October 14, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: File Code CMS 3372-P2: Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary

Dear Administrator Brooks-LaSure:

Life Sciences Pennsylvania (LSPA), and the 21 medical technology entities below thank you for the opportunity to comment on the Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary (MCIT/R&N) final rule. We understand the Centers for Medicare and Medicaid Services (CMS) proposed repealing the final rule on September 15. Life Sciences Pennsylvania and the medical technology entities listed below are disappointed in CMS' decision to repeal the final rule. We wish to reaffirm our collective support for the MCIT/R&N rule and urge CMS to move expeditiously on a new proposed rule to create a reimbursement pathway for novel medical technologies.

The pathway created by the MCIT/R&N rule would have allowed for Medicare coverage of medical devices that receive the "breakthrough" designation by the U.S. Food and Drug Administration (FDA) on the same day they are given FDA market authorization. Qualifying devices would be covered under MCIT for four years. This rule would have been a major step forward in addressing the long delay that Medicare beneficiaries often face in accessing new medical devices, something that Congress, CMS and stakeholders have been working collaboratively to achieve for some time. Additionally, this pathway would have ensured new technologies are available to Medicare beneficiaries as medical device manufacturers continue to build evidence on the value of their new technology. This was nearly impossible under current rules as the lack of coverage inhibited widespread use in Medicare and limited the ability of companies to demonstrate their technology's suitability for Medicare beneficiaries.

After four years, manufacturers would have the option of seeking local coverage determinations (LCD) or a national coverage determination (NCD) for qualifying devices. This would have represented an important change as manufacturers – many of them small and growing companies – whose products receive the "breakthrough" designation currently face delays upwards of three years before receiving coverage determinations from Medicare. Regulatory standards were also proposed in making "reasonable and necessary" coverage determinations.

This change would have provided patients with access to innovative medical technologies and ensured medical technology companies, many of whom are pre-revenue, have a market through which to disburse their technology. Unless reimbursement through Medicare or a commercial insurer is in place medical providers will not purchase and use the new medical device, which could prevent patient access to lifesaving technology. Without reimbursement a "breakthrough" device, and the company

manufacturing it, could face future research and commercialization delays after having already spent many years and millions of dollars developing their medical technology.

The medical device industry is a unique American success story, both for patients and our economy. The U.S. is the world leader in manufacturing lifesaving and life-enhancing treatments, and the industry is an important engine for economic growth. Pennsylvania and its neighboring states are an important component of the United States' leadership in this industry. The Commonwealth alone is home to more than 330 medical device and diagnostic establishments. These medical technology companies provide 22,000 jobs to Pennsylvanians and the industry contributes $13.1 billion to the state economy.

Nationwide, the industry employs more than 400,000 workers, generates approximately $25 billion in payroll, pays out salaries that are 40 percent greater than the national average ($58,000 vs.$42,000) and invests nearly $10 billion in research and development (R&D) annually. The industry is fueled by innovative companies, the majority of which are small businesses – 80 percent of companies employ fewer than 50 people and 98 percent employ fewer than 500.

The federal government continues to work closely with medical technology companies to invest in and encourage the development of new technologies that help patients with COVID-19. It is critical the Administration promote rules ensuring patients have access to those products and help foster a market that incentivizes investment in innovative technologies. Most commenters responding to the original and interim final rule – patients, providers, innovators, investors, and others - supported final rule implementation. We must do all we can to encourage and promote research, development, investment and innovation, and this final rule was an important step in that direction. We urge CMS to move expeditiously on a new proposed rule to address the Medicare coverage gap and remain dedicated to working with the Administration, and Congress, to finalizing this important coverage decision.

Sincerely,

Christopher P. Molineaux
President & CEO – Life Sciences Pennsylvania
Wayne, PA

Wamis Singhatat
CEO – ActiveProtective Technologies
Fort Washington, PA

Bruce Shook
President & CEO – Vesper Medical
Wayne, PA

Jeb Connor
Chairman, CEO and Co-Founder – Genome Profiling
Wayne, PA

Nance Dicciani
Co-Founder & CEO – RTM Vital Signs
Philadelphia, PA

Stephen R. Popielarski
Co-Founder & CEO – Thermaquil
Philadelphia, PA

Mark Burrows
President – DoseCue
Philadelphia, PA

Baruch Ben-Dor
President & CEO – InfraScan
Philadelphia, PA

Dawn T. Gulick
CEO – Therapeutic Articulations
Spring City, PA

John Witkowski
President – DSM Biomedical
Exton, PA

Randy Hubbell
Chairman of the Board, CEO & President – Carmell Therapeutics
Pittsburgh, PA

Todd Wallach
President & CEO – Evogen
Lower Gwynedd, PA

Mark E. Schafer
President and Chief Technology Officer – PhotoSonix Medical
Fort Washington, PA

Doug Evans
CEO – Lungpacer Medical
Exton, PA

Jim Moran
CEO – Biocoat
Horsham, PA

Tao Song
Chief Executive Officer – Ultratellege USA
Erie, PA

Pete DeComo
Chairman and CEO – ALung Technologies
Pittsburgh, PA

Richard Russo
President & CEO – Endomedix
Montclair, NJ

Liam Kelly
Chairman, President and CEO – Teleflex
Wayne, PA

Eric Rugart
Co-Founder – ZSX Medical
Philadelphia, PA

Damien McDonald
CEO – LivaNova
Pittsburgh, PA

Christian Manders
COO – Promethean LifeSciences
Pittsburgh, PA

Ernest Manders
CSO – Promethean LifeSciences
Pittsburgh, PA