AdvaMed
Advanced Medical Technology Association

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The Honorable Mariannette J. Miller-Meeks, M.D.
U S. House of Representatives
Washington, DC 20515

The Honorable H. Morgan Griffith
U.S. House of Representatives
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The Honorable Mike Kelly
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Representatives Meeks, Griffith, and Kelly:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to respond to the Request for Information from the Modernization Subcommittee of the Healthy Future Task Force regarding the utilization of wearable technologies, the expansion of telemedicine, and the digital modernization efforts of the U.S. healthcare system. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings. Our responses follow the order in which the Modernization Subcommittee solicits input from stakeholders.

Questions on Wearable Technologies and Telehealth for Manufacturers and Developers

AdvaMed member companies produce a wide range of wearable technologies treating a variety of health care conditions, including diabetes, monitoring of cardiac arrhythmias, monitoring the risk of cardiac failure, and breathing/sleeping disorders. Each of the technologies discussed below has digital components that have opened 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. The report further argues that CMS should review its regulatory frameworks to improve coverage of digital health technologies. 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.

Diabetes and Continuous Glucose Monitoring (CGM)

How does CGM improve the lives of those with chronic conditions and disabilities?

- Continuous glucose monitoring (CGM) has been demonstrated in clinical trials and real-world studies to have significant benefits for patients with diabetes, including:*[1-8]
  - Reduced A1C*[1,2], increased Time in Range (TIR)*[3,5], reduced hospitalizations*[8], reduced absenteeism*[7], and improved quality of life.*[7] For example, increased HbA1c results in an average increase in diabetes-related costs of $789 per patient with Type 1 diabetes and $440 per patient with Type 2 diabetes.[9,10]
- CGM has enabled diabetes care with telemedicine during the COVID pandemic. Clinicians have been able to evaluate remotely the glucose data generated by CGMs with their patients and make treatment changes to enable appropriate care.[11] CGM and telemedicine together allow patients to follow up with clinicians with higher frequency and with less disruption to their daily lives. A meta-analysis by Tchero et al, showed that telemedicine was at least as effective as face-to-face visits for managing care for people with diabetes.[12]

How do coverage and reimbursement policies affect utilization of CGM? Should CGM be covered under Medicare as durable medical equipment DME? What are barriers to the development of wearables?

- CGM is now covered under Medicare as DME. However, Local Coverage Decisions (LCDs) by DME Medicare Administrative Contractors (MACs) have restricted coverage and continue to create barriers to CGM access for Medicare beneficiaries. MAC coverage criteria should be updated to reflect standards of care and current clinical evidence.
  - For example, MAC LCDs should allow coverage of CGMs for persons using insulin, without a requirement for multiple daily insulin injections or administrations, or use of an insulin pump, since current clinical evidence indicates CGMs improve patient health and outcomes regardless of the frequency of daily insulin administration or pump use. The American Diabetes Association's Standards of Care in Diabetes provide that use of CGM should be considered from the outset of the diagnosis of diabetes that requires insulin management. This would allow close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent blood glucose monitoring (BGM with traditional fingerstick testing).

- MACs and CMS struggle to keep up with the fast-paced evolution of Diabetes Standards of Care as well as innovation in the digital health domain. For example, Medicare regulations require beneficiaries using CGM to use a durable CGM receiver in conjunction with a digital app, when a smartphone would function just as well and for which Medicare beneficiaries would not incur a coinsurance charge.
- Disparities in access to CGM, by race and ethnicity, also exist. AdvaMed data show that Black Medicare beneficiaries with diabetes have lower use of CGM when compared to the prevalence of diabetes among Black Americans.

How can Medicaid programs cover wearable technologies and are any states having success using them to improve health outcomes and lower costs?

- States have flexibility in defining specific services they will cover under their Medicaid plans. There is no consistent CGM coverage policy in Medicaid with wide variation in coverage.[16]
  - The ADA's Health Equity and Diabetes Technology: A Study of Access to Continuous Glucose Monitors by Payer and Race[17] found that poorer, older, Black and Brown Americans have less access to CGMs than their counterparts. Three trends emerged:
    - Individuals with Medicaid are the least likely to use a CGM, especially people of color with Medicaid.
    - Young people are more likely to get CGMs than older Americans are.
    - Black Americans are at the most pronounced disadvantage when it comes to CGM access
- We recommend that States:
  - Cover CGMs for both adults and children
  - Cover CGMs for those with Type 1 and Type 2 diabetes
  - Provide access to the full-range of CGM devices necessary to meet patients'' treatment needs
  - Consider covering CGM as a pharmacy benefit rather than a DME benefit.

*****Data from these studies were collected with the outside US version of FreeStyle Libre 14-day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional, real-time glucose alarms. Therefore, the study data is applicable to both products.
† Costs updated to reflect 2020 dollars, based on medical CPI conversion from April 2008 to April 2020

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Long Term Continuous Electrocardiographic (LT-ECG) Devices

How does LT-ECG improve the lives of those with chronic conditions and disabilities?

- Long Term Continuous Electrocardiographic (LT-ECG) monitoring devices are used to detect cardiac rhythm disorders associated with approximately one-third of the deaths from heart disease, approximately one-fourth of strokes, and the dominant cause of loss of consciousness associated with heart disease resulting in fractures and accidents in the elderly.
- Cardiac rhythm disorders are often transient and not easily recognized on a routine electrocardiogram (ECG), and thus the major reason for the need of extended, long-term monitoring. There have been many types of cardiac monitors over the years, for example, Holter is one type, but the most recent advance in cardiac monitoring has been LT-ECG.
- LT-ECG monitors, because of their engineering, software, and practical wearability allow long-term recordings up to 14 days, a critical factor in detecting cardiac rhythm disorders, also known as arrhythmias.
- LT-ECG uniquely allows for the continuous recording of the ECG over long periods of time. This is a key aspect of improved diagnostics. Continuous ECG recording allows a more detailed analysis of the ECG by well-trained technicians using sophisticated diagnostic software. This is critical in proper patient care as to what causes and what terminates a rhythm disorder aiding the physician in patient management. Pure algorithmic approaches, e.g., watch technologies, cannot yield this depth of analysis nor contend with more abstruse cardiac rhythm problems.
    - LT-ECG has been evaluated in over 35[1] peer-reviewed published articles to have significant diagnostic sensitivity and direct impacts on care management pathways for patients with known or suspected arrythmias. *[2-5] Studies have shown that LT-ECG has proven greater diagnostic results, higher arrhythmia detection rate and longer wear times than other, older technologies. [6.]
- Critically, during the COVID pandemic, LT-ECG has enabled care with telemedicine during the COVID pandemic. Clinicians have been able to receive prescribe, and review LT-ECG data generated by patients remotely. This has enabled continuous, appropriate diagnosis and care for those at risk.

How do coverage and reimbursement policies affect utilization of LT-ECG? Should LT-ECG be covered under Medicare as durable medical equipment DME? What are barriers to the development of wearables?

- LT-ECG devices are generally single use and therefore, do not qualify as DME under Medicare.

- Despite its proven value to public health, LT-ECG technology faces significant Medicare reimbursement challenges because CMS has left to Medicare Administrative Contractors (MACs) the responsibility to set payment rates. These rates have failed to recognize the total costs of providing LT-ECG services to Medicare beneficiaries, as determined by a KPMG cost analysis commissioned by AdvaMed. The MAC rates have failed to recognize the costs of the technology's components, technician evaluation of recordings, complex and ever-improving diagnostic and visualization software, continual improvements in artificial intelligence tools, and continual evolution in electronic medical records integration.
- Without appropriate reimbursement, these services cannot respond to even the current knowledge of cardiac arrhythmias and their diagnoses let alone make ongoing investment to address the continuous advances in their understanding.

How can Medicaid programs cover wearable technologies and are any states having success using them to improve health outcomes and lower costs?

- States have flexibility in defining specific services they will cover under their Medicaid plans, and in many cases do not currently cover LT-ECG. This is in contrast to older monitoring technologies, which are covered by all Medicaid plans.
    - Previously LT-ECG services were described by Category III CPT or "T" codes which Medicaid programs were challenged to implement.
    - Given the many policy changes affecting Medicaid programs in recent years, including growth in use of managed care and expansion of the program in many states to non-disabled adults, LT-ECG is well-positioned to provide vital diagnostic care to this population.

References: 1. https://go.irhythmtech.com/hubfs/PDFs/ZIO-XT/Publication%20Summaries.pdf. **2.** Rosenberg, et.al. Pacing and Clinical Electrophysiology (2013) https://onlinelibrary.wiley.com/doi/full/10.1111/pace.12053 **3.** Barrett, et al, American Journal of Medicine (2014) https://www.amjmed.com/article/S0002-9343(13)00870-X/fulltext **4.** Tung, et al, Frontiers in Neurology, (2015) https://www.frontiersin.org/articles/10.3389/fneur.2014.00266/full **5.** Arnold, et al. Journal of Health Economics and Outcomes Research, (2015) https://jheor.org/article/9897-cost-analysis-and-clinical-outcomes-of-ambulatory-care-monitoring-in-medicare-patients-describing-the-diagnostic-odyssey **6.** Yenikomishain, et al. Clinical Medical Research and Opinion (2019) https://www.tandfonline.com/doi/full/10.1080/03007995.2019.1610370 .

Wearable Cardioverter Defibrillator (WCD)

How does WCD improve the lives of those with chronic conditions and disabilities?

- The wearable cardioverter defibrillator (WCD) is a treatment option to provide protection for sudden cardiac arrest (SCA). The WCD offers patients at high risk for SCA advanced protection and monitoring while their longer-term risk profile is assessed and allows them to return to their activities of daily living. There is a large body of clinical evidence comprising over 20,000 patients that supports the efficacy of the WCD. Trials have demonstrated that when worn, the WCD reduces arrhythmic death by 62% (CI: 0.17,

0.86; p=0.02) and total mortality by 75% (CI: 0.13, 0.48; p<0.001).

- Beyond the defibrillation benefits, software, and artificial intelligence within the WCD supports physician in patient management by providing actionable data and physician-set alerts about a patient during their cardiac recovery which assist the physician in achieving a range of treatment goals including optimization of medical therapy, monitoring of activity trends, and body position.
- A real-life example:
    - A nurse practitioner noted in the health survey conducted with the patient through the monitor, reported shortness of breath, a >2lb weight gain, and swelling. Average daily heart rates climbed from 78 to 82 to 85 and sleep position changed from 4 degrees to 9 degrees to 14 degrees. A walk test was aborted by the patient for both shortness of breath and fatigue. The nurse practitioner called the patient, confirmed the trends visible through the WCD, and made medication adjustments over the phone.

Should WCDs be covered under Medicare as durable medical equipment DME?

- The WCD is currently covered under Medicare as DME. This remains the best classification of these types of devices. However, the current payment model in the DME benefit category does not provide a clear-cut reimbursement path for the ongoing and additional investments made by manufacturers to develop and offer additional software enhancements that allow physicians to better manage these high-risk patients proactively and remotely. Medicare regulations should be revised to explicitly recognize the costs of software and other digital enhancements in DME-covered devices for a benefit category that is intended to serve beneficiaries in their homes. These changes to reimbursement for DME would also complement the incentives CMS has established during the past few years for physicians to use new remote patient monitoring codes for monitoring care they provide to patients in their home rather than only through in-person office visits.

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[1] Olgin JE, Lee BK, Vittinghoff E, et al. Impact of wearable cardioverter-defibrillator compliance on outcomes in the VEST trial: As-treated and per-protocol analyses. *J Cardiovasc Electrophysiol* 2020;1-10. https://doi.org/10.1111/jce.14404.

Chronic Respiratory Disease (e.g. Sleep Apnea, Chronic Obstructive Pulmonary Disease (COPD) and Cloud-Connected Medical Devices

How do Sleep and Respiratory Care medical devices improve the lives of those with chronic conditions and disabilities? Chronic respiratory devices, especially those with cloud-connected digital technologies have transformed care for people with sleep apnea, COPD, and other chronic diseases. Today, many continuous positive airway pressure (CPAP) devices, bilevel respiratory

devices, and home mechanical ventilators are cloud-connected, enabling physicians and respiratory specialists to remotely monitor their patients.

- Respiratory devices that incorporate fully integrated cloud-based technologies that capture real-time physiological data aid physicians in providing targeted patient care and enable coordination between care settings and providers.
    - Secure, cloud-based software systems that communicate data from the devices helps providers manage patients with sleep-disordered breathing and respiratory insufficiency; enabling quicker access to patient data, sharing of clinical insights with other health professionals and reduced costs related to patient follow-up.
    - Online support programs and patient-facing engagement applications empower patients to stay engaged and their therapy.
- When used together, a patient-facing therapy engagement application and secure cloud-based provider-facing software system have been shown to increase 90-day, CMS-defined therapy adherence to 87% compared to 70% of patients being monitored in a provider-facing system alone.[1] The importance of this digital transformation in these wearable technologies becomes obvious when the extent of respiratory disease in the world is considered:
    - Sleep Apnea
        - The US ranks second to China among the countries with the highest number of affected individuals at an estimated 78 million people in the US.[2]
        - In 2015, the costs attributable to sleep deficiency in the U.S. workplace were estimated to exceed $410 billion, equivalent to 2.28 percent of GDP.[3]
        - 4% fewer inpatient and emergency dept. visits for every nightly hour slept on CPAP[4]
        - 62% lower all-cause mortality rate when treating sleep apnea with CPAP[5]
    - COPD/Asthma/Lung Disease
        - In a recent model of the health and economic of COPD in the US from 2019-2038[6]:
            - Direct medical costs attributable to COPD in the US are estimated to be $800.90 billion: $337.13 billion in men and $463.77 in women
            - The estimated indirect costs of work absenteeism due to COPD is $101.30 billion
            - In the U.S. alone, the estimated COPD deaths = 9.42 million
        - Non-invasive ventilation (NIV) reduces one-year risk of death by 76%.[7]
        - Portable oxygen enables mobility; regular physical activity is linked to lower risk of hospitalization, death.[8]

How do coverage and reimbursement policies affect utilization of respiratory devices? What are barriers to the development of wearables? Should devices be covered under Medicare as DME?

Continuous positive airway pressure (CPAP), bilevel, and home mechanical ventilation devices are covered by Medicare under the Durable Medical Equipment (DME) category. However, low payment rates for chronic respiratory devices under Medicare's Competitive Bidding Program create disincentives for developers of these technologies to continue to innovate with new patient-facing digital features that will improve health care outcomes. Medicare has also failed through its coding process for new technologies to recognize the extra value cloud-based features bring to patients and providers alike for managing chronic respiratory conditions.

References 1. Malhotra A et al. Chest 2018 **2.**Benjafield AV et al. Lancet Respir Med 2019 **3.**Hafner et al. RAND Corporation. 2016 **4.**Kirsch DB et al. J Clin Sleep Med 2019 **5.** Lisan Q et al. JAMA Otolaryngol Head Neck Surg 2019 **6.**Zafar Zafari, Shukai Li, Michelle N. Eakin, Martine Bellanger, Robert M. Reed, Projecting Long-term Health and Economic Burden of COPD in the United States, Chest, Volume 159, Issue 4, 2021, Pages 1400-1410, ISSN 0012-3692. https://doi.org/10.1016/j.chest.2020.09.255.**7.**Kohnlein T et al. Lancet Respir Med 2014 **8.**Barrett M et al. Health Aff 2018

Questions on Telemedicine Expansion

Which flexibilities created under the COVID-19 public health emergency (PHE) should be extended?

Because of waivers provided by Congress at the very onset of the pandemic, Medicare beneficiaries living in urban areas have been able to receive telehealth services, restricted by Medicare statute to rural areas, and have also been able to receive telehealth visits in their homes, as opposed to being in a health care facility or physician's office as required by law. We believe that waiving these two requirements during the PHE has demonstrated the effectiveness of telehealth as an important source of care for Medicare beneficiaries, and especially for the growing number of patients aged 85+ and those with multiple chronic conditions. Beneficiaries should be able to make decisions about the most appropriate site and source of their care, and recent surveys show that they are able to do that, with significant declines in telehealth visits and more beneficiaries seeking care through in-person visits.

The immediate uptake in telehealth by providers and patients alike has also demonstrated the agility of the health care system to scale up to provide telehealth—in the process transforming the delivery system through innovative technologies, telehealth, and digital technologies more broadly, that can improve health outcomes and reduce the rate of growth in health care spending. After this experience, to return to the status quo following the end of the PHE will have the effect of turning back the clock on this innovation, which has positively transformed the delivery of health care services. AdvaMed has strongly advocated for efforts in the Congress to address the statute's limitations that severely impede beneficiary access to telehealth.

With this RFI, AdvaMed continues to be on record as supporting these changes and we urge Congress to expand, without delay, access to telehealth by eliminating the two statutory restrictions. Short of immediate action by the Congress to implement any expansion that eliminates these restrictions, we urge Congress to support a continuation of existing waivers for telehealth until the end of 2023, corresponding to the extension of Category 3 telehealth services

provided by CMS, to demonstrate, through evaluation, the need for changes to statute to avoid an abrupt end to the benefits expanded telehealth has provided to Medicare beneficiaries.

We note that it is not just telehealth that has been the focus of expanded waivered services, but also more broadly other communication technology-based services, such as expanded remote patient monitoring services, that have also been at the heart of increased access. During the past two years, patients and their physicians and other providers have learned a great deal about the health benefits and efficiencies that come with expanded coverage and payment of a wide variety of digitally based health care services. We describe several of these in the first sections of this letter. In many ways, the flexibilities CMS has introduced for increasing access to care have transformed our understanding and assumptions about the nature of health care services delivery and expanded our perspectives on the appropriateness of serving patients in the community and their homes.

At the present time, some are anticipating an end of the PHE, even though the omicron infection and hospital admission rates are still very high in many parts of the nation. During this period of perhaps transition out of the PHE, we urge CMS to exercise the same leadership it showed during the earliest months of the pandemic and take actions to evaluate as soon as possible the specific flexibilities it introduced during the PHE to determine which of these should lead to legislation and/or specific policy changes that would ensure continuation of the benefits both patients and providers have seen from the flexibilities introduced by CMS. The end of the PHE should not mean the immediate end of changes to the delivery of health care that patients and providers have become accustomed to. Patients and providers alike need a glide path to transition out of the PHE, especially when hospitals and other providers are experiencing staffing shortages and the health system has not fully recovered from the pandemic. If CMS requires more time to evaluate the benefits of its flexibilities and Congress to deliberate on changes to Medicare's telehealth benefit, it should support a glide path plan through the end of 2023 to continue the flexibilities, rather than reverting to pre-PHE statutory and implementing requirements on the day the PHE ends. We look forward to working with the Committee on this important transition.

How will artificial intelligence affect access, delivery, and cost of healthcare and the role it plays in modernization?

The variety of different AI and software algorithmic technologies used in health care delivery today and expanding significantly in the future, with their different designs and intended uses, makes it very difficult to generalize about the impact these technologies will have on payment methodologies used by public and private health care plans. One key application of AI today is in clinical decision support (CDR) for practitioners. CDR has proved to be very useful in reducing diagnostic errors, reducing unnecessary testing and treatments, and improving outcomes for patients from earlier and appropriate treatments. It is for that reason that we focus our comments on AI's role in physician and other practitioner services.

AdvaMed has urged CMS to reevaluate several of the assumptions underlying its reimbursement methodology for physician and other practitioner services. For example, CMS should evaluate if and how AI and other software may require new uses of physician time. In addition to creating a need to review additional data, these innovative technologies can improve coordination and support of physician interactions as they provide more team-based care. Services using AI may also require additional time with patients to explain the findings of AI powered services. All of these uses of AI may point to a need to factor more time and intensity into a physician service.

In addition, 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 the rapidly evolving AI and other algorithmic technologies used in physician services. Regarding practice expenses, we have argued to CMS that 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. The difference in attribution has a large impact on the dollar value of an individual physician service using AI. If Medicare beneficiaries and other patients are to have the benefits of AI and other software, it is critical that Medicare's physician reimbursement methodology appropriately recognize that the technologies are direct practice expenses involving costs in use, costs of innovation through research and development, and costs of updating AI and other software. AI should not be viewed as "operating in the background" and simultaneously for hundreds of patients. Some types of AI should be paid separately because of the added value it provides for a specific patient's condition, while other AI may not need to be paid separately.

We ask that the Committee recommend to CMS that the Agency hire a contractor with expertise in AI to review different types of AI (algorithmic, self-learning, augmented intelligence, e.g.) to review how each type of AI functions, and what clinical utility it provides and how it interacts with the clinician and extracts more information from data. That information should then be translated into revisions in the values of individual physician services for purposes of reimbursement.

We appreciate this opportunity to bring to your attention issues of great importance to our members. If you have any questions, please contact Richard Price in AdvaMed's Payment and Health Care Delivery Department at rprice@AdvaMed.org.

Sincerely yours,

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