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Note: *Due to the structure and formatting constraints of this Request for Information, AdvaMed's comments were written in response to individual questions and submitted using a web-based form. This letter captures these comments in a single document, with AdvaMed's responses appearing in italics below each question. Questions for which AdvaMed did not submit a response have been removed.*

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Taskforce Subcommittee Asks Health Care Stakeholders for Information to Help Foster Patient Access to Life Saving Cures

The Treatments Subcommittee of the Republican-led Healthy Future Task Force in the U.S. House of Representatives is seeking information from stakeholders and other interested parties regarding medical innovation so that we can supercharge the availability and development of life-saving treatments, devices, and diagnostics, while addressing the rising costs to patients.

The Subcommittee has four primary goals:

- **Goal 1**: Evaluate potential innovative payment solutions for expensive curative therapies in Medicare and Medicaid.
- **Goal 2**: Encourage innovation and make the Medicare system more flexible to be able to absorb new innovative drugs, devices, diagnostics while being good stewards of taxpayer dollars.
- **Goal 3**: Continue U.S. leadership in medical innovation.
- **Goal 4**: Increase access to medical innovation.

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What barriers to innovation in the drug, device, or diagnostic space should Congress address?

With respect to innovation in medical technologies, including diagnostics, Medicare's requirements and processes for coverage and reimbursement are complex and

challenging to navigate. There can be a long delay between the time of FDA approval or clearance and CMS coverage. This is caused by number of reasons, including having to navigate or understand multiple payment systems, coding approaches, and evidence requirements, and the result is often delayed access to new technologies by patients who need them.
AdvaMed has long advocated for a more streamlined approach to coverage, coding and reimbursement for new technologies and diagnostics. Such an approach is needed to expedite access to new technologies that can improve health outcomes for patients who need them.
Additionally, challenges exist for both small and large device and diagnostics manufacturers. Smaller manufacturers often focus on early-stage goals of innovation and technology development but may have limited experience with the complexities of the health care coverage and payment systems. Larger manufacturers, who may be knowledgeable and resourced to engage traditional reimbursement systems, still encounter difficulties when certain rules and requirements are unclear or not well-specified to the public.
Difficulty in securing coverage and reimbursement for devices and diagnostics is increasingly viewed as a barrier to investment and capital dedicated to new technology development, and reductions in such investment may lead to fewer innovations and medical breakthroughs that improve care and advance well-being.

One major area of innovation in medtech that is transforming the delivery of health care services is the development of digital health care technologies. Digital technologies are opening new frontiers in diagnosis, health care delivery, and health management of patient conditions they are designed to treat. However, Medicare regulations and other coverage and payment policies, implemented by the program long before digital health technologies played the major role they are assuming today, do not offer clear and explicit pathways for many digital health technologies or medical technologies with digital components to be covered and appropriately reimbursed by the program. As AdvaMed's report, Modernizing Medicare's Coverage of Digital Health Technologies, argues updating program regulations and other policies is necessary to accommodate digital advances in medical technologies that improve the standard of care and patient engagement. In addition, given Medicare's importance in the health care marketplace, CMS and policymakers in Congress must take a leadership role in coordinating and collaborating with stakeholders. This report with its specific recommendations for updating Medicare's regulatory framework can be found at: https://www.advamed.org/wp-content/uploads/2020/09/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf.

On October 29, 2021, the Biden Administration repealed the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule.

AdvaMed was discouraged that CMS repealed the MCIT final rule, which would have expedited access to breakthrough diagnostic and therapeutic devices for Medicare

beneficiaries suffering from debilitating conditions, such as heart disease, diabetes, kidney disease, acute infections, sepsis, and cancer, which are prevalent in the Medicare population and represent a significant burden of disease, as well as societal cost.

AdvaMed supported repeal of the finalized definition of "Reasonable and Necessary" and recommended that CMS separate the R&N Rule from MCIT and seek additional stakeholder input.

a. The Administration claimed that the rule was "not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose." How can the policy be improved to respond to CMS' concerns? How can "adequate evidence" be gathered in the most efficient and effective way to show an innovative technology is reasonable and necessary for the Medicare population?

AdvaMed has recommended that CMS establish a process by which manufacturers of innovative devices and diagnostics could engage earlier in the process, to allow CMS to evaluate the evidence developed to date and its appropriateness for the Medicare population, and to identify evidence gaps, if any, and ways to develop evidence to fill those gaps. Such a process would provide CMS with a level of assurance that the necessary evidence is being developed. The process could also include a feedback loop, e.g., regular "check-ins" with CMS to ensure proper evidence development, as well as review and evaluation of results.

Regarding the best interests of Medicare patients, AdvaMed has suggested that any coverage should include all of the safeguards CMS currently uses for removing or modifying coverage. For example, CMS could issue a non-coverage NCD, or otherwise remove or revise coverage if the Agency learns that a particular device does not provide clinical benefit. Any process that would allow CMS to withdraw or remove coverage should be open and transparent, and provide for stakeholder input, particularly regarding whether a device is reasonable and necessary, or potentially harmful, based on clinical evidence.

b. If the goals of this rule were to be met with legislation, what would you want to see? What did the rule get right, get wrong, and what should be expanded on?

The rule would have provided for expedited coverage of innovative technologies and would have closed the gap between FDA approval or clearance and CMS coverage for that subset of technologies. While the final MCIT rule addressed Medicare coverage, it did not provide guidance on operational issues, such as determination of appropriate coding or payment-level assignment. The rule also

did not address certain emerging technologies that may not have a specific Medicare benefit category but show promise for improving health outcomes for Medicare beneficiaries. These technologies could include certain screening tests or technologies with digital components or that use AI.

c. **What other types of products and technologies, besides FDA breakthrough devices, should be considered for expedited Medicare coverage under an MCIT-like paradigm? And what safeguards should accompany new or temporary coverage to protect the solvency of the Medicare program?**

CMS has signaled it is considering a new proposed rule entitled "Transitional Coverage for Emerging Technologies" (TCET) and is holding public forums to gather stakeholder input to inform this proposed rule. AdvaMed has stated its desire to work with CMS to identify a definition of "emerging technology."

AdvaMed also supports H.R. 4043, Ensuring Patient Access to Critical Breakthrough Products Act, that creates a path to coverage for breakthrough designated devices, including those without a benefit category. The bill includes a timeline for the development of evidence collection and a permanent coverage decision from CMS.

What kind of flexibilities in the Medicare Advantage program or other value-based programs within Medicare could be adopted to test enhanced coverage of innovative products and technologies in a fiscally responsible manner?

Medicare Advantage plans are required to cover all Part A and Part B covered services. However, although MA plan coverage policies need to align with traditional Medicare coverage, MA plans can include prior authorization requirements that will exacerbate the coverage gap for those beneficiaries enrolled in those plans. In addition, the challenges presented by existing traditional Medicare coverage policies limits the innovative technologies that MA plans need to cover. All of this affects the access and pipeline of innovation targeting unserved or underserved patient populations.

MA plans have an incentive to offer innovative treatments, including digital technologies—to the extent they offer value and assist plans in keeping costs for services provided below the capitated payments they receive from Medicare for enrolled beneficiaries and/or improve quality of care. However, restrictions in coverage of telehealth services under Medicare's statute limited the interest of plans in providing services that would not otherwise be covered. In the Bipartisan Budget Act of 2018, Congress permitted MA plans to include some of the costs of expanded telehealth services in their annual plan bid amounts. This same flexibility could be provided to MA plans that would like to cover innovative and digital technologies that do not have benefit categories and therefore would not be covered by Medicare.

MA plans should ensure coverage of and access to innovative technologies. AdvaMed is committed to working with Congress to achieve our mutually-shared goal of timely access of new innovations in health care diagnosis and treatment to all Medicare patients – in traditional Medicare (fee-for-service) or Medicare Advantage.

How can the FDA's Accelerated Approval Program be improved upon and better integrated with Medicare coverage determinations to expand access to innovative treatments, therapies, and devices while maintaining consumer protections?

AdvaMed is confident that CMS can implement a program that would enable all Medicare beneficiaries to benefit from access to important innovations in health care, including emerging medical technologies. We believe that expedited or streamlined coverage of innovative/emerging technologies can be accomplished. Creation of an expedited, transitional pathway to national coverage for emerging technologies could also become one of several strategies that CMS could use to help address health inequities, particularly for vulnerable patients in underserved communities.

For technologies being evaluated by the FDA, earlier engagement between FDA, CMS and manufacturers, on a voluntary basis, might allow CMS the opportunity to learn about an emerging technology, its intended use, and benefits in the Medicare population. Early engagement would allow CMS to evaluate the existing evidence for a new technology, and ask questions or provide feedback, for example, on additional evidence development that would support Medicare coverage, both immediately and in the long term.

A voluntary (opt-in) and early engagement process also might ease CMS concerns regarding the number of devices that may seek coverage, as manufacturers of devices that are not Medicare-relevant or for which other existing coverage pathways exist might not need to be participants in an expedited coverage program. This approach would facilitate access to those emerging technologies that are approved for patients who have very limited disease monitoring and treatment options.

What are the various categories of Digital Health that need to be recognized from the standpoint of reimbursement to begin exploring the mechanisms for coverage, coding, and payment that may already exist, and to understand where gaps remain under current regulatory and statutory frameworks?

a. For example, would it be helpful to distinguish software applied to Durable Medical Equipment, from software applied to implantable devices?

A wide variety of digital technologies—artificial intelligence (AI), apps, algorithms--are now being incorporated into health care services and medical

technologies. What is key in thinking about how digital technologies can be incorporated into a program like Medicare is whether they can be covered and paid for within the program's benefit category structure, which has requirements and rules that vary by whether a service is considered inpatient hospital care, a physician service, a diagnostic test, durable medical equipment, etc.

Medicare statute does not directly address coverage of digital health technologies; nor does the statute specifically limit or prohibit coverage of digital health technologies within the program's benefit categories. In the absence of an explicit benefit category or categories called digital, digital health technologies should be able to be eligible for reimbursement by Medicare under existing benefit pathways and the incentives to use the technology will be dependent on adequate coverage and reimbursement policies under Medicare.

As we noted above, the Medicare statute was written, and Medicare regulations and other coverage and payment policies were implemented long before digital health technologies played the major role they are assuming today. Therefore, neither offer clear and explicit pathways for many digital health technologies or medical technologies with digital components to be covered and appropriately reimbursed by the program. The regulations themselves can also create barriers to coverage and payment. As AdvaMed's report, Modernizing Medicare's Coverage of Digital Health Technologies, argues, updating program regulations and other policies is necessary to accommodate digital advances in medical technologies that improve the standard of care and patient engagement.

CMS has been taking steps showing that this is possible: establishing new codes that allow Medicare to pay for remote physiologic monitoring and remote therapeutic monitoring and approving a New Technology Add-On Payment (NTAP) application that used AI with a CT scan technology allowing physicians to diagnose a stroke in patients many hours sooner than a CT scan alone would allow. It is, however, the pace at which CMS is accommodating and recognizing coding, coverage, and payment of digital technologies that needs to be accelerated.

b. Are there important distinctions among AI, algorithms, software, and other types of Digital Health technology that should be contemplated?

The variety of different AI and software algorithmic technologies used in health care delivery with their different designs and intended uses, makes it very difficult to generalize about how a program like Medicare should accommodate technologies. We would suggest that it is not the distinction among the digital technologies that is as important as the need for Medicare to find and apply appropriate coding, coverage, and payment policies for services and procedures using the individual digital technologies. For example, FDA has cleared and/or approved prescription digital therapeutics that treat a treat a wide range of serious diseases and conditions, including attention-deficit hyperactivity

disorder, autism, chronic insomnia, irritable bowel syndrome, mental health conditions (such as schizophrenia and post-traumatic stress disorder), and substance and opioid use disorders. However, CMS has yet to find a pathway to coverage and payment under Medicare for these proven treatments for very serious conditions. We ask that the Healthy Future Task Force encourage CMS to recognize that the delivery of health care is changing rapidly and that digital technologies may require a perspective different from existing assumptions underlying current policies determining coverage and payment under the program. Digital therapeutics is but one area in digital technologies where this different perspective is required. This is the only pathway forward to ensuring that Medicare beneficiaries (and other patients as well because the example Medicare sets for coverage policies of private plans) will see the benefits of digital health technologies' deployment.

c. **What current mechanisms are in place to facilitate initial access to Digital Health technologies under the Medicare fee-for-service payment systems? How can those be improved, and where are there gaps?**

We argue that the regulations for each of Medicare's benefit categories can be revised to provide appropriate coverage and reimbursement for the service or procedure using digital technologies—so long as CMS approaches the challenge with a willingness to recognize that the delivery of health care is changing rapidly and that digital technologies may require a different perspective on existing assumptions underlying current policies.

For example, AdvaMed has urged CMS to reevaluate several of the assumptions underlying its reimbursement methodology for physician and other practitioner services using AI-powered technologies. We argue that AI and other software may require new uses of physician time, including reviewing of data generated by AI or time spent supporting coordination and team-based care because of the data.

We have also argued that Medicare's practice expense (PE) methodology, which is a component of the total dollar value of a particular physician service, must be rethought to reflect when software-powered services are not simply part of equipment hardware, and instead can be attributed to a specific service and should be considered direct costs themselves, rather than an indirect expense.

In addition, AdvaMed's report, Modernizing Medicare's Coverage of Digital Health Technologies, provides examples of the different perspective CMS might bring to Medicare's benefit category, durable medical equipment (DME), a benefit that was intended at the beginning of Medicare to be a home benefit. Currently CMS's regulatory definition narrows the broad statutory definition of DME and limits coverage of digital health technologies, especially software-based technologies that can be used on devices in the home. Medicare regulations require that a covered DME item meet a definition of durability of having a minimum life of three years. What Medicare has in mind with this requirement is

a traditional and tangible technology. But why should an app or algorithm used strictly for a medical purpose not also meet the durability requirement of three years. Another related example of CMS's reluctance to think in terms of a digital world for the DME benefit was in a final DME rule from December 2021. The rule stated that a continuous glucose monitor system (for managing diabetes) that consists of a software application added to a smart phone would not be covered as DME because smart phones can be useful in the absence of illness or injury—another Medicare regulation that we argue fails to recognize the reality of a new digital health care world and the need for revision of existing policies.

d. For example, the New Technology Add-on Payment (NTAP) may be available for AI software used in hospital inpatient settings to help cover hospitals' costs for initial investment in technologies that meet certain standards. What improvements could be made to support adoption of Digital Health used in inpatient care? Are similar mechanisms needed in other settings, such as hospital outpatient departments?

We offer two specific opportunities for CMS to enable quicker access to innovative digital technologies including Robotic-assisted surgeries (RAS), computer-assisted navigation (CAN), and artificial intelligence (AI) in the outpatient hospital setting. The first is relative to the qualifying criteria for medical devices to be considered for transitional pass-through payments. The current criteria specifically require a device must —

a) Be an integral part of the service furnished;
b) Be used for one patient only;
c) Come in contact with human tissue; and
d) Be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.

Furthermore, the device cannot be any of the following:

a) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets
b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than radiological site marker).

As RAS, CAN, and AI technologies are increasingly introduced for more and more procedures and frequently include components that do not come into contact with patients or represent a capital expenditure, these criteria are inappropriately exclusionary for these technologies. In particular, because capital costs are included in establishing the APC payment rate, the same rationale should equally apply when calculating the operating costs for pass-through payments.

A second opportunity is for CMS to consider that the use of RAS, CAN, and AI may represent new and significantly different procedures eligible for consideration under the New Technology APC policy. As these technologies evolve, they are changing procedures in important ways that improve efficiency and clinical outcomes. But their introduction is frequently hindered by payment policies that require hospitals to absorb their costs without any payment adjustment until claims data become available 2 or 3 years later. AdvaMed has urged CMS to consider using its approach to evaluating such technologies under its New Technology APC policy to help encourage faster introduction and development of these important innovations by providing additional payments reflecting hospitals' costs.

How do plans under Medicare Advantage reimburse for Digital Health technologies? What is take-up of these technologies under Medicare Advantage?

a. How can adequate reimbursement be ensured, and where are there access gaps?

b. How should CMS approach pricing for AI used in physician office settings to ensure accurate and adequate payments in the long term?

See above.

c. What mechanisms exist under alternative payment models to facilitate access to Digital Health technologies? What improvements could CMMI potentially pursue to specifically enable health systems to invest in Digital Health technologies?

Analogous to our comments on MA plans above, alternative payment models (APMs) sharing in risks of savings/losses have an incentive to offer innovative treatments, including digital technologies—to the extent they offer value and assist plans in keeping costs for services provided below the capitated payments they receive from Medicare for enrolled beneficiaries and/or improve quality of care. However, without clarity and specificity in coverage and payment for digital technologies in Medicare regulations, APMs may be reluctant to cover digital technologies because their benchmarks against which actual spending are compared will not include spending for digital technologies that are not covered by Medicare. In the Bipartisan Budget Act of 2018, Congress permitted APMs to cover expanded telehealth services, because being at risk for incurring losses for expanded services not included in their benchmarks, would encourage the APM to make sure that the expanded services would be cost effective. This same flexibility could be provided to APMs that would like to cover innovative and digital technologies that do not have benefit categories and therefore would not be covered by Medicare and not included in the calculation of benchmarks.

Does the existing FDA framework adequately facilitate innovation in digital health?

Yes, we believe the existing FDA framework adequately addresses digital health to encourage innovation and advancements of these products. For nearly a decade the FDA has led the development of digital health regulatory policies that are now emulated throughout the world. FDA continues to be a leader in developing forward-thinking digital health policies, such as those concerning cybersecurity, artificial intelligence, and software development. Indeed, because of the FDA's work in this space, the US digital health market has grown year-over-year since 2017, and is projected to continue its current growth trend (see https://www.statista.com/outlook/dmo/digital-health/united-states#revenue).

Of course, there is always more that can be done. And we are encouraged that the Agency continues to modify and update its digital health policies to keep pace with innovation in the field. We believe FDA's current open discussions about change protocols for artificial intelligence and machine learning devices is a positive step and have commended the Agency for its international leadership on developing Good Machine Learning Practices with the Canadian and UK governments, as well as its leadership of the IMDRF AI Working Group.