will allow patients to receive cardiac and pulmonary rehabilitation services virtually in their homes since access to these virtual services expired when the COVID-19 public health emergency (PHE) did on May 11, 2023. AARC represents more than 47,000 respiratory therapists who treat patients with chronic respiratory diseases such as chronic obstructive pulmonary disease (COPD) and asthma.

COPD is a costly and prevalent disease and the third leading cause of death in the United States. The hospital readmission rate for COPD is one of the highest, with Medicare beneficiaries presenting with five or more conditions in addition to COPD that add to the cost of their care. COPD and other lung diseases are leading causes of death and growing problem in the United States, and cardiac and pulmonary rehabilitation programs are an important part of the recovery for patients with lung disease who deal with acute events and exacerbations of their conditions. H.R. 1406 will enable more Medicare patients to access these beneficial and life-saving programs.

Participation in pulmonary rehabilitation reduces morbidity, mortality, and hospitalizations while improving patients' quality of life.[1] Despite their effectiveness, participation in cardiac and pulmonary rehabilitation services is low, in part because of the limited availability of hospital-based programs and because the length and frequency of rehabilitation is time-consuming and can be disruptive to patients' lives – especially if it requires significant travel.[2] During the COVID-19 PHE, the Centers for Medicare & Medicaid Services (CMS) temporarily allowed cardiac and pulmonary rehabilitation to be delivered via telehealth under the Hospital Without Walls program. AARC members report, and preliminary research shows, that virtual delivery of pulmonary rehabilitation services increased utilization by eligible patients, resulted in earlier intervention, and improved patient adherence while demonstrating comparable safety and effectiveness to traditional in-person programs.[3,4]

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[1] Zhang, H., Hu, D., Xu, Y., Wu, L., & Lou, L. (2022). Effect of pulmonary rehabilitation in patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis of randomized controlled trials. *Annals of Medicine, 54(1), 262-273*. https://doi.org/10.1080/07853890.2021.1999494.

[2] Augustine, A., Bhat, A., Vaishali, K., & Magazine, R. (2021). Barriers to pulmonary rehabilitation – A narrative review and perspectives from a few stakeholders. *Lung India*. https://doi.org/10.4103/lungindia.lungindia_116_20.

[3] Moulson, N., Bewick, D., Selway, T., Harris, J.R., Suskin, N., Oh, P., Coutinho, T., Singh, G., Chow, C., Clarke, B., Cowan, S., Fordyce, C.B., Fournier, A., Gin, K., Gupta, A.K., Hardiman, S., Jackson, S.K., Lamarche, Y., Lau, B.,…Krahn, A.D. (2020). Cardiac Rehabilitation During the COVID-19 Era: Guidance on Implementing Virtual Care. *Canadian Journal of Cardiology, 36(8), 1317-1321*. https://doi.org/10.1016/j.cjca.2020.06.006.

[4] Reychler, G., Piraux, E., Beaumont, M., Caty G., & Liistro, G. (2022). Telerehabilitation as a Form of Pulmonary Rehabilitation in Chronic Lung Disease: A Systematic Review. *Healthcare, 10(9), 1795*. https://doi.org/10.3390/healthcare10091795.

Unfortunately, without Congressional action, pulmonary and cardiac rehabilitation services provided virtually via hospital outpatient providers are and will not be available to this vulnerable patient population, which has caused a major disruption for Medicare patients receiving virtual rehabilitation care and the clinicians providing it. The Sustainable Cardiopulmonary Rehabilitation Services in the Home Act ensures that Medicare permanently covers pulmonary rehabilitation services provided or supervised virtually for patients in their homes. The bill expands access to innovative modes of care delivery. Continuing coverage of telerehabilitation will improve health outcomes for Medicare beneficiaries with chronic lung disease.

The AARC is pleased to support the Sustainable Cardiopulmonary Rehabilitation Services in the Home Act, and we urge the Energy & Commerce Health Subcommittee to advance this bill. For additional information questions, please contact Miriam O'Day at [redacted].

May 16, 2024

The Honorable Brett Guthrie
Chair, Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Anna Eschoo
Ranking Member, Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
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The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
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The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
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**Re: House Energy and Commerce Subcommittee on Health Markup of Healthcare Legislation, May 16, 2024**

Dear Chair Guthrie, Ranking Member Eschoo, Chair McMorris-Rodgers, and Ranking Member Pallone:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) submits the following comments in advance of the House Energy and Commerce Subcommittee on Health's May 16th, 2024 markup of healthcare legislation, including proposals on telehealth. APTA is dedicated to building a community that advances the physical therapy profession to improve the health of society. As experts in rehabilitation, prehabilitation, and habilitation, physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability for individuals across the age span, helping individuals improve overall health and prevent the need for avoidable health care services. Physical therapists' roles include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession's vision of transforming society by optimizing movement to improve the human experience.

"The Economic Value of Physical Therapy in the United States," a recently released APTA report, showcases the cost-effectiveness and economic value of physical therapist services for a broad range of common conditions. The report compares physical therapy with alternative care across a suite of health conditions commonly seen within the U.S. health care system. The report underscores and reinforces the importance of including physical therapists and physical therapist assistants as part of multidisciplinary teams focused on improving patient outcomes and decreasing downstream costs. The committee should consider the insights provided in this report to support access to, coverage of, and payment for physical therapist services, and to support policies that position physical therapists as entry-point providers to ensure beneficiaries have timely access to proven, cost-effective care.

As digital health technologies, including telehealth, expand into the health sector, physical therapists' and physical therapist assistants' access to these delivery tools should be considered in decisions regarding payment, coverage, broadband, and technology infrastructure policies. For example, the APTA report demonstrates that physical therapy-based cancer telerehabilitation programs deliver a net cost-benefit of approximately $4,000 per episode of care.

In the 118th Congress, APTA is supporting several proposals to ensure that Medicare patients maintain coverage of a telehealth visit to their physical therapist or physical therapist assistant. To permanently include physical therapists and physical therapist assistants as authorized telehealth providers in Medicare, APTA strongly endorses H.R. 7623 – the Telehealth Modernization Act, H.R. 8151 – to amend the Social Security Act to expand eligible practitioners to furnish telehealth services, and H.R. 3875 – the Expanded Telehealth Access Act.

The expansion of telehealth payment and practice policies under the Section 1135 waivers during the public health emergency, including permitting physical therapist services to be furnished via telehealth by PTs and PTAs across settings, has demonstrated that many health care needs can be safely and effectively met and that patients can have improved access to skilled care by leveraging these resources. This has been especially beneficial for those patients residing in rural areas who often have access to far fewer providers than other regions and may live a very considerable distance from medical facilities and other health care professionals.

Physical therapists and physical therapist assistants use telehealth as a supplement to in-person services to evaluate and treat a variety of conditions prevalent in the Medicare population, including but not limited to Alzheimer's disease, arthritis, cognitive/neurological/vestibular disorders, multiple sclerosis, musculoskeletal conditions, Parkinson disease, pelvic floor dysfunction, frailty, and sarcopenia.

Physical therapists make determinations, in consultation with patients and caregivers, regarding the appropriate mix of in-person and telehealth services to meet the goals in the plan of care. The evaluation and treatment of a patient via the use of telehealth allows the physical therapist to interact with the patient within the real-life context of their home environment, which is not easily replicable in the clinic. Patient and caregiver self-efficacy are inherent goals of care, and telehealth not only allows a physical therapist to maintain the continuity of care anticipated in the plan of care, but also allows for immediate and effective engagement when a specific challenge arises.

Skilled physical therapist interventions delivered through an electronic or digital medium have the potential to prevent falls, functional decline, costly emergency room visits, and hospital admissions and readmissions. Further, physical therapists already are experienced in modifying exercises for the patient to perform them safely at home, as a home exercise program is a common element of a treatment plan for patients who are treated in person. Examples of PTs and PTAs using telecommunications technology to provide real-time, interactive care include the following:

- Physical therapy practitioners use telehealth technologies to conduct evaluations or reevaluations or provide quicker screening, assessment, and referrals that improve care coordination.

- Physical therapy practitioners provide interventions using telehealth by interacting with the patient in real time to provide instruction in exercise and activity performance; observe return demonstration and offer instruction in modifications or progressions of a program; provide caregiver support; and promote self-efficacy.

- Physical therapy practitioners provide verbal and visual instructions and cues to modify how patients perform various activities. They also may suggest that the patient or caregiver modify the environment for safety reasons or to potentially produce even more optimal outcomes.

- Physical therapy practitioners use telehealth technologies to provide prehabilitation and conduct home safety evaluations.

- Physical therapy practitioners use telehealth technologies to observe how patients interact with their environment and/or other caregivers, and to provide caregiver education.

- Physical therapy practitioners can assess the influence of activity modification strategies and activities to determine effectiveness immediately rather than waiting for the next in-person visit.

- Physical therapists use telehealth to reduce the number of in-clinic visits and still maintain important follow-up care. This might reduce travel time and/or burden for a patient, which, for some conditions, might result in faster healing. This also prevents any delays in modifying a program when it needs to be upgraded or downgraded.

- Physical therapists can use technology to satisfy supervision requirements.

- A physical therapist can co-treat with another clinician who is treating via real-time audio and visual technology.

- A treating physical therapist can consult directly with another physical therapist or physical therapist assistant for collaboration and/or to obtain specialty recommendations to incorporate into an existing plan of care.

- Physical therapists use telehealth for quick check-ins with established patients.

**Policy Recommendation**

APTA supports the ability of Medicare beneficiaries to maintain the option, when appropriate, to have physical therapist services provided via telehealth. Permitting services to be furnished via telehealth by PTs and PTAs has provided greater options for patients to access care. APTA strongly urges Congress to enact legislation to maintain the current policy and add physical therapists and physical therapist assistants as permanently authorized telehealth providers under Medicare before the expiration of the current waiver on Dec. 31, 2024.

Again, we urge the Subcommittee to consider and pass the following APTA-endorsed legislation to ensure that physical therapists and physical therapist assistants are permanent authorized telehealth providers in Medicare: H.R. 7623 – the Telehealth Modernization Act, H.R. 8151 – to amend the Social Security Act to expand eligible practitioners to furnish telehealth services, and H.R. 3875 – the Expanded Telehealth Access Act. However, we understand that the Subcommittee will consider a two-year extension of current Medicare telehealth policy. While we prefer permanence, such an extension will ensure some certainty for providers and help patients maintain continuity of care while Congress considers developing longer term telehealth legislation.

We appreciate the opportunity to share our views on this issue. Should you have any questions, please contact APTA Congressional Affairs Specialist Steve Kline at [redacted]. Thank you for your time and consideration.

Sincerely,

Roger Herr
President, American Physical Therapy Association.

ASHA
American
Speech-Language-Hearing
Association

May 16, 2024

The Honorable Brett Guthrie
Chair
Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
Committee on Energy and Commerce
Subcommittee on Health
2322A Rayburn House Office Building
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Dear Chairman Guthrie and Ranking Member Eshoo:

I am writing to share the American Speech-Language-Hearing Association's (ASHA) strong support for ensuring that audiologists and speech-language pathologists (SLPs) can continue providing telehealth services to Medicare beneficiaries beyond December 31, 2024.

ASHA is the national professional, scientific, and credentialing association for 234,000 members, certificate holders, and affiliates who are audiologists; SLPs; speech, language, and hearing scientists; audiology and speech-language pathology assistants; and students. Audiologists specialize in preventing and assessing hearing and balance disorders as well as providing audiologic treatment, including hearing aids. SLPs identify, assess, and treat speech, language, swallowing, and cognitive communication disorders.

ASHA supports several bills that would ensure audiologists and SLPs are able to continue providing Medicare telehealth services on a permanent basis. These bills include H.R. 7623, the Telehealth Modernization Act of 2024; H.R. 3875, the Expanded Telehealth Access Act; and H.R. 8151, the Telehealth Practitioners Act. ASHA appreciates the committee's inclusion of H.R. 7623 in today's markup—and supports a two-year extension of Medicare telehealth authority proposed by the amendment in the nature of a substitute rather than expiration of such flexibility—but believes audiologists and SLPs should be permanent Medicare telehealth providers. We particularly appreciate Representative Harshbarger's leadership in building bipartisan support for a permanent telehealth policy for audiologists, SLPs, and other nonphysician providers through the introduction of H.R. 3875, which has 55 bipartisan cosponsors—including five members of the Energy and Commerce Committee.

Throughout the COVID-19 pandemic, the Centers for Medicare & Medicaid Services has used authority provided by Congress to cover key audiology and speech-language pathology telehealth services. However, Secretary Becerra has repeatedly implored Congress to provide the Department of Health and Human Services (HHS) guidance through statute to enshrine such temporary flexibilities more concretely. Failing to do so could jeopardize continuity of care if the Department misinterprets congressional intent or modifies current coverage of these services for other reasons.

Data from ASHA's National Outcomes Measurement System has shown that patients receiving services via telehealth improved their conditions at comparable rates to patients who received services in person.[1] This data also indicated that telehealth helped patients save money by decreasing lost wages to themselves or their caregivers from missing work and reducing transportation costs traveling to and from appointments.[2] Further, the HHS inspector general also found that only 0.2% of Medicare claims for telehealth during the COVID-19 pandemic were at high risk of being fraudulent.[3] Making this authority permanent for audiologists and

SLPs beyond the current December 31, 2024 deadline will ensure Medicare beneficiaries have continued access to critical and cost-effective services that improve their health and quality of life.

ASHA urges the Subcommittee to favorably report legislation that ensures audiologists and SLPs can continue providing telehealth services to Medicare beneficiaries beyond the current expiration of this authority on December 31, 2024, for the longest possible period. If you or your staff have any questions, please contact Josh Krantz, ASHA's director of federal affairs, health care, at [redacted].

Sincerely,

Tena L. McNamara, AuD, CCC-A/SLP
2024 ASHA President

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[1] Warren, S. (2022). *New Outcomes Data Support Making Telehealth Policies Permanent*. LeaderLive. https://leader.pubs.asha.org/do/10.1044/leader.PA.27072022.telehealth-data.16/full/

[2] American Speech-Language-Hearing Association. *Telehealth Improves Patient Access to Care*. https://www.asha.org/siteassets/advocacy/telepractice-data-fact-sheet.pdf

[3] U.S. Department of Health and Human Services, Office of Inspector General. (2022). *Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks*. https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf

ABHW
Advancing Health Care Policy for
Mental Health & Substance Use Disorders

Statement for the Record by
The Association for Behavioral Health and Wellness (ABHW) to the
U.S. House Energy and Commerce Committee
Health Subcommittee Markup held on May 16, 2024

Dear Chairman Guthrie and Ranking Member Eshoo,

The Association for Behavioral Health and Wellness (ABHW) appreciates the Committee's support and leadership in addressing mental health (MH) and substance use disorder (SUD) issues. ABHW is the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in the public and private sectors to treat MH, SUD, and other behaviors that impact health and wellness. The COVID-19 Public Health Emergency (PHE) resulted in a rise in mental health disorders. Telehealth has been a critical modality for those seeking mental health care, and utilization of tele-mental health services has remained high following the end of the PHE.[1]

We applaud the Committee for highlighting the importance of telehealth and respectfully submit this statement for the record supporting the Committee's efforts to identify solutions and opportunities to ensure access to telehealth services. ABHW member companies are invested in ensuring their members have access to care. We are grateful for the Committee's attention to telehealth and the extension of vital flexibilities. ABHW supported the extension of current telehealth guidance and flexibilities in response to the PHE through December 2024. These long overdue changes to telehealth policies have allowed payers and providers to ensure patients can access necessary MH and SUD services long after the PHE has ended.

[1] KFF: Telehealth has Played an Outsized Role Meeting Mental Health Needs During the COVID-19 Pandemic, https://www.kff.org/mental-health/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/; Healthcare Dive: Rise of Telehealth During Pandemic Boosted Mental Health Treatment Rates, https://www.healthcaredive.com/news/telehealth-mental-health-JAMA-pandemic/639905/

While we appreciate the steps the Committee is taking to extend the current telehealth flexibilities, ABHW urges the Committee to consider making this critical modality of care permanent. H.R. 4189/S. 2016, the *Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2023*, makes these important Medicare flexibilities permanent and expands access to telehealth care. We urge the Committee to work to pass this legislation through Congress.

As the Committee considers proposals to extend these flexibilities, ABHW urges the Committee and Congress to pass and sign into law telehealth legislation as soon as possible instead of waiting until December 2024. Delaying action on these issues until later in the year will result in confusion as payers will likely already have established their 2025 benefit package. Extending the flexibilities sooner will allow patients, payers, and providers to make informed decisions and plan for care.

ABHW recommends the following to strengthen access to telehealth:

Repeal of the Medicare In-Person Requirements on Tele-Mental Health

ABHW encourages the Committee to repeal the Medicare in-person visit requirement on tele-mental health. Many individuals with mental health disorders may not be able to leave their homes at all or without significant assistance. Requiring that individuals must have an in-person visit with a provider within six months before receiving a tele-mental health service creates an unnecessary and stigmatizing burden to care. ABHW supports individuals accessing appropriate, quality care; however, this requirement is an additional barrier to those seeking MH services that are not imposed on individuals seeking care for other medical conditions or SUDs. We are grateful that the amendment in the nature of a substitute to H.R. 7623, the *Telehealth Modernization Act of 2024,* includes an extension of the delay for the in-person requirement. ABHW urges that the Committee remove the Medicare six-month in-person requirement for patients and make this delay permanent and recommends that H.R. 3432/S. 3651, the *Telemental Health Care Access Act of 2023*, be passed through the Committee and Congress.

Medication-Assisted Treatment In-Person Evaluation

Enhancing access to medication-assisted treatment (MAT) is more critical than ever, with increasing annual deaths from overdoses. The Centers for Disease Control and Prevention (CDC) estimates nearly 112,000 deaths in the 12 months ending in June 2023. The Kaiser Family Foundation reports that in 2020, 31% of these deaths were Black, Hispanic, or Asian individuals. Medications like buprenorphine are the best way to treat opioid use disorder

(OUD) and curb overdose deaths. Still, these medications are often unavailable to those who need them. Fewer than 1 in 5 people with an OUD receive medication.[2]

During the COVID-19 PHE, the Drug Enforcement Administration (DEA) waived the requirement to be seen in-person before prescribing buprenorphine, enabling providers to safely prescribe controlled substances using telemedicine. The DEA in April 2023 released a pair of rules, one focusing on the telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation; the second rule focused on the induction of buprenorphine via a telemedicine encounter. Both rules required that 30 days after a telehealth visit, an in-person visit was necessary. The DEA received 38,000 comments in response to these rules, with a significant majority expressing concern. Due to the overwhelming response to the regulations, the DEA extended the COVID-19 flexibilities until November 2023 and again extended the flexibilities until December 2024.

We urge you to consider H.R. 5163/S. 3193, the *Telehealth Response for E-Prescribing Addiction Therapy Services (TREATS) Act*. This legislation would waive the in-person requirement for prescribing buprenorphine and would permanently authorize patients to start buprenorphine through an audio-only or audio-video telehealth appointment. A *Journal of Substance Abuse Treatment* study found that removing the in-person requirement significantly increased access to care and addressed health inequities in primary care programs providing buprenorphine treatment.[3] Providers have noted that prescribing buprenorphine via telehealth has led to better patient engagement and treatment adherence. ABHW was disappointed that this critical policy was not included in the subcommittee markup. We urge you to consider this legislation in any full committee markup on telehealth.

<u>Telehealth Coverage in High Deductible Health Plans</u>

As a part of the Coronavirus Aid Relief and Economic Security (CARES) Act, telehealth access was expanded to eligible Health Savings Account (HSA) plans as a pre-deductible benefit. In the face of rising symptoms of anxiety or depression, employers have worked to provide new and expanded behavioral health resources to their employees. In 2022, 75% of large employers offered access to lower- or no-cost mental health support through

[2] SAMHSA, Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health, HHS Publication No. PEP23-07-01-006, NSDUH Series H-58 (2023), https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report.

[3] P. Treitler et al., *Perspectives of opioid use disorder treatment providers during COVID-19: Adapting to flexibilities and sustaining reforms*, JOURNAL OF SUBSTANCE ABUSE TREATMENT, accessed at https://www.sciencedirect.com/science/article/pii/S0740547221002403

their tele-mental health provider, and 33% provided lower-cost counseling services at the worksite.[4] By expanding this HSA safe harbor, employers were able to continue to support individuals who were leveraging virtual care. H.R. 1843/S. 1001, *the Telehealth Expansion Act of 2023*, would permanently expand this exemption. While we understand this legislation is not in Energy & Commerce's jurisdiction, we urge the Committee to work with the House Ways & Means Committee to pass comprehensive telehealth legislation through Congress.

We look forward to working with the Committee and other stakeholders to identify solutions to ensure permanent access to telehealth. We appreciate the Committee addressing this critical issue and encourage swift action to move telehealth legislation through Congress for final passage. We thank you for the opportunity to submit ABHW's comments for the record. If you have any questions, please contact Maeghan Gilmore, Vice President of Government Affairs, at [redacted] or [redacted].

Sincerely,

Pamela Greenberg

Pamela Greenberg, MPP
President and CEO

[4] Business Group on Health, 2022 Large Employers' Health Care Strategy and Plan Design Survey: https://www.businessgrouphealth.org/resources/2022-large-employers-health-care-strategy-and-plan-design-survey

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May 16, 2024

The Honorable Cathy McMorris Rodgers
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The Honorable Frank Pallone
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The Honorable Brett Guthrie
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The Honorable Anna Eshoo
Ranking Member
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272 Cannon House Office Building
Washington, DC 20515

Dear Chair Rodgers, Ranking Member Pallone, Chairman Guthrie, and Ranking Member Eshoo:

On behalf of the Children's Hospital Association (CHA), representing over 200 children's hospitals nationwide, we are grateful that the Health Subcommittee is marking up a number of bills today that will benefit the health of America's children. We strongly support the advancement of legislative proposals to address critical gaps in pediatric medical research and treatment, especially the Accelerating Kids' Access to Care Act.

Children and families affected by rare diseases and other chronic or complex conditions often face barriers to accessing care that is timely and coordinated given the range of specialists and subspecialists that may be involved in their care and the regionalized nature of pediatric specialty care. It is not uncommon for children, particularly those with medical complexity or specialized health care needs, to travel out of their community, state, or region to receive the care that can only be provided at a children's hospital. For these children, a children's hospital is the focal point of care, as pediatric specialists are frequently needed to provide expertise in treating their rare and complex clinical conditions. In recognizing these immense challenges, we emphasize the importance of legislative solutions that address the barriers faced by children and families seeking specialized care, particularly those compelled to travel for treatment at children's hospitals.

**CHA strongly supports the Accelerating Kids' Access to Care Act (H.R. 4758)** sponsored by Representatives Trahan and Miller-Meeks and appreciates the committee including it in this markup. The strongly bicameral, bipartisan bill will improve children's access to needed out-of-state care by streamlining the burdensome and time-consuming Medicaid provider screening and enrollment process. We look forward to continuing to work with the committee to advance.

Medicaid plays a pivotal role for children, providing coverage for about half of the nation's children, including 3 million children in military-connected families, and essential wrap-around care to many children with complex needs who have private insurance. Children on Medicaid often require out-of-state care, particularly those with medically

complex conditions like cancer or other rare diseases treated in children's hospitals. Today, children on Medicaid needing care outside their home states often experience delays due to the cumbersome provider enrollment process. By facilitating and streamlining this enrollment, the bill ensures that pediatric patients with rare diseases have timely access to specialized care, irrespective of their location. We appreciate the commitment of the sponsors to improve the overall well-being of pediatric patients, including those served by children's hospitals across the country. We appreciate that the bill is included in today subcommittee markup and look forward to supporting its continued movement through the legislative process to ensure children get the care they need when and where they need it.

Children are not little adults. They are constantly growing and developing, and their health care needs, the delivery system to meet those needs, and support systems (e.g., schools, childcare settings) are different from those of adults. Pediatric care requires specialized medications, therapeutics, and equipment, as well as extra time, monitoring, and specially trained health care providers who are compassionate and understand kids of all ages and from all backgrounds. It is critical that pediatric-focused innovations for rare diseases, including childhood cancers, are developed, reimbursed, and available to meet children's unique needs.

Children's hospitals dedicate significant efforts to advancing knowledge and improving access to essential treatments for children facing childhood cancers and rare diseases through studies, trials, and innovations. Unfortunately, the promising outcomes of their work often face obstacles in becoming readily available bedside treatments, as manufacturers' and payers' policies can hinder children's access to care. Recognizing the urgency, children's hospitals, as hubs for pediatric medical research, emphasize the need to address impediments and incentivize the development, study, dissemination, and accessibility of these crucial treatments for children with rare diseases. In appreciation of the subcommittee's steadfast commitment to addressing critical issues affecting the well-being of the nation's children and families, CHA also supports the following bills slated for consideration during today's markup:

**H.R. 3433 – Give Kids A Chance Act:** CHA enthusiastically supports H.R. 3433, Give Kids A Chance Act, sponsored by Representatives McCaul and Eshoo. This legislation grants the FDA the authority to guide drug companies in conducting targeted clinical trials for combinations of pediatric cancer treatments. Currently, most pediatric cancer trials focus on children with advanced cancer, and the FDA is limited to directing trials for one drug given by itself. However, one-drug treatments are very unlikely to help children with advanced cancers. In fact, almost all curative treatments for cancer in adults and children are with drug combinations. That is why it is so important to explore drug combinations in pediatric as well as adult patients. The bill marks a significant step in advancing pediatric oncology research, providing hope to children and families grappling with these devastating diseases. The sponsors' dedication to prioritizing research and development for pediatric cancer treatments is commendable and aligns seamlessly with our mission to enhance the overall well-being of children nationwide.

**H.R. 7384 – Creating Hope Reauthorization Act:** CHA proudly supports H.R. 7384, Creating Hope Reauthorization Act led by Representatives McCaul, Eshoo, Bilirakis, Barragán, Trahan, and Burgess. This bipartisan legislation extends the authority to issue priority review vouchers, providing crucial incentives for the development of treatments targeting rare pediatric diseases. Since this program's inception, these vouchers have played a pivotal role in accelerating pharmaceutical innovation and expediting the approval process for therapies that address the unique health care needs of children with rare diseases. By extending this authority until September 30, 2030, this legislation ensures a sustained commitment to advancing the treatment of rare pediatric medical

conditions. We commend the bipartisan efforts behind this bill, and as supporters of the original legislation, we urge the committee to advance the Creating Hope Reauthorization Act, which continues to contribute to advancements in pediatric rare disease treatments.

These bills collectively address crucial gaps in pediatric medical research and treatment, demonstrating a steadfast commitment to improving the accessibility of lifesaving health care for children. From streamlining Medicaid processes to enhancing pediatric cancer research, each bill addresses unique challenges faced by pediatric patients. Moreover, the extension of priority review vouchers underscores a vital measure in incentivizing treatments for rare pediatric diseases, thereby contributing to advancements in pediatric rare disease treatments and the overall health outcomes of our nation's youngest citizens.

As CHA stands in strong support of these legislative proposals, we are confident that the subcommittee's consideration will lead to positive outcomes for pediatric patients and their families. Thank you for your continued bipartisan efforts to champion policies that positively impact the health and well-being of children. If you have any questions, please contact Aimee Ossman at [redacted].

Sincerely,

Leah Evangelista
Chief Public Affairs Officer
Children's Hospital Association

CC: Reps. Barragán, Bilirakis, Burgess, McCaul, Miller-Meeks, and Trahan

May 16th, 2024

The Honorable Brett Guthrie, Chairman
House Energy and Commerce Committee
Subcommittee on Health
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo, Ranking Member
House Energy and Commerce Committee
Subcommittee on Health
272 Cannon House Office Building
Washington DC 20515

Dear Chairman Guthrie and Ranking Member Eshoo:

In service of the neuromuscular disease (NMD) patient community, the Muscular Dystrophy Association (MDA) thanks the Energy and Commerce Committee's Subcommittee on Health for convening an impactful markup on access to Medicaid, telehealth services, and development and access to therapies for those living with rare diseases. We appreciate the opportunity to provide our viewpoints.

MDA is the #1 voluntary health organization in the United States for people living with muscular dystrophy, ALS, and related neuromuscular diseases. For over 70 years, MDA has led the way in accelerating research, advancing care, and advocating for the support of our community. MDA's mission is to empower the people we serve to live longer, more independent lives.

The NMD community has a wide variety of needs that intersect with all of the policy areas considered by the Subcommittee today. Living with an NMD often means navigating an environment with incredibly limited access to specialists and effective treatments. This, in turn, necessitates seeking care across state lines, which, in the context of Medicaid programs, requires healthcare providers to engage in the lengthy process of enrolling in an out-of-state Medicaid program, or making use of expanded telehealth flexibilities made possible during the Public Health Emergency. Similarly, the small number of available treatments for those living with a neuromuscular disease poses a major problem. The bills before the Subcommittee today seek to ease the burden of researching and developing these therapies which will spur development for more much-needed treatment options for the community. For these reasons and more, we appreciate the Subcommittee's consideration of our comments below.

**H.R. 7383, Retaining Access and Restoring Exclusivity (RARE) Act:** MDA strongly supports the RARE Act and encourages the Subcommittee to swiftly recommend this legislation for full E&C Committee consideration.

When Catalyst Pharmaceuticals successfully retained exclusivity for Firdapse, an FDA-approved treatment for Lambert-Eaton Myasthenic Syndrome (also a disease that falls under MDA's umbrella), a loophole was opened within the Orphan Drug Act that counters FDA's long-term interpretation and implementation of the statute.[4] Under this decision, the FDA must more strictly interpret the Orphan Drug Act's "same disease" definition, thus handcuffing FDA in designating and subsequently approving therapies for subpopulations of rare diseases.

This is problematic for several reasons. First, under the current interpretation, approved orphan products would retain orphan drug exclusivity for the "same disease or condition" no matter the specificity within the approved label. Consequently, under this paradigm, an approved product could only be approved for a narrow subset of a rare disease, but retain orphan exclusivity for the entire population regardless of the label.

This would prevent innovative products that treat subsets of rare disease communities from reaching the market because the FDA has lost the authority to offer approvals and exclusivity to subpopulations of a disease community.

Congress must restore this authority through the RARE Act, and we are grateful that the Subcommittee is considering the legislation for recommendation to the full Committee. We urge every Subcommittee member to support the bill's advancement to the full Committee.

**H.R. 7384, Creating Hope Reauthorization Act of 2024:** The Rare Pediatric Disease Priority Review Voucher (RPD PRV) program has been instrumental in encouraging therapeutic development in challenging pediatric neuromuscular diseases that otherwise may not receive biopharmaceutical commercial attention. Already, several FDA-approved rare neuromuscular disease treatments have received a PRV upon approval, including seven treatments for Duchenne muscular dystrophy (DMD) three treatments for spinal muscular atrophy (SMA), and one treatment Friedreich's Ataxia.

Most notably, all of the products are innovative and unique, and some may not have come to market without the voucher's incentive. For example, of the approved-DMD treatments, several are exon-skipping treatments that target ultra-rare subpopulations of the Duchenne community, thus not exactly offering a financially-lucrative opportunity for the sponsors bringing them to market. The voucher has also encouraged innovation in corticosteroid treatments for DMD as not only has a more advanced version of Prednisone been tested and approved for DMD (deflazacort), but a dissociative steroid without the problematic side effects (Vamoralone) has been approved as has an innovative nonsteroidal treatment that preserves muscle function (Duvystat). Perhaps most notably, the very first gene therapy for a muscular dystrophy, Elevydis, was approved for Duchenne last summer and received a voucher.

In SMA, each of the three FDA-approved treatments that have received vouchers are incredibly innovative and unique in their own ways. The SMA community will often opt for one over the others due to administration and side effect profiles, and sometimes families will choose a combination of two of the therapies to target the disease. In the end, these three treatments have transformed the experience of living with SMA: while previously infants with SMA might die before their first birthday, children with SMA are living full childhoods, almost visibly unaffected by the SMA. Within Friedreich's Ataxia (FA), Skyclarys was the first and only FDA-approved therapy for the FA disease population, a community that has fought for FDA-approved treatments for decades.

All three of these diseases had zero FDA-approved treatments prior to the creation of the RPD PRV program. Today, collectively, there are twelve approved treatments across these three diseases.

While the RPD PRV program has contributed to the success of therapeutic development in these three disease areas, countless other rare pediatric disease populations are counting on the voucher to remain in place to continue to incentivize development in their disease area. The limb-girdle muscular dystrophy, congenital muscular dystrophy, mitochondrial myopathy, and many more communities are counting on the voucher to create similar success stories to those already written for Duchenne, SMA, and FA.

MDA has also heard from several small biotechnology companies developing treatments for ultra-rare pediatric neuromuscular diseases that the presence of the voucher upon approval, which they can then sell, is a major incentive for the continued activity in the space. Otherwise, the incentives are still far too inadequate to outweigh the risks of development in ultra-rare pediatric rare diseases where commercialization, even with high prices, will not be lucrative whatsoever.

We are grateful for the Subcommittee's consideration of the Creating Hope Reauthorization Act, and urge every Subcommittee member to support its favorable recommendation to the full Committee.

**H.R. 4758, Accelerating Kids Access to Care Act**: MDA stands in strong support of the Accelerating Kids Access to Care Act. The bill serves as a common-sense solution to the needs of the many children living with rare diseases who experience delays in receiving care caused by traveling out of state. Children account for, roughly, half of total Medicaid enrollment, and nearly one third of those children have complex medical needs. Unfortunately, there are often an incredibly limited number of clinicians who specialize in a given rare disease. Additionally, as the number of FDA approvals for novel gene therapies grows, and administration of these therapies is incredibly complex and specialized, traveling out of state is often necessary for appropriate care. A 2019 study by the National Organization for Rare Disorders (NORD) found that 39% of respondents traveled more than 60 miles to receive care, which often means crossing state lines and utilizing an out-of-state Medicaid agency or Managed Care Organization.

Given that there is no federal pathway for out-of-state providers to be screened by a child's home Medicaid program, providers are often required to be screened every time they see that child. This process can cause delays in treatment, which, given the progressive nature of many NMDs, means the disease progression experienced while waiting for treatment cannot be reversed. MDA supports the Accelerating Kids Access to Care Act's creation of a voluntary pathway to expeditiously enroll providers in out-of-state plans when needed, all without interfering with state Medicaid plans' authority to authorize out-of-state care or negotiate payment.

Between the Subcommittee's hearing in February considering this bill and this markup much work has been done to ensure the bill's Congressional Budget Office score reflects the realities

of the expedited enrollment process, and while we are pleased with where the work with committee staff has left the bill, it is worth reiterating two key points. First, this bill does nothing to interfere with individual state determinations of what care is or is not covered under a Medicaid plan. It simply allows healthcare providers to deliver covered care more quickly to patients. Second, this bill is not expected to result in new care burdening state Medicaid programs. It, again, simply allows for care that would already be provided in the state to occur more quickly, which, when dealing with progressive neuromuscular conditions, is vital to ensure that more muscular tissue and functionality is not lost to these conditions while waiting for appropriate care.

**H.R. 7623, the Telehealth Modernization Act of 2024:** We learned during the COVID-19 pandemic that telehealth could serve as a vital tool for delivering care to vulnerable populations who need it most while allowing them to stay in the safety of their homes. As we have come out of the pandemic it has become readily apparent that telehealth can serve as a further lifeline to rare disease populations by granting them greater access to specialists in virtual settings where appropriate. As noted above, seeing a specialist across state lines can be incredibly challenging, and the provision of telehealth flexibilities has been key to relieving some of those struggles. The telehealth Modernization Act takes an important step in continuing these flexibilities, granting patients the peace of mind knowing that a virtual option will continue to be available to them, and allows healthcare providers and hospital systems to plan for the future, knowing that these services will be covered permanently.

Specifically, we would like to express our support for the provisions which would continue to support the provision of telehealth services for rural populations, remove geographic requirements for originating sites, and the expansion of the types of providers who may deliver these services. Continuing to remove geographic barriers to care is key in instances where one is unable or it is impractical to travel to receive care. The support of audio only telehealth modalities and support for Federally Qualified Health Centers are key for those in all areas, but particularly rural populations, for whom these modalities may be their best option. Finally, while we would like to see more robust consideration given to tweaking state licensure requirements for those that wish to practice telehealth across state lines (as noted above this can be vitally important), expanding the kinds of care which can be given under these telehealth provisions is a key step forward. We stand in strong support of the Telehealth Modernization Act of 2024.

MDA is committed to ensuring that individuals with neuromuscular diseases and other rare diseases have access to safe and effective therapies and robust access to care. We appreciate this opportunity to provide the Subcommittee with the perspectives of the NMD community. For questions regarding MDA or the above comments, please contact either Paul Melmeyer, Executive Vice President, Public Policy and Advocacy, at [redacted] or Joel Cartner, Director of Access Policy, at [redacted].

Sincerely,

Paul Melmeyer, MPP
Executive Vice President, Public Policy and Advocacy
Muscular Dystrophy Association

Joel Cartner, Esq
Director, Access Policy
Muscular Dystrophy Association

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

**Center for Clinical Standards and Quality/Quality, Safety & Oversight Group**

**Ref: QSO-22-15-NH & NLTC & LSC**

**DATE:** **April 7, 2022**

**TO:** State Survey Agency Directors

**FROM:** Director
Quality, Safety & Oversight Group

**SUBJECT:** Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers

**Memorandum Summary**

- CMS continues to review the need for existing emergency blanket waivers issued in response to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- Over the course of the COVID-19 PHE, skilled nursing facilities/nursing facilities (SNFs/NFs), inpatient hospices, intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and end-stage renal disease (ESRD) facilities have developed policies or other practices that we believe mitigates the need for certain waivers.
- Applicable waivers will remain in effect for hospitals and critical access hospitals (CAH).
- CMS will end the specified waivers in two groups:
    - 60 days from issuance of this memorandum
    - 30 days from issuance of this memorandum

## Background

In response to the COVID-19 PHE and under the Secretary's authority set out at section 1135 of the Social Security Act, CMS enacted several temporary emergency declaration blanket waivers which were intended to provide health care providers with extra flexibilities required to respond to the COVID-19 pandemic.[1] CMS continues to evaluate the impact of these waivers on patient care and providers along with corresponding data.

While the waivers of regulatory requirements have provided flexibility in how nursing homes may operate, they have also removed the minimum standards for quality that help ensure residents' health and safety are protected. Findings from onsite surveys have revealed significant concerns with resident care that are unrelated to infection control (e.g., abuse, weight-loss, depression, pressure ulcers, etc.). We are concerned that the waiver of certain regulatory requirements has contributed to these outcomes and raises the risk of other issues. For example, by waiving requirements for training, nurse aides and paid feeding assistants may not have received the necessary training to help identify and prevent weight-loss. Similarly, CMS waived requirements for physicians and practitioners to perform in-person assessments, which may have

[1] COVID-19-emergency-declaration-waivers.pdf

prevented these individuals from performing an accurate assessment of the resident's clinical needs, contributing to depression or pressure ulcers. Lastly, due to the waiver of certain life-safety code requirements, facilities may not have had their fire prevention systems inspected to ensure they operate effectively to detect or prevent fire. As a result, CMS is very concerned about how residents' health and safety has been impacted by the regulations that have been waived, and the length of time for which they have been waived.

We note that CMS is still concerned about the risk COVID-19 poses to nursing home residents. We expect providers to continue to implement actions to reduce the likelihood of COVID-19 transmission and follow all existing requirements. For example, COVID-19 vaccines are the strongest tool we have to protect the health and safety of residents and staff, and facilities should use all available resources to support their residents and staff in getting vaccinated, and in doing so, adhere to the requirements for educating residents and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine (per Interim Final Rule CMS-3414-IFC).

However, in addition to taking actions to reduce the likelihood of the transmission of COVID-19, the minimum regulatory requirements need to be restored to protect residents' health and safety. This is particularly true in light of the increased protection against serious illness and death from COVID-19 afforded by the high and growing vaccination rates among nursing home residents and staff (see generally https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html), including as a result of the implementation and enforcement of Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021). Therefore, we believe it is imperative that requirements to protect residents' health and safety be restored as soon as possible. The waivers listed below have been identified as those requirements that should be restored to address the risks to resident health and safety that are not related to infection control. Furthermore, we believe that at this time, nursing homes should be able to adjust their operations to meet these regulatory requirements, while also addressing any issues related to COVID-19. We note that states and individual facilities are still able to request regulatory waivers for issues unique to their facility or location (similar to actions taken in response to natural disasters) to provide flexibility.

**Waiver Terminations:**

CMS is ending the specific emergency declaration blanket waivers for SNFs/NFs, inpatient hospices, ICF/IIDs and ESRD facilities listed below. The termination of these blanket waivers will have no effect on other blanket waivers that remain in place such as those for hospitals and CAHs. Those blanket waivers remain in effect to assist hospitals and CAHs, among others, in dealing with their response to the surges of COVID-19 cases in the community. Providers are expected to take immediate steps so that they may return to compliance with the reinstated requirements according to the timeframes listed below. We also recommend that providers continue to follow CDC guidance for preventing the spread of COVID-19 especially during activities that may increase patient or resident contact. For additional information on individual waivers or flexibilities providers can apply for, please visit the Coronavirus waivers & flexibilities webpage.

**Emergency Declaration Blanket Waivers Ending for SNF/NFs 30 Days from Publication of this Memorandum:**

- Resident Groups - 42 CFR §483.10(f)(5)

    - CMS waived the requirements which ensure residents can participate in-person in resident groups. This waiver permitted the facility to restrict in-person meetings during the COVID-19 PHE.
- Physician Delegation of Tasks in SNFs - 42 CFR §483.30(e)(4)
    - CMS waived the requirement that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gave physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist, but specified that any task delegated under this waiver must continue to be under the supervision of the physician.
- Physician Visits - 42 CFR §483.30(c)(3)
    - CMS waived the requirement that all required physician visits (not already exempted in §483.30(c)(4) and (f)) must be made by the physician personally. The waiver modified this provision to permit physicians to delegate any required physician visit to a nurse practitioner, physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope-of-practice laws.
- Physician Visits in Skilled Nursing Facilities/Nursing Facilities - 42 CFR §483.30
    - CMS waived the requirement for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- Quality Assurance and Performance Improvement (QAPI) – 42 CFR §483.75(b)–(d) and (e)(3)
    - CMS modified certain requirements which require long-term care facilities to develop, implement, evaluate, and maintain an effective, comprehensive, data-driven QAPI program. This waiver gave providers the ability to focus on adverse events and infection control, and those aspects of care delivery most closely associated with COVID-19 during the PHE.
- Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities - 42 CFR §483.21(c)(1)(viii)
    - CMS waived the discharge planning requirement which requires LTC facilities to assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and resource use. CMS maintained all other discharge planning requirements.
- Clinical Records - 42 CFR §483.10(g)(2)(ii)
    - CMS modified the requirement which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident).

**Emergency Declaration Blanket Waivers For Various Provider-Types Ending <u>60 Days</u> from Publication of this Memorandum:**

- Physical Environment for SNF/NFs - 42 CFR §483.90
    - CMS waived requirements to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there were needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19, provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff.

    - Certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.
    - Requirements to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity.
- Equipment Maintenance & Fire Safety Inspections for ESRD facilities - 42 CFR §494.60(b) and(d)
    - CMS waived the requirement for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS waived the requirements for ESRD facilities to conduct on-time fire inspections.
- Facility and Medical Equipment Inspection, Testing & Maintenance (ITM) for Inpatient Hospice, ICF/IIDs and SNFs/NFs – 42 CFR §§418.110(c)(2)(iv), 483.470(j), and 483.90
    - CMS waived ITM requirements for facility and medical equipment to reduce disruption of patient care and potential exposure/transmission of COVID-19.
- Life Safety Code (LSC) and Health Care Facilities Code (HCFC) ITM for Inpatient Hospice, ICF/IIDs and SNFs/NFs - 42 CFR §§ 418.110(d)(1)(i) and (e), 483.470(j)(1)(i) and (5)(v), and 483.90(a)(1)(i) and (b)
    - CMS waived ITM required by the LSC and HCFC, with specified exceptions, which permitted facilities to adjust scheduled ITM frequencies and activities to the extent necessary.
- Outside Windows and Doors for Inpatient Hospice, ICF/IIDs and SFNs/NFs – 42 CFR §§418.110(d)(6), 483.470(e)(1)(i), and 483.90(a)(7)
    - CMS waived the requirement to have an outside window or outside door in every sleeping room. This permitted spaces not normally used for patient care to be utilized for patient care and quarantine.
- Life Safety Code for Inpatient Hospice, ICF/IIDs, and SNFs/NFs - 42 CFR §§418.110(d), 483.470(j), and 483.90(a)
    - CMS waived these specific LSC provisions:
        - Fire Drills: Due to the inadvisability of quarterly fire drills that move and mass staff together, CMS permitted a documented orientation training program related to the current fire plan, which considered current facility conditions.
        - Temporary Construction: CMS waived requirements that would otherwise not permit temporary walls and barriers between patients.
- Paid Feeding Assistants for LTC facilities: 42 CFR §§483.60(h)(1)(i) and 483.160(a)
    - CMS modified the requirements regarding required training of paid feeding assistants to allow that training can be a minimum of one hour in length. CMS did not waive other requirements related to paid feeding assistants or required training content.
- In-Service Training for LTC facilities – 42 CFR §483.95(g)(1)
    - CMS modified the nurse aide training requirements for SNFs and NFs, which required the nursing assistant to receive at least 12 hours of in-service training annually.
- Training and Certification of Nurse Aides for SNF/NFs - 42 CFR §483.35(d) (Modification and Conditional Termination)
    - CMS waived the requirements which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under §483.35(d). CMS previously provided information related to

nurse aides working under this blanket waiver in CMS memorandum QSO-21-17-NH. This memo provides additional information as well on the modification of this waiver below.

We remind states that all nurse aides, including those hired under the above blanket waiver at 42 CFR §483.35(d), must complete a state approved Nurse Aide Competency Evaluation Program (NATCEP) to become a certified nurse aide. State approved NATCEPs must have a curriculum that includes training in the areas defined at 42 CFR §483.152(b), such as respecting residents' rights, basic nursing skills, personal care skills, and caring of cognitively impaired residents. Additionally, the requirements at 42 CFR §483.154(b)(i) and (ii) requires these nurse aides pass a written or oral exam, and demonstrate skills learned. Lastly, we note that CMS did not waive the requirement that the individual employed as a nurse aide be competent to provide nursing and nursing related services at 42 CFR §483.35(d)(1)(i), and that requirement must continue to be met.

We are aware that there may be instances where the volume of aides that must complete a state approved NATCEP exceed the available capacity for enrollees in a training program or taking the exam. This may cause delays in in nurse aides becoming certified. If a facility or nurse aide has documentation that demonstrates their attempts to complete their training and testing (e.g., timely contacts to state officials, multiple attempts to enroll in a program or test), a waiver of these requirements (42 CFR §483.35(d)) is still available and the aide may continue to work in the facility while continuing to attempt to become certified as soon as possible. However, **for all other situations, this waiver is terminated**. When capacity issues exist, facilities should inform their state officials of the issue. State agencies should also verify the capacity issues that are reported. Lastly, state agencies should provide their CMS Location with information about the status of their NATCEPs.

Poor quality of care, such as improper transfers, turning and positioning, poor incontinent/skin care, or weight loss related to poor assistive dining techniques could be related to inadequate training, as these skills are required components of NATCEP programs. We acknowledge that federal requirements allow states to use a variety of means to administer the curriculum (e.g., online, classroom, or onsite training). However, all programs must adequately provide the required training. For example, if a state has approved a NATCEP that allows for the time worked onsite by a nurse aide over the COVID-19 PHE to qualify for the 75 hours training in the required areas, yet, observes trends in poor quality of care among certified nurse aides that were hired under the nurse aide training waiver, this could indicate that the NATCEP does not adequately address the components of the required curriculum specified at 42 CFR §483.152(b). In these cases, the state should re-evaluate the approved NATCEP to see if the components of the program need to be adjusted to ensure the regulatory requirements are met and avoid poor quality of care. As stated in CMS memorandum QSO-21-17-NH, "states must ensure that all of the required areas of training per 42 CFR §483.152(b) are addressed, and any gaps in onsite training that are identified are fulfilled through supplemental training."

**Contact:**
DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;
QSOG_LifeSafetyCode@cms.hhs.gov for questions related to physical environment and life safety code.

**Effective Date:** The emergency declaration blanket waivers identified above will end according to the timeframes described in this memorandum.

/s/
David R. Wright

cc: Survey and Operations Group Management

May 7, 2024

The Honorable Anna Eshoo
U.S. House of Representatives
272 Cannon House Office Building
Washington, DC 20515

The Honorable Michael McCaul
U.S. House of Representatives
2300 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Eshoo and McCaul:

On behalf of the undersigned organizations, we write to offer our strong support for your legislation, the *Innovation in Pediatric Drugs Act of 2023* (H.R. 6664). Children are not just small adults. Drugs work differently in children and adolescents and must be studied specifically for their use. Yet too often, drug development leaves children behind. H.R. 6664 will help speed therapies to the children and adolescents who need them—including children with rare diseases—by making needed changes to the pediatric drug laws.

The pediatric drug laws—the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA)—have together revolutionized medicines for children. Since their enactment over twenty years ago, the laws have resulted in almost 1,200 drug labels changed with new pediatric information.[1] PREA requires certain new drugs to be studied in children and BPCA offers an incentive of six months of marketing exclusivity for drugs that are studied in children at the request of FDA. BPCA also authorizes a program at the National Institutes of Health (NIH) to fund the pediatric study of older, off-patent drugs that BPCA's incentive and PREA's requirements are unable to reach.

The *Innovation in Pediatric Drugs Act of 2023* would do three critical things to improve BPCA and PREA: increase the number of rare disease drugs studied in children, ensure that required PREA studies actually get completed, and give the NIH BPCA program its first funding increase in 22 years.

There more than 10,000 rare diseases without appropriate treatments, and the vast majority of orphan diseases affect children. Unfortunately, in most cases, FDA is not allowed to require orphan drugs to be studied in children under PREA. When PREA was first passed in 2003, orphan drugs made up a small minority of annual drug approvals. Yet today, the majority of drugs approved are orphan drugs, meaning that the majority of newly approved drugs are exempt from pediatric study requirements. H.R. 6664 would amend PREA to lift its blanket orphan drug exemption, while instructing FDA to promulgate guidance on when and how pediatric studies for rare disease drugs may be impossible or require modifications to the standard PREA requirements (i.e., deferrals and full or partial waivers), helping to ensure that more children with rare diseases can benefit fully from the pediatric research requirements. FDA confirmed the need for this policy change in 2019 when it released an evaluation of the pediatric research gaps that have resulted from the PREA orphan exemption. The report showed that 36% of pediatric-relevant orphan drugs approved since 1999 lack some or all pediatric data.[2]

PREA requires drug companies to study adult drug indications in children when children could benefit from pediatric studies. However, far too many pediatric studies required by FDA have never been completed.[3] If a company fails to complete adult postmarket studies, FDA can penalize the

company by imposing a fine but it is prohibited, by law, from applying those penalties to pediatric postmarket studies under PREA. The *Innovation in Pediatric Drugs Act* would correct this discrepancy.

Finally, while the incentives and requirements under BPCA and PREA are effective in spurring the study of newer drugs in children, they are unable to encourage studies of older drugs. Congress authorized the BPCA NIH program to fund studies of off-patent drugs used in children that companies cannot be incentivized or required to conduct. Despite the increasing costs of drug studies, this program has been flat-funded at $25 million since its original authorization in 2002. When accounting for biomedical research inflation, the purchasing power of the program in 2022 was only 56% of what it was in 2002. The *Innovation in Pediatric Drugs Act* would address this inequity by amending BPCA to increase the authorization level of this program to $50 million to keep up with the increasing need for and cost of these studies.

When drugs are studied for their use, children are safer and the clinicians who care for them are better equipped to make medical decisions. We are grateful for your work to improve the study of drugs in children and adolescents and look forward to working with you to advance the *Innovation in Pediatric Drugs Act*.

Sincerely,

Academic Pediatric Association
American Academy of Family Physicians
American Academy of Pediatrics
American Association of Child and Adolescent Psychiatry
American Childhood Cancer Organization
American College of Rheumatology
American Pediatric Society
American Psychiatric Association
American Society of Pediatric Hematology/Oncology
American Society of Pediatric Nephrology
American Thoracic Society
Arthritis Foundation
Association of Medical School Pediatric Department Chairs
Association of University Professors of Ophthalmology
Child Neurology Society
Children’s Hospital Association
Children's Brain Tumor Foundation
Children's Cancer Cause
Children's Oncology Group Foundation
Children's Wisconsin
Council on Pediatric Subspecialties
Dana-Farber Cancer Institute
Elizabeth Glaser Pediatric AIDS Foundation
Family Voices
Leukemia & Lymphoma Society
March of Dimes
Mattie Miracle Cancer Foundation

MultiCare Mary Bridge Children's Hospital and Health Network
National Association of Pediatric Nurse Practitioners
National Organization for Rare Disorders
Nemours Children's Health
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Pediatric Infectious Diseases Society
Pediatric Orthopaedic Society of North America
Pediatric Pharmacy Association
Pediatric Policy Council
Society for Adolescent Health and Medicine
Society for Developmental and Behavioral Pediatrics
Society for Pediatric Research
St. Baldrick's Foundation
St. Jude Children's Research Hospital

[1] Food and Drug Administration, Pediatric Label Changes Database: https://www.fda.gov/science-research/pediatrics/pediatric-labeling-changes.
[2] Food and Drug Administration, Pediatric Labeling of Orphan Drugs: https://www.fda.gov/media/130060/download.
[3] Food and Drug Administration, PREA Non-Compliance Letters, CDER and CBER: https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act and https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/prea-non-compliance-letters.

May 15, 2024

The Honorable Brett Guthrie, Chairman
The Honorable Anna Eshoo, Ranking Member
Energy and Commerce Subcommittee on Health
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Guthrie and Ranking Member Eshoo:

On behalf of the 1.4 million members of the American Federation of State, County and Municipal Employees (AFSCME), I am writing in opposition to two bills slated for subcommittee markup: Building America's Health Care Workforce Act (H.R. 468) and Ensuring Seniors' Access to Quality Care Act (H.R. 3227). Both of these bills undermine the training standards essential for maintaining high-quality care, potentially compromising both patient safety and employee preparedness.

**Building America's Health Care Workforce Act (H.R. 468)**

H.R. 468 proposes to revive the temporary nurse aide (TNA) program introduced during the COVID pandemic, which waived federal training requirements. AFSCME opposes this legislation. Facilities would only be obligated to offer state-mandated training, which can be as brief as an 8-hour module. Additionally, the bill suggests allowing competency assessments to occur onsite for TNAs, even in facilities with egregious health and safety violations. H.R. 468 would undermine the federal 75-hour training standard mandated by the 1987 Nursing Home Reform Act, signed into law by President Reagan, which is essential for ensuring care quality and workplace safety. While there is an urgent need to bolster the workforce, creating a segment of inadequately trained workers risks compromising care standards. Moreover, this legislation could expose the nation to risks witnessed during the recent COVID crisis, where insufficiently trained personnel led to tragic consequences for both workers and residents.

**Ensuring Seniors' Access to Quality Care Act (H.R. 3227)**

Current law prevents nursing homes that have a history of poor performance from conducting nurse aide training. We strongly believe the guardrails, which bar the lowest performing nursing home facilities from training nurse aides that are mandated in current law, need to remain in place. Allowing such facilities to train nurse aides could perpetuate substandard care practices and potentially put vulnerable individuals at further risk. Nurse aide training should be conducted by facilities with a proven track record of providing

high-quality care, ensuring that future health care workers receive the best education possible and ultimately safeguarding the well-being of the residents they will serve.

Thank you for considering our views in opposition to both these pieces of legislation that would weaken nursing aide training standards and undermine the quality of care in nursing homes. We urge you to oppose to oppose H.R. 468 and H.R. 3227.

Sincerely,

Edwin S. Jayne
Director of Federal Government Affairs

ESJ:DH:ei

cc: Members of the Energy and Commerce Committee, Subcommittee on Health

SEIU
Stronger Together

MARY KAY HENRY
International President

APRIL VERRETT
International Secretary-Treasurer

NEAL BISNO
Executive Vice President

JOSEPH BRYANT
Executive Vice President

HEATHER CONROY
Executive Vice President

LESLIE FRANE
Executive Vice President

ROCIO SÁENZ
Executive Vice President

SERVICE EMPLOYEES
INTERNATIONAL UNION
SOC, CLC

1800 Massachusetts Ave., NW
Washington, DC 20036

202.730.7000

www.SEIU.org

May 15, 2024

Dear Representative:

On behalf of the Service Employees International Union (SEIU), I am writing to express our support for and strong opposition to several legislative proposals currently under consideration in the House of Representatives.

The United States is grappling with a growing long-term care crisis. With at least 14 million older adults and people with disabilities in need of long-term care services and support, the demand for accessible, high-quality care continues to rise, particularly as our population ages. The majority of individuals prefer to receive these vital services at home rather than in institutional settings, emphasizing the need for care and services that meet the highest standards for quality and safety. Therefore, it is crucial that we prioritize solutions that improve job quality and enhance resident care without exacerbating the crisis.

SEIU brings a critical perspective to this issue, representing over one million healthcare workers nationwide. Our membership includes workers across various healthcare settings, including hospitals, nursing homes, home care, ambulatory care, and mental health services. We also represent dietary workers, housekeeping workers, registered nurses, and licensed practical nurses in nursing homes and other settings. Given the indispensable roles these workers play in delivering quality care, congressional authorization and funding of programs or initiatives to enhance care quality and access remain deeply important to our membership and the residents they serve.

We strongly support recent efforts by the Centers for Medicare & Medicaid Services (CMS), including the finalized rules on Ensuring Access to Medicaid Services (CMS-2442-F) and Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting (CMS-3442-F). These rules mark significant progress in addressing the long-term care crisis and workforce challenges. The Medicaid Access rule's requirement that 80 percent of home care payments go to worker compensation will provide vital support to these workers, many of whom are women of color. Similarly, the Long-Term Care Facilities rule establishes minimum staffing standards for nursing homes and strengthens requirements for facility assessments, recognizing the valuable experience of direct care workers.

However, we are deeply concerned about certain legislative proposals in the House of Representatives that could undermine the progress made by these rules. Bills such as H.R. 7513 or H.R.5796, which aims to prevent the implementation of minimum staffing standards in nursing homes, and H.R. 8114, which seeks to rescind the rule supporting direct care worker compensation, would worsen the crisis and compromise the quality of care. SEIU urges you to vote against these bills and any substitute proposal that would seek to further delay or prohibit the implementation of these critical rules.

Adequate staffing levels are essential for ensuring the safety and quality of care in nursing homes; and claims of financial hardship fail to acknowledge the industry's capacity to afford additional staff without resorting to questionable practices. Efforts to extend waivers allowing nurse aides to work without meeting federal training requirements, as proposed in H.R. 468, and to permit nursing homes with deficiencies to operate training programs, as outlined in H.R. 3227, pose significant risks to resident well-being and undermine quality standards. Thus, SEIU urges you to vote No against these bills as well.

In contrast, SEIU supports bills such as H.R. 8109 and H.R. 8110, which aim to make critical programs permanent and promote community-based care options. Additionally, H.R. 7573 seeks to halt unfair Medicaid recovery practices, while H.R. 8106 proposes to remove institutional care criteria for Home and Community-Based Services (HCBS) eligibility, improving access and equity within the long-term care system. Therefore, we fully endorse and urge your support of H.R. 8109, H.R. 8110, H.R. 7573 and H.R. 8106.

In conclusion, I urge you to carefully consider the impact of each legislative proposal on the long-term care sector and prioritize measures that uphold high-quality standards, support the frontline workforce, and ensure equitable access to care for all individuals in need. Thank you for your attention to this critical issue. Please do not hesitate to contact Dalen A. Harris, SEIU's Assistant Legislative Director for Healthcare at [redacted], if you require additional information. I look forward to your continued advocacy on behalf of our nation's long-term care recipients, caregivers and workforce.

Sincerely,

Mary Kay Henry
International President

dh:JG:MKH

May 15, 2024

The Honorable Brett Guthrie, Chairman
The Honorable Anna Eshoo, Ranking Member
Energy and Commerce Subcommittee on Health
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Guthrie and Ranking Member Eshoo:

The underlying organizations representing nursing home residents and family members, as well as nursing home workers, strongly urge you to oppose H.R. 468 and H.R. 3227/H.R. 8244. These bills would weaken training requirements for nursing home workers and would place our nation's 1.2 million nursing home residents and more than half a million nursing home workers at increased risk of harm. While we acknowledge that the nursing home industry is facing staffing challenges, we reject the idea that relaxing training standards is the solution to this problem. Instead, Congress should be focusing on efforts to make jobs in nursing homes better by increasing wages and benefits, improving training, and providing career opportunities.

**Building America's Health Workforce (H.R. 468)**

The passage of H.R. 468 would be devastating for nursing home residents. H.R. 468 seeks to revive a COVID-19 pandemic era-related waiver that permitted untrained nurse aides to work in nursing homes for longer than four months without meeting a state's training and certification requirements. This waiver was understandable several years ago at the beginning of the pandemic, but circumstances have changed. The primary barriers to certification, such as testing, are no longer present today.

Importantly, the Centers for Medicare & Medicaid Services (CMS) noted, when lifting the waiver, that waiving longstanding nurse aide training requirements had adversely impacted quality of care. According to CMS, onsite surveys during the waiver period revealed significant concerns with:

- Abuse
- Weight loss,
- Depression
- Pressure Ulcers.

CMS went on to note that poor quality of care, such as improper transfers, turning and positions, poor incontinence and skin care could be related to inadequate training, as all of these skills are

required to be learned as part of each state's Nurse Aide Competency Evaluation Program. This waiver harmed residents.

Additionally, H.R. 468 would allow time worked to count toward the requirement that each nurse aide have 75-hours of training. This 75-hour requirement must be composed of training on resident rights, communicating with cognitively impaired residents, personal care skills, and other important issues that are likely not to be addressed while staff are working.

H.R. 468 may have made sense several years ago. However, we now have clear evidence that the waiver harmed residents. The offered amendments to this bill will not address the fact that residents will be at an increased risk of harm should the bill go into effect. We cannot go back to the days of the pandemic when untrained workers were still expected to provide quality care to residents. We have seen the impact on care outcomes.

**Ensuring Seniors' Access to Quality Act (H.R. 3227/H.R. 8244)**

Current law allows nursing homes to operate their own CNA training programs under certain circumstances, if permitted by the state. However, federal law prohibits nursing homes that have been cited for certain violations from running their own training programs. Current law allows facilities to petition the Secretary of Health and Human Services to waive a violation that would exclude a facility from running its own CNA program if it can show the violation was not related to the quality of care provided to residents. H.R. 8244 would make this waiver automatic and remove the Secretary's discretion to issue a waiver.

We urge you to oppose this bill. The bill contains no clear definition of what quality of care means, which could lead to confusion and result in disparate outcomes across the country. Critically, there are egregious violations that might not be related to "quality of care" that should still disqualify a facility from running its own training program. For instance, when this bill was considered in the Ways & Means Committee, Patrick Dumas, Staff Director for the Ways and Means Committee Subcommittee on Health admitted that the following violations would likely be the type of violations automatically waived under H.R. 8244

- Record falsification.
- Failing to report resident abuse or a reasonable suspicion of a crime against a nursing home resident.
- Retaliating against a nursing home worker who is a whistleblower.

Although these violations may not be called quality of care, we do not believe nursing homes committing these types of violations should be allowed to operate their own training program. These examples are why it is so important that the Secretary have discretion to determine whether a violation is so egregious that although it may not be related to quality of care, it disqualifies the facility from running its own training program.

We are in a critical time, where nursing home residents are forced to live in facilities with inadequate staffing , and workers are confronted daily with myriad challenges, including poor wages and benefits, inadequate training, and few career advancement opportunities. The solution to these

problems is not to make residents and workers less safe by decreasing training requirements. Please stand with nursing home residents and workers and oppose these bills.

Sincerely,

AFL-CIO
AFSCME
Center for Medicare Advocacy
The Elder Justice Coalition
The Hale Group, an Iowa Based Advocacy Firm
Justice in Aging
Kelinson & Lerner, PLC
Michigan Elder Justice Initiativeɔalition
National Association of Local Long Term Care Ombudsman
National Consumer Voice for Quality Long-Term Care
PHI
Service Employees International Union (SEIU)

May 16th, 2024

The Honorable Brett Guthrie
Chairman Subcommittee on Health
House Energy & Commerce Committee
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member Subcommittee on Health
House Energy & Commerce Committee
272 Cannon House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Chairwoman
House Energy & Commerce Committee
2188 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy & Commerce Committee
2107 Rayburn House Office Building
Washington, DC 20515

Re: House Energy and Commerce Health Subcommittee Markup on Legislative Proposals to Strengthen America's Healthcare System

Dear Chairs and Ranking Members of the Energy and Commerce, Full Committee and Health Subcommittee,

On behalf of the Cystic Fibrosis (CF) Foundation, we thank the House Energy and Commerce Health Subcommittee for its dedication to strengthening the healthcare system for all Americans, including the nearly 40,000 children and adults living with cystic fibrosis in the United States. CF is a complex, multi-system genetic disease that can affect people of every racial and ethnic group. It causes the body to produce thick, sticky mucus that clogs the lungs and digestive system and can result in life-threatening infections; if left untreated, these infections and other exacerbations caused by CF can result in irreversible lung damage and early death, usually due to respiratory failure.

The CF Foundation is a national organization dedicated to ensuring that people with CF live long, fulfilling lives, with the ultimate goal of curing CF. We achieve this by investing in research and development of new CF therapies, advocating for access to care for people with CF, and funding an accredited network of specialized CF care centers. In response to this markup of legislative proposals aimed at strengthening America's healthcare system, the CF Foundation offers support for several pieces of legislation tackling orphan drug exclusivity and telehealth—topics that are critical to the CF community. **In addition to the bills slated for markup, the CF Foundation urges the Committee to recognize the critical issue of antimicrobial resistance, particularly for patients with chronic diseases, and take up and pass H.R. 2940, the Pioneering Antimicrobial Subscriptions To End Upsurging Resistance (PASTEUR) Act.**

Protecting Orphan Drug Exclusivity:

The CF Foundation supports **H.R. 7383, the Retaining Access and Restoring Exclusivity (RARE) Act,** which would restore the FDA's long-standing system for awarding orphan drug exclusivity (ODE) based on "use or indication" within a disease or condition. To incentivize the development of drugs for rare and orphan diseases, the Orphan Drug Act established a term of market exclusivity for drugs intended to treat those populations. ODE protects companies from parties seeking approval for the "same drug for the same disease or condition" for seven years. Importantly, the FDA has historically interpreted this as protecting exclusivity for the "same use or indication" within a disease or condition. However, the *Catalyst Pharms., Inc. v. Becerra* court decision would require the FDA to grant ODE based on "disease or condition," not "approved use or indication" within the disease or condition. Under the *Catalyst* decision, once an orphan drug is approved for a single use or indication, the FDA cannot approve another company's application for the same drug for any additional use or indication within that disease (e.g., pediatric populations).

In the case of CF therapeutics, sponsors often pursue label expansions to add additional indications, such as new genotypes or age groups, to a drug's label. Each label expansion receives an additional, but separate orphan drug exclusivity period. Without the clarification provided by the RARE Act, these additional label expansions could block generic drugs from coming to market for the populations included in previous labels, even when those earlier exclusivity periods expire. This means that patients may wait longer for more affordable options. The CF Foundation therefore asks Congress to support the RARE Act and restore FDA's long-standing policy on orphan drug exclusivity.

Ensuring Access to Telehealth Services:

The CF Foundation also supports **H.R. 7623, the Telehealth Modernization Act,** which updates coverage restrictions in Medicare and ensures continued access to telehealth services for beneficiaries with cystic fibrosis. With the telehealth flexibilities initiated during the public health emergency set to expire at the end of 2024, this legislation is essential for patients who have come to rely on telehealth for necessary care. .

Prior to the COVID-19 pandemic, Medicare rules largely limited use of a patient's home as the originating site to those living in rural areas or with a specific condition. The drastic increase in telehealth usage during the public health emergency demonstrated the burden of geographic restrictions and shown it is appropriate and safe for patients to receive care from their homes. While telehealth visits are not suitable for all health care services and are not a substitute for in-person care, there are several aspects of a regular CF visit that can be conducted through telehealth. For instance, clinicians can easily review medical history, current medications and symptoms, and adjust a patient's care plan. CF patients and care teams can also review data from home spirometers to track trends in lung function. This legislation permanently removes these antiquated location requirements, permitting people with CF to access their established care team from their homes.

Beyond eliminating originating site restrictions, the temporary flexibilities have increased the types of providers who are eligible to provide telehealth services. The CF clinical care team includes physicians, nurses, dietitians, social workers, and respiratory therapists – each of whom plays a unique role in managing CF care. Having access to all members of the care team helps patients better maintain and manage their care, leading to more consistent and better outcomes. This legislation enables the HHS Secretary to maintain and expand providers

eligible to deliver telehealth services, therefore increasing access to care and improving care continuity for patients with CF.

The pandemic demonstrated the importance of access to telehealth services and provided evidence that certain barriers to access are no longer necessary or beneficial to patients or providers. The CF Foundation thanks you for your leadership on this important issue for people with cystic fibrosis and we support your efforts to extend and expand access to critical telehealth services post the public health emergency.

Combatting the Threat of Antimicrobial Resistance:

AMR poses a rapidly-growing threat to both CF patients and the entire United States population. According to the 2019 CDC *Antibiotic Resistance Threats in the United States* report[1], AMR causes 2.8 million infections and claims over 35,000 lives in the United States each year. The COVID-19 pandemic only worsened this crisis: in 2020, the U.S. experienced a 15% increase in hospital-onset AMR infections and deaths, and experts do not expect a return to pre-pandemic levels without concerted action.[2] The economic toll of the AMR crisis is also staggering: according to a 2022 report from the National Academies of Sciences, Engineering, and Medicine, the direct medical costs in the U.S. of treating only six of the most common drug-resistant pathogens is $4.6 billion per year[3]. Notably, this figure does not include associated and downstream costs, including the cost to the health system after discharge, lost wages, diminished worker productivity, short- and long-term disability, mortality, and cost burden on family and caregivers. The AMR threat is particularly dangerous for people with CF, who are extremely vulnerable to pathogenic colonization and life-threatening infections due to the thick, sticky mucus in their lungs. These infections often require hospitalization and treatment with antimicrobials and can lead to losses in lung function and death. For these reasons, the CF Foundation urges this subcommittee to take up the **H.R. 2940, the Pioneering Antimicrobial Subscriptions To End Upsurging Resistance (PASTEUR) Act** in your next legislative hearing.

It is critical that the United States invest in innovative approaches to combatting the AMR crisis, especially those that would incentivize the development of new antimicrobial products. Despite the magnitude of the AMR crisis, the antimicrobial ecosystem is remarkably weak. Fewer than 50 antibacterial therapeutics are currently in clinical development worldwide, only a handful of which are for the most threatening gram-negative pathogens[4]. In recognition of the dire unmet need for innovative antimicrobial products, the GAO formally recommended in a March 2020 report that the Department of Health and Human Services develop a strategy to further incentivize the development of new antimicrobial products for drug-resistant infections, including through the use of post-market financial incentives.[5]

Under PASTEUR's subscription model, the federal government can enter into contracts with developers of innovative antimicrobials to pay for a reliable supply of product. Payments are decoupled from the volume of antimicrobials used, thereby removing the incentive for companies to promote the widespread use that often results in the development of drug-resistant pathogens. Critically, PASTEUR contracts are awarded exclusively on

[1] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.
[2] CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2022.
[3] National Academies of Sciences, Engineering, and Medicine. 2022. Combating Antimicrobial Resistance and Protecting the Miracle of Modern Medicine. Washington, DC: The National Academies Press. https://doi.org/10.17226/26350.
[4] https://www.who.int/publications/i/item/9789240047655
[5] Government Accountability Office. (2020). ANTIBIOTIC RESISTANCE: Additional Federal Actions Needed to Better Determine Magnitude and Reduce Impact. (GAO Publication No. 20-341). Washington, D.C.: U.S. Government Printing Office. Retrieved from https://www.gao.gov/products/gao-20-341

the basis of innovation and success. PASTEUR will only fund antimicrobials that have been approved by the FDA and meet established criteria for novelty and fulfilling unmet AMR needs—in other words, products with a significant impact on patients and public health. Furthermore, the subscription contract is all-inclusive, and the federal government only pays once. Economic modeling performed by the Center for Global Development suggests that this sort of subscription-based approach to incentivizing antimicrobial development would generate a significant return on investment in both the short- and long-term.[6] From the U.S. domestic perspective, taking into consideration the value of averted death and disease plus associated hospital costs, the predicted ROI for an annual $1 billion investment in new, high-impact antimicrobials was calculated at 6:1 over ten years and 28:1 over thirty years.

**Without innovative, cost-effective strategies for tackling the AMR crisis, the tremendous impact of AMR on people with CF and the broader United States population will continue to worsen. Because the PASTEUR Act presents an opportunity to strengthen the incredibly weak antimicrobial research and development pipeline, stabilize the broken market for antimicrobial products, and ensure that patients have access to the novel treatment options they need, the CF Foundation urges the Energy and Commerce Committee to prioritize this urgent health issue and support passage of this vital legislation.**

*****

The CF Foundation appreciates the opportunity to support and provide feedback on the subcommittee's critical efforts to strengthen America's healthcare system. We look forward to continuing this dialogue and serving as a resource for the committee going forward.

For questions or additional information, please contact David Elin at [redacted].

Sincerely,

Mary Dwight

Senior Vice President
Chief Policy and Advocacy Officer
Cystic Fibrosis Foundation

[6] Adrian Towse and Rachel Silverman Bonnifield. 2022. "An Ambitious USG Advanced Commitment for Subscription-Based Purchasing of Novel Antimicrobials and Its Expected Return on Investment." CGD Policy Paper 277. Washington, DC: Center for Global Development.

Charles N. Kahn III
President and CEO

**STATEMENT**
**of the**
**Federation of American Hospitals**
**to the**
**U.S. House of Representatives**
**Committee on Energy and Commerce**
**Subcommittee on Health**

**Re: Markup of 23 Legislative Proposals**

The Federation of American Hospitals (FAH) submits the following statement for the record in advance of the House Committee on Energy and Commerce's Health Subcommittee markup of 23 bills. We appreciate the Committee's efforts to advance legislation that strengthens America's health care system and maintains access to vital telehealth services, and we look forward to continuing to work with the Committee on these critical issues.

The FAH is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. Tax-paying hospitals account for approximately 20 percent of community hospitals nationally.

Telehealth and remote patient monitoring has transformed our health care system by utilizing technology to modernize and redesign how care is delivered, and hospitals have been at the forefront of making these technologies an integral part of our operations. We thank Congress for its swift action and leadership in expanding access to telehealth during the COVID-19 public health emergency (PHE) and maintaining access to telehealth coverage through December 2024 in the *Consolidated Appropriation Act of 2023*. This mark-up builds on past progress to advance vital telehealth extensions that provide certainty to patients and providers alike to meet America's future health care needs.

## Telehealth and Remote Patient Monitoring

The past four years of telehealth expansion has set in motion a large-scale transformation of our nation's health care system and demonstrated strong patient interest and demand for continued telehealth access.

The FAH supports legislation that would make permanent the Medicare flexibilities implemented during the COVID-19 PHE, such as H.R.7623, *the Telehealth Modernization Act*. This bill would remove geographic and originating site restrictions to ensure that all patients can access care where they are, rural or urban. This bill is a critical solution for improving access to care in rural areas, where many patients travel over an hour for a routine doctor's appointment, and often much further to seek specialty care. Additionally, in many cases (particularly in rural areas where it is difficult to recruit physicians and other highly trained staff), telehealth and other remote technologies help make up for staffing shortfalls or staff burnout, aiding rural hospitals struggling with recruiting and retaining qualified staff.

Telehealth also has proven critical to improving access to mental and behavioral health care delivery, acting as a lifeline to close significant gaps in patient access to these scarce and much-needed services. The FAH supports H.R.7858, the *Telehealth Enhancement for Mental Health Act of 2024*, which would expand access to underserved and at-risk populations by establishing a new modifier or code tailored explicitly for telehealth-delivered mental health services. This bill ensures that individuals receiving mental health services remotely can access seamless and equitable reimbursement processes. Removing restrictions on mental and behavioral health is a solution to a currently unmet need in our health care ecosystem.

Additionally, the FAH supports H.R. 5394, the *Expanding Remote Monitoring Access Act*, which would ease restrictions on health care providers by extending the two-day CMS billing threshold for two years and allow more seniors to benefit from remote monitoring services. Remote patient monitoring technology enables health care providers to observe and treat patients from the comfort of their homes which increases access to care (especially in rural areas), improves health outcomes, and has the potential to reduce long-term health care costs by keeping patients out of the acute care setting unnecessarily.

Without action from Congress, Medicare beneficiaries could abruptly lose access to expanded coverage of telehealth in January 2025. This would have a chilling effect on access to care across the entire health care system. Telehealth and remote patient monitoring have brought our health care delivery system into the 21st century, and the foregoing permanent telehealth policies would foster further innovation and long-term investment in advanced technologies. Congress should provide certainty to providers and patients that access to care when and where they need it via telehealth will be a permanent part of our nations' health care delivery.

**The Dangerous Precedent of Budget Neutral Proposals in OPPS**

While FAH supports the intent behind H.R.1199, *the Facilitating Innovative Nuclear Diagnostics Act of 2023* to preserve Medicare beneficiary access to diagnostic radiopharmaceuticals, we have concerns with the budget neutrality provision in the legislation. Financing proposals of this nature in a budget neutral manner elevates payments for one product or service at the expense of all others, causing a rippling and distorting impact to hospital payments under the Outpatient Payment System (OPPS) across the board. We urge the Committee to reconsider the budget neutral language contained in this legislation.

We appreciate the opportunity to work with the Committee on legislation to extend Americans' access to telehealth and remote patient monitoring services, which are crucial for our seniors and

those in rural and underserved areas. If you have any questions or want to discuss these comments further, please contact Charlene MacDonald at [redacted].