



February 14, 2025

ELECTRONIC SUBMISSION via MEDCACnomination@cms.hhs.gov

Leah Cromwell
Coordinator
Medicare Evidence Development & Coverage Committee
1100 17th Street NW, Suite 400
Washington, DC 20036

RE: ITEM Coalition Support for Mary Ann Clark's Nomination to Serve on the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)

Dear Ms. Cromwell:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition write to offer our strong support for Mary Ann Clark, MHA, to be appointed to the Medicare Evidence Development & Coverage Advisory Committee ("MEDCAC") as an industry representative. Since 1989, Ms. Clark has spent her entire career working with the Centers for Medicare and Medicaid Services ("CMS"), commercial payers, and providers to improve patient access to critical and innovative medical devices and technologies. We believe that her research and analytical skills combined with her passion for demonstrating improvement in patient outcomes by the highest quality of evidence possible make her a particularly strong candidate for the Committee's consideration.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for people with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including spinal cord injury, brain injury, stroke, limb loss, multiple sclerosis, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, as well as other life-altering conditions.

Ms. Clark is known for her expertise in Medicare data and reimbursement and has authored over 40 publications on the health outcomes and economic impact for the innovative medical devices and technologies she researches and analyzes. As Medicare coverage is pursued for an increasing number of innovative medical devices and technologies, a trend that is expected to accelerate with time, we believe it is imperative to include informed participation on the MEDCAC Committee from experts who understand medical, rehabilitation, and disability policy from a variety of perspectives, especially the observational research and analytical perspective.

In her current role as the Global Health Economics and Reimbursement and Real-World Data Strategist at W.L. Gore & Associates, Ms. Clark develops global strategies for Gore's aortic (vascular/endovascular/cardiothoracic surgery) products to create and implement value propositions and evidence plans ensuring payer, provider, and patient needs are considered. Furthermore, she also works to advance strategies to overcome payer and provider barriers to adoption in both pre- and post-market phases, including clinical trial design and evidence requirements and assessing/evolving short and long-term reimbursement opportunities.

Ms. Clark is also a technical advisor on Gore's Medicare data assets and Medicare payment policy analyses. She currently serves as a member of the Medical Device Innovation Consortium ("MDIC") Health Economics and Patient Value Executive Committee, and has been an invited participant as a speaker for the Dartmouth 3D Medical Device Symposium for many consecutive years.

Ms. Clark's qualifications for serving on the MEDCAC Committee are further demonstrated by her extensive previous experience on various guideline and measure development committees. Notably, she has contributed to the National Quality Forum's (NQF) Cardiovascular and Diabetes Resource Use Measures Technical Advisory Panel and the Steering Committee on Cost and Resource Use Measures. Additionally, she has served on the American Heart Association's Council on Quality of Care and Outcomes Research and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force on Retrospective Databases. This breadth of experience underscores the level of her expertise and would make her a valuable asset to MEDCAC.

Ms. Clark's deep expertise in the innovative device and technology field, commitment to evidence-based policymaking, and ability to thoughtfully analyze complex healthcare issues make her exceptionally well-suited for this role. The ITEM Coalition is confident that her contributions will be invaluable to MEDCAC's mission of ensuring Medicare coverage decisions are grounded in rigorous scientific evidence and the best interest of Medicare beneficiaries.

For these reasons, the ITEM Coalition strongly supports the nomination of Mary Ann Clark to membership on the Medicare Evidence Development & Coverage Advisory Committee.

We greatly appreciate your consideration of our endorsement of Mary Ann's candidacy to be appointed to MEDCAC. Should you have any further questions, please contact Peter Thomas and Michael Barnett, coordinators for the ITEM Coalition, by e-mailing Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.

ALS Association*

American Cochlear Implant Alliance

American Congress of Rehabilitation Medicine

American Music Therapy Association

American Occupational Therapy Association

American Therapeutic Recreation Association

Center on Aging and DIS-Ability Policy

Clinician Task Force

3DA

International Eye Foundation

Long Island Center for Independent Living

National Association for the Advancement of Orthotics and Prosthetics

National Association of Rehabilitation Providers and Agencies

Prevent Blindness

RESNA

Rifton Equipment

United Spinal Association*

****Indicates ITEM Coalition Steering Committee Member***