April 16, 2021

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT); Delay of Effective Date; Public Comment Period (CMS-3372-IFC)

Dear Acting Administrator Richter:

The State Medical Technology Alliance (SMTA) offers the following comments on the Centers for Medicare & Medicaid Services' (CMS) Interim Final Rule (IFC) delaying the effective date and requesting comments on the recent final rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."[1] SMTA has long advocated for streamlined approaches to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients who suffer from debilitating or life-threatening illnesses. **SMTA urges CMS to implement the MCIT final rule without further delay.**

As members of the SMTA, we are state and regional life sciences associations representing biotechnology, medical device companies, universities, research institutions, and venture capital firms across the country, all dedicated to developing and delivering life-enhancing and life-saving products. Medical technology innovators who are members of SMTA associations range from the largest to the smallest medical technology innovators and companies.

SMTA is concerned that additional delay in implementing MCIT could compromise access to breakthrough diagnostic and therapeutic devices for Medicare beneficiaries suffering from debilitating conditions, such as heart disease, diabetes, kidney disease and cancer. We urge CMS to implement the MCIT program expeditiously so that all Medicare beneficiaries, including the most vulnerable patients, beneficiaries with multiple comorbid conditions, and beneficiaries at various points along the social and economic spectrum, can benefit from access these important breakthroughs. In doing so, MCIT may become one of several different strategies that CMS can use to help address the impact of health inequities and social disparities in health.

[1] 86 *Fed Reg* 14542, et seq, March 17, 2021; *see* https://www.govinfo.gov/content/pkg/FR-2021-03-17/pdf/2021-05490.pdf.

CMS also highlighted in the proposed rule concerns from stakeholders that "breakthrough devices are not automatically covered nationally by Medicare once they are FDA market authorized," noting that variation in coverage from one jurisdiction to another is also a concern. The MCIT program would improve this long-standing issue of regional coverage inconsistency by ensuring nationwide access to these new technologies.

In 2016, Congress enacted the 21st Century Cures Act[2], which among other things advanced medical device innovation by creating a new Food and Drug Administrative (FDA) program to expedite review of diagnostics and devices that represent breakthrough technologies and to promote their use in health care delivery. The MCIT rule would extend the spirit of 21st Century Cures by accelerating the coverage process, thus expediting access to innovative breakthrough devices for the patients who need them most.

In the fiscal year 2020 Hospital Inpatient Prospective Payment System (IPPS) final rule[3], CMS provided for an alternative new technology add-on payment (NTAP) pathway for breakthrough technologies, deeming such technologies to meet criteria for newness and substantial clinical improvement and thus to automatically qualify for NTAP if the cost criterion was also met. In the calendar year 2020 Hospital Outpatient Prospective Payment System (OPPS) final rule[4], CMS provided for an alternative transitional pass-through payment (TPT) for breakthrough technologies, deeming such technologies to meet the substantial clinical improvement and thus to automatically qualify for TPT payment if the newness, cost, and other criteria are also met.

These actions by CMS demonstrate a recognition of the role breakthrough technologies play in improving the lives of patients with debilitating illness. The MCIT rule that was finalized on January 14, 2021, further advanced CMS' commitment to ensuring that Medicare beneficiaries have access to new and innovative breakthrough technologies that improve health and outcomes.

Recommendation:

SMTA strongly supports the MCIT pathway to coverage for FDA-designated breakthrough technologies and urges CMS to implement the final rule as soon as possible. The MCIT program will provide meaningful access to breakthrough devices and diagnostics for Medicare beneficiaries without other options.

Combined with the breakthrough pathway for inpatient NTAP and outpatient TPT payment, MCIT will help to promote future advancements in patient care. Implementation of MCIT signals to the entire innovation ecosystem that taking the risk to develop breakthrough technologies is important to improving patient care and can be rewarded if those devices receive FDA marketing authorization.

[2] P.L. 114-255, December 13, 2016.
[3] 84 FR 42047.
[4] 84 FR 61295.

SMTA urges CMS to make the MCIT provisions of the final rule effective without further delay.

SMTA applauds CMS's commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve the lives of patients with debilitating conditions. We greatly appreciate the opportunity to comment on this proposed MCIT coverage rule.

Sincerely,

Arizona Bioindustry Association, Inc. (AZBio)
Biocom California
BioFlorida
BioForward Wisconsin
BioOhio
BioUtah
California Life Sciences Association (CLSA)
Colorado BioScience Association (CBSA)
Florida Medical Manufacturers Consortium (FMMC)
Georgia Bio (GaBio)
HealthCare Institute of New Jersey (HINJ)
Illinois Biotechnology Innovation Organization (iBIO)
Indiana Health Industry Forum
Indiana Medical Device Manufacturers Council (IMDMC)
Kentucky Life Sciences Council (KLSC)
Life Science Tennessee
Life Sciences Pennsylvania
Life Science Washington
MassBio
Massachusetts Medical Device Industry Council (MassMEDIC)
MedTech Association (NY)
Michigan Biosciences Industry Association (MichBio)
Missouri Biotechnology Association (MOBIO)
New Mexico Biotechnology & Biomedical Association (NMBio)
North Carolina Bioscience Organization (NCBIO)
Oregon Bio
South Carolina Biotechnology Industry Organization (SCBIO)