November 2, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT)

Dear Administrator Verma:

The State Medical Technology Alliance (SMTA) is pleased to offer the following comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Medicare Coverage of Innovative Technology (MCIT).[1] SMTA has long supported a swift and streamlined approach to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients with debilitating or life-threatening illnesses, and we commend CMS for taking this important step.

As members of the State Medical Technology Alliance (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.

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 the development of diagnostics and devices that represent breakthrough technologies and to promote their use in health care delivery. At that time, Congress did not include provisions that would have created a streamlined approach to coverage, coding and payment for those innovations.

However, in its fiscal year (FY) 2020 Hospital Inpatient Prospective Payment System (IPPS) final rule, 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 (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS provided for an alternative transitional pass-through payment (TPT) for breakthrough

[1] *Federal Register*, Vol. 85, No. 170, pp. 54327-39, September 1, 2020.
[2] P.L. 114-255, December 13, 2016.

technologies, deeming such technologies to meet the substantial clinical improvement and thus to automatically qualify for TPT payment if the newness and cost criteria are also met. Later that year, the October 13, 2019, Executive Order 13890 (E.O. 13890) directed the Secretary to issue proposals that would encourage innovation for patients, including such streamlined approaches.

We applaud these efforts by CMS to recognize the importance of new innovations and the role they play in improving the lives of patients with debilitating illness. The MCIT proposed rule represents CMS' continuing commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve health and outcomes.

Overarching Recommendations:

SMTA strongly supports the MCIT pathway proposal for FDA-designated breakthrough technologies and urges CMS to finalize the MCIT portion of the proposed rule as quickly as possible. In the final rule, CMS should make clear that the MCIT pathway applies to diagnostic tests. The MCIT provisions are critical for Medicare beneficiary access to breakthrough devices and diagnostics.

Combined with the new breakthrough pathway for inpatient NTAP and outpatient TPT, MCIT will help to spur future advancements in care because CMS is sending a signal to the entire innovation ecosystem that taking the risk to develop breakthroughs in patient care will be rewarded if those devices receive FDA marketing authorization.

Again, we appreciate CMS's efforts to improve access to new medical technologies in this rule, and offer the following specific comments for your consideration:

<u>Opt-In Approach</u>
MCIT is a voluntary program. SMTA supports an opt-in approach under which a manufacturer would voluntarily notify CMS of its interest in pursuing the MCIT pathway. An opt-in approach will allow manufacturers to pursue their own business judgment rather than rely on an assumption by Medicare about the manufacturer's preference. Further, manufacturers should have the opportunity to opt-in at any point in time, although a delay in notifying CMS of a manufacturer's intention to pursue the MCIT coverage pathway may result in a period of coverage of less than four years, depending on the date of FDA market-authorization or market availability (see below).

Recommendation:

- **SMTA supports an opt-in approach under which a manufacturer would voluntarily notify CMS of its interest in pursuing the MCIT pathway.**

<u>Posting of Covered MCIT Pathway Devices on CMS Website</u>
CMS states that it intends to put devices that are covered through the MCIT pathway on the CMS website so that stakeholders can be aware of what is covered through the MCIT pathway. SMTA supports efforts by CMS to be transparent about this new program and sharing information with stakeholders regarding MCIT-covered devices, similar to the way CMS posts information about Medicare coverage of Investigational Device Exemption (IDE) studies.

Recommendation:

- **SMTA supports the proposal to post devices covered through the MCIT pathway on the CMS website.**

Four-Year Coverage Period

SMTA supports the proposed four-year MCIT coverage period. We agree with CMS statement that, while MCIT should have some time-limit on how long a breakthrough device can be considered "new" for purposes of MCIT coverage, manufacturers can leverage this period to demonstrate the value of innovative new devices in the marketplace. The proposed four-year period appears adequate to allow for coverage and market access while also allowing manufacturers that choose to do so to further develop clinical evidence.

SMTA supports the proposed four-year coverage period, beginning with the date of FDA market authorization as a breakthrough technology, unless there is a documented delay in U.S. market availability, in which case coverage should begin on the date of market availability. This option is consistent with the way CMS determines the start of coverage for new technology add-on payments under the Inpatient Hospital Prospective Payment System (IPPS) or transitional passthrough payments under the Hospital Outpatient Prospective Payment System (OPPS). Furthermore, it would be meaningful to smaller companies for whom the cost of evidence generation studies is very often prohibitively expensive without a stream of revenue from coverage.

For the small handful of FDA-designated breakthrough devices that obtained FDA marketing authorization prior to the effective date of the final MCIT regulation, SMTA believes CMS should provide four years of coverage beginning with the effective date of the final rule, or the date of FDA-market availability, whichever comes second. Those early entrants into the FDA Breakthrough Pathway program should be able to receive the benefit of four full years of coverage. To deny or truncate the coverage period for early entrants would not meet the spirit of the rule nor the Executive Order, which were intended to encourage access to innovative technologies for patients who need them.

Recommendation:

- **CMS should finalize the four-year MCIT coverage period.**
- **CMS should begin coverage on the date of FDA market authorization or, in the event of delay, on the date of market availability, as attested by the manufacturer.**
- **For early entrants to the Breakthrough Pathway program that have already received market authorization, CMS should provide the full four years of coverage, beginning on the date the final rule becomes effective, or the date of market availability, whichever comes second.**

Four-year Coverage for FDA-Designated Breakthrough Devices and Second-to-Market Breakthrough Devices

SMTA supports coverage under the MCIT pathway for every device that is *designated as a breakthrough device by the FDA*. Notably, the FDA Breakthrough Devices Program is designed to

be product-specific, which may conflict with CMS's traditional categorical approach to coverage, under which CMS typically covers and pays for similar products, or procedures in which similar technologies are used, in the same way. In other words, similar technologies manufactured by different companies may be covered in a procedure under a single NCD, for example, and reported using the same codes. When new but similar products are approved or cleared by the FDA, they may use the available coverage and payment pathway.

SMTA believes that the MCIT pathway should be available to an FDA-designated breakthrough device that is authorized for marketing. MCIT should apply to these breakthrough technologies regardless of whether the breakthrough device is the second- or third-to-market of that device type. We also believe that those breakthrough technologies should be eligible to receive coverage for the full four-year period. Additionally, existing technologies that receive breakthrough designation from the FDA for a novel indication also should be eligible for coverage under the MCIT program for that new indication.
The situation where a subsequent similar technology also receives breakthrough designation should be infrequent, given FDA's narrow definition and the fact that breakthrough-designated devices are designed to meet serious debilitating or life-threatening diseases or conditions, it makes sense to ensure, as CMS has proposed, that these technologies should be eligible for four years of coverage under MCIT.

FDA has contemplated situations where multiple devices with the same intended use may be granted breakthrough designation. Under FDA's guidance for Breakthrough Pathway devices,:

> *Breakthrough Device designation may be granted for multiple devices with the same proposed intended use, and a Breakthrough Device designation will not be revoked solely on the basis of another designated device obtaining marketing authorization. As a consequence, multiple Breakthrough Device designations for the same intended use may be granted and have subsequent submissions pending simultaneously. However, when a Breakthrough Device has been approved or cleared or has had a De Novo request granted, no additional devices with the same intended use will be designated as a Breakthrough Device, unless the criteria for designation described above are still met in light of the first Breakthrough Device's market availability.*[3]

While we believe these situations will be rare, a challenge lies in how CMS should address coverage and payment for second-to-market (or any subsequent) devices that are <u>not</u> designated as breakthroughs by the FDA.

While the MCIT pathway would not be available to a non-breakthrough device under the proposed rule, a manufacturer should be able to pursue coverage through existing processes (national or local coverage determination process, claim-by-claim adjudication, etc.). Yet, for these non-breakthrough technologies, an existing coverage pathway *should also include* the coverage determination for an MCIT-approved device.

[3] *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program, Guidance Document, FDA Breakthrough Devices Program, December, 2018

The subsequent-to-market non-breakthrough device could potentially be covered for the remainder of the MCIT coverage period if the device is appropriately described by the available coverage and coding parameters. Similarly, if the similar, non-breakthrough device applies for and receives a coverage determination (such as an NCD) outside of the MCIT pathway, the breakthrough device potentially could be covered after the MCIT period under the NCD.

CMS will certainly encounter implementation issues as this new program develops and new technologies enter the market, and SMTA stands ready to work with CMS to address these and other issues that may not have been contemplated in the development of the proposed rule. Patient access to these innovative technologies should serve as an important guiding principle and would support the spirit of the proposed regulation. .While these are important issues to resolve over time, contemplation of how all future scenarios can be addressed should not delay issuance of the final rule.

Recommendation:

- **SMTA supports MCIT coverage for all FDA-designated breakthrough technologies for the full four-year coverage period. Second-to-market (or subsequent) devices of the same type, even for the same indication, that are designated as breakthrough devices should be eligible for the full four-year MCIT coverage period.**
- **Similar, subsequent-to-market non-breakthrough devices that fall under the same class or category as the breakthrough device may pursue coverage through existing processes, including the remainder of the four-year MCIT coverage period, if appropriate.**

Coverage Beyond the MCIT Coverage Period

CMS states in the preamble that, at the conclusion of the four-year MCIT coverage period, several scenarios are possible, including (1) a CMS National Coverage Determination (NCD); (2) a negative, or non-coverage, CMS NCD; (3) a local coverage determination (LCD) or claim-by-claim adjudication based on the discretion of a local Medicare Administrative Contractor (MAC). CMS specifically solicits feedback on whether CMS should initiate a national coverage analysis if a MAC has not issued an LCD for a breakthrough device within six months of the expiration of the four-year MCIT coverage period.

SMTA does not support the automatic initiation of a national coverage analysis if a MAC has not acted by issuing an LCD. We believe the best approach is to allow manufacturers to decide which option to pursue as the four-year MCIT coverage period draws to a close. Because the MCIT pathway is voluntary, and each specific breakthrough device unique, companies should have flexibility to pursue the option for coverage that meets the needs of the population being served. Companies desiring an NCD at the end of the four-year coverage period could apply for that option. On the other hand, companies that prefer a local coverage option should have the flexibility to pursue that option as well. Further, CMS should consider a fourth option – extension of MCIT coverage for some period of time (e.g., 1-2 years) to allow companies that are conducting studies to support coverage beyond the four-year MCIT coverage period to complete those studies. A determination to continue MCIT coverage could be made on a case-by-case basis, depending on

the nature of the evidence collection, as it could take longer than four years to complete some studies.

While nothing in these comments would preclude CMS from acting on its own to open a national coverage analysis, SMTA does not support a process where this happens automatically or is triggered by inaction on the part of the MACs. This approach would provide flexibility for manufacturers to pursue a range of options that may be appropriate for the company, the technology, and most importantly for clinicians and patients. A flexible approach would also allow for ongoing discussions between CMS and manufacturers regarding the best approach to take.

Recommendation:

- **The MCIT coverage pathway should allow manufacturers to have flexibility in determining the appropriate approach for continued coverage beyond the four-year MCIT coverage period.**
- **This flexibility includes a company's ability to seek national or local coverage, as appropriate for the technology and the affected patient population, or to not seek a formal coverage determination and rely instead on claim-by-claim adjudication by the MAC.**

Ensure a Process for MCIT Covered Technologies to Receive Appropriate Coding and Payment

CMS states that once a manufacturer has notified CMS of its intention to utilize the MCIT pathway, CMS proposes to subsequently coordinate with the manufacturer regarding steps that need to be taken for "MCIT implementation purposes."[4] The Agency further states that the frequency of engagement will be driven largely by whether the manufacturer has questions for CMS. SMTA has long advocated for, and strongly supports, true engagement and dialogue between device companies and CMS.

When CMS issued the proposed rule for MCIT, the agency also announced that it had reorganized by establishing a new Technology, Coding and Pricing Group that could better coordinate and manage policies related to new technology innovations in care. CMS also announced that it was creating a new pilot program to help medical technology companies "navigate" the complex process of ensuring coverage, coding and payment. We applaud CMS for taking these steps and we urge CMS to engage with companies that have breakthrough products as early in the process as possible – even before the product is granted market authorization – to ensure that MCIT technologies can receive coding and payment as quickly as they receive Medicare coverage.

Clear processes should be articulated to allow manufacturers to pursue appropriate coding, appropriate placement in payment system categories or establishment of new payment categories, and adequate reimbursement to support new breakthrough innovations. Without coding and clearly designated payment categories established at the beginning of the four-year automatic coverage period, manufacturers will be challenged to generate the evidence CMS expects for continuation of coverage beyond that period. Because of the need to have a code as soon as a device is approved for MCIT, SMTA also recommends that CMS create a process that assigns a specific code to each

[4] 85 F.R., p. 54330.

MCIT approved technology that needs it for use, if only temporarily, immediately upon approval for coverage.

These coordination issues are important and will require the work of multiple groups within CMS. While it may take time to resolve all of these coordination issues, CMS can manage these issues through subregulatory guidance and payment regulations and should not delay issuance of the final MCIT rule.

Recommendation:

- **CMS should ensure there are appropriate processes in place to facilitate engagement with CMS (even before FDA market authorization), and to ensure timely coding and payment for new technologies in the MCIT coverage pathway. SMTA looks forward to working with CMS on implementation of the MCIT coverage pathway.**
- **CMS should clearly articulate the process for code assignment or acquisition for breakthrough technologies that qualify for MCIT coverage.**
- **CMS should create a process for assigning a specific code to MCIT-approved technologies immediately upon approval for coverage, so that codes are available for use at the start of the MCIT coverage period.**
- **Similarly, CMS should establish payment immediately upon coverage of a breakthrough technology.**

<u>NTAP and Outpatient Passthrough Approval and Medicare Coverage of Approved Technologies by Medicare Administrative Contractors (MACs)</u>

CMS solicits comments from the public regarding whether existing pathways should be modified. While we recognize that NTAP, outpatient transitional passthrough payment (TPT) and new technology Ambulatory Payment Classification (NT APC) approval processes and Medicare coverage policies are different, CMS should develop policies that would require MACs to recognize and cover NTAP/TPT/NT APC approvals and associated services (e.g., physician services to implant or provide the technology), and the extra payment that approved technologies are eligible to receive. Local MACs have issued non-coverage determinations for technologies that CMS had approved for NTAP, effectively denying beneficiaries in many States access to a new technology. Often, companies with new technologies have limited resources. Thus, when faced with MAC non-coverage determinations, despite showing substantial clinical improvement and having been approved for NTAP/TPT/NT APC, the prospect of pursuing a MAC-by-MAC strategy for coverage can be challenging. Additionally, this problem raises an inconsistency between the purpose of NTAP/TPT/NT APC to provide beneficiaries access to innovative technologies and procedures, on the one hand, and Medicare coverage policies, on the other. Further, the MCIT regulation should not limit MCIT coverage to only implanted devices, but should make clear that non-implanted breakthrough devices are eligible for the MCIT coverage pathway.

For approved NTAP, TPT and NT APC applications (for non-FDA designated breakthroughs), CMS central headquarters has determined that those technologies and procedures provide substantial clinical improvement and improved clinical outcomes for patients. Last year, in the FY2020 final IPPS and OPPS rules, CMS deemed FDA-approved breakthrough technologies to have met the criteria for newness (in the case of NTAP) and substantial clinical improvement

criteria. However, MACs can still deny coverage for these technologies and procedures because NTAP/TPT/NT APC are not coverage decisions. While the MCIT proposal will prevent this from happening for FDA-designated breakthrough products with MCIT coverage, other products that receive NTAP/TPT/NT APC would not have the same protection. MACs should be prohibited from questioning CMS's decision making on these technologies and from denying coverage for any NTAP/TPT/NT APC product (though this would not preclude the CMS Coverage and Analysis Group from making a coverage decision).

Recommendation:

- **When CMS determines an NTAP-approved or TPT-approved technology provides substantial clinical improvement, or deems a breakthrough technology to have met the criteria for NTAP or NT APC, beneficiaries residing in all MAC regions should have access to the technology; and MACs should be prohibited from issuing noncoverage policies in those cases.**
- **MACs should be prohibited from denying coverage and add-on payments for medical services or technologies approved for NTAP or pass-through status, or NT APC, by the Secretary. Coverage should also extend to the associated service codes that are required to utilize the device or procedure.**
- **In the final rule, CMS should amend the proposed regulatory language at 405.605(b) by adding "or use" after "to implant" to clarify that covered items and services include:**

  (b) any reasonable and necessary procedures to implant *or use* the breakthrough device.

Clarify Application to Diagnostic Tests

CMS states in the preamble to the proposed rule that it is limiting MCIT to medical devices "because that is a category of products explicitly identified in EO 13890, and [CMS] has identified that breakthrough devices can experience variable coverage across the nation shortly after market authorization."[5] In other preamble language, CMS makes contradictory statements about the application of the MCIT to diagnostic technologies. For instance, CMS states that "the MCIT pathway can provide a fast-track to Medicare coverage of innovative devices that may more effectively treat or diagnose life-threatening or irreversibly debilitating human disease or conditions."[6] CMS should clarify in the final rule that FDA-approved breakthrough diagnostic technologies are breakthrough devices and therefore are eligible for the MCIT coverage pathway.

CMS proposes a regulatory definition of "breakthrough device" in a new section 42 CFR 405.601(b) to mean "a device that receives such designation by the Food and Drug Administration (FDA)(Section 515B(d)1) of the FD&C Act (21 U.S.C. 360e-(d)(1))."[7] FDA's Breakthrough Devices Program is for medical devices and device-led combination products that "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."[8] Therefore, CMS's proposed regulatory language would apply the new MCIT

[5] 85 F.R., p. 54329.
[6] Ibid. at p. 54333.
[7] Ibid. at p. 54338.
[8] Ibid. at p. 54329.

coverage pathway to diagnostic technologies that are designated by the FDA as breakthrough devices.

Recommendation:

- **CMS should clarify in the final rule that FDA-approved breakthrough diagnostic technologies are breakthrough devices and therefore are eligible for the MCIT coverage pathway.**

MCIT Coverage for Humanitarian Use Devices (HUDs) with Humanitarian Device Exemption (HDE) Status

CMS states that the MCIT coverage pathway shall be available to FDA-designated breakthrough devices that are FDA market authorized (that is, the date the medical device receives Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request) for the breakthrough device, and that fit within a Medicare benefit category. CMS should clarify that Humanitarian Use Devices intended to benefit patients with rare diseases or conditions that are designated as breakthrough devices by the FDA should also be eligible for the MCIT coverage pathway. Per the FDA, these devices, by definition, are intended to diagnose or treat very rare diseases that occur in small patient populations where there is an inability to follow the typical clinical pathway.

FDA may grant a Humanitarian Device Exemption (HDE) from certain requirements of the Food, Drug & Cosmetic Act if the device, among other criteria, demonstrates probable benefit that outweighs the risk of injury or illness from its use and would not be available to a person with the disease or condition in question without the HDE, and no comparable device exists to treat or diagnose the rare disease or condition.

Recommendation:

- **Given the unique nature of devices with HDEs, CMS should make clear that such devices, are eligible for the MCIT pathway.**

Medicare Benefit Category

CMS proposes to automatically cover breakthrough technologies unless CMS determines that a device does not have a Medicare benefit category. The proposed regulation would apply the MCIT pathway to any FDA cleared or approved breakthrough device that is "within a Medicare benefit category" and is not excluded by statute, regulation, or NCD. SMTA supports the broad definition of "within a benefit category," as this approach aligns with the purpose of the MCIT to provide an additional pathway to Medicare coverage for innovative breakthrough devices (including diagnostic and screening tests) in order to avoid unnecessary access delays following FDA authorization.

SMTA has supported legislation that would cover technologies that do not fall within an existing benefit category. We urge CMS to support this legislation. But recognizing that CMS does not on its own have authority to include technologies that do not fit within a benefit category, we urge CMS to work with industry and other stakeholders to review and consider changes to existing

regulatory policies that lack clarity or specification and actually create unnecessary barriers to coverage of some breakthrough technologies.

One area where review and consideration of changes to regulations can create opportunities for coverage within Medicare's current benefit category structure is the area of digital health technologies, for example those using apps, algorithms, augmented or artificial intelligence, and software as a medical device. Many FDA-designated breakthrough technologies use digital technologies or have components that are digital technologies that define their uniqueness among those technologies used in health care delivery. We believe that many of these technologies could be covered under Medicare's existing benefit categories if a clearer pathway were established through regulation for their coverage.

For example, the FDA has approved a technology that would function as an artificial pancreas for persons with diabetes and FDA has defined the technology as having three components: a continuous glucose monitor (CGM), an insulin pump, and an algorithm. The algorithm allows the CGM and insulin pump to talk to each other and automatically adjust the patient's glucose levels. Medicare now covers and pays for each of the first two components as durable medical equipment but regulations do not provide clarity or specification for how the algorithm could be covered and paid for separately.

We believe that the algorithm could be covered and paid for separately as a supply necessary for the functioning of the technologies that qualify for coverage under the Medicare DME benefit category—just the way Medicare now covers non-durable test strips used with durable blood glucose monitors and oxygen used in durable oxygen canisters. This example and many others are offered as pathways to coverage for digital technologies in a recently released SMTA-CapView study, *Modernizing Medicare Coverage of Digital Health Technologies*. The study examines each of Medicare's major benefit categories to illustrate how coverage and payment for digital technologies can be accommodated through review and changes to existing Medicare regulations, rather than through changes to Medicare statute.[9]

Recommendation:

- **CMS should use its existing regulatory authority to ensure AI, virtual, app-based and other digital technologies will be eligible for the MCIT coverage pathway.**
- **CMS should apply its discretion to determine the appropriate benefit category to cover certain devices, such as diagnostic testing, cancer screening or devices used in asymptomatic and/or at-risk and high-risk populations, given breakthrough technologies likely will not have NCCN, USPSTF or other relevant guidelines at the time of FDA market authorization.**

Clinical Study Requirements

[9] For a deeper discussion on this topic focusing on the growth of digital technologies and their implications for the Medicare Program, see SMTA-CapView September 2020 report entitled, "Modernizing Medicare Coverage of Digital Health Technologies," https://www.SMTA.org/sites/default/files/resource/SMTA-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf

Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during the proposed four-year coverage period under the MCIT program. However, CMS solicits comments on whether the Agency should require or otherwise incentivize manufacturers to collect and provide additional data in order to track clinical outcomes for the patients that receive these breakthrough devices. CMS recognizes in the preamble that some manufacturers may be required by the FDA to conduct post-market data collection as a condition of market authorization, and notes that the proposed rule would not alter such requirements.

SMTA supports CMS's proposal not to require additional evidence development during the MCIT period as a condition for coverage. However, SMTA also agrees with CMS's statements that evidence may be needed for continued coverage beyond the four-year MCIT coverage period, and this could serve as an incentive to collect and provide additional data. CMS further encourages early manufacturer engagement with CMS to discuss and receive feedback on potential clinical study designs and clinical endpoints that can produce such evidence. It is important that companies understand CMS's expectations regarding the evidence necessary to support coverage beyond the MCIT period and that those companies are able to work together with CMS in an open and transparent manner.

SMTA has long-supported such an approach, under which CMS can create opportunities for dialogue and feedback, which will go a long way toward achieving greater transparency in the coverage process long term, will facilitate better understanding by both parties of the evidence expectations over time, and will assist manufacturers in planning and development as these new innovations become more widely accepted by clinicians and patients alike, and their uses potentially expand. We therefore support CMS's encouragement of continued evidence generation that may inform future Agency decision-making about permanent coverage of a breakthrough medical device or diagnostic technology near the end of the four-year MCIT coverage period. SMTA would also support continued evidence development after the four-year period, potentially in connection with a coverage determination, in order to learn about long-term outcomes, to study additional populations as indications expand, and to track quality over time.

SMTA has previously commented, and maintains, that where additional clinical or scientific evidence is needed (beyond FDA requirements for safety and effectiveness), CMS should:

1) collaborate with stakeholders to clearly identify the data collection objectives;
2) consider the minimum data necessary to achieve those objectives;
3) clearly identify, with input from interested stakeholders, scientifically supported study endpoints and the duration of data collection in advance (including clear stopping rules for data collection, and
4) identify appropriate mechanisms to ensure continuous coverage of an item or service after a study (or other evidence collection) ends, to avoid disruption in coverage and continue to allow Medicare beneficiaries to benefit from important FDA-approved technologies and services until a new or revised coverage determination is issued.

As evidence is generated to support the use of a new innovation or service, SMTA believes that Medicare's coverage policies should reflect these outcomes and minimize additional requirements.

Recommendation:

- **SMTA supports CMS proposal not to require additional evidence development during the MCIT period.**
- **SMTA agrees that evidence may be needed for continued coverage beyond the four-year MCIT coverage period and supports early manufacturer engagement with CMS to discuss and receive feedback on potential clinical study designs and clinical endpoints that can produce such evidence.**

As stated above, 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 Bioscience Industry (AZBio)
Biocom California
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)
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)
South Carolina Biotechnology Industry Organization (SCBIO)