1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

August 30, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1807-P/RIN 0938-AV33

Dear Administrator Brooks-LaSure:

The Consumer Technology Association (CTA®) appreciates the opportunity to comment on the Calendar Year 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies proposed rule.

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most powerful tech event in the world. CTA is the trade association representing more than 1300 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA's Health Division strives to increase the use of technology-enabled value-based health care to reduce health care costs and drive better health outcomes. The Division, which is made up of cutting edge small and large companies in the health care and technology sectors, including telehealth and personal health wearable companies, health care payers, health systems and biopharmaceutical innovators, provides policy advocacy, health care market research and standards initiatives that advance the appropriate use of consumer technologies in the health care context.

General Comments

CTA appreciates the Centers for Medicaid and Medicare Services' (CMS) continued focus on advancing access to health care. We believe technology can be leveraged to bridge gaps of time, distance, and provider availability. Specifically, CTA supports CMS' proposals around telehealth and digital mental health treatment (DMHT).

We recognize that under current law, critical statutory flexibilities that expand access to Medicare telehealth services expire on December 31, 2024. We encourage CMS to continue its work with Congress to expand these authorities and to act swiftly if and when extension legislation is passed to provide certainty to providers and patients as quickly as possible.

As stated in our comments on the CY 2024 Medicare Physician Fee Schedule proposed rule, CTA believes the adoption of artificial intelligence (AI) in health care is being impeded by CMS' lack of clear, consistent, and robust policies related to coverage and reimbursement. CMS broadly and incorrectly categorizes "computer software" —whether SaMD or off-the-shelf word processing—as "indirect" PE, thus mostly a non-allocable expense. This issue of categorizing all software (whether medical device software or not), as non-allocable indirect PE is an ongoing challenge for medical device software manufacturers and developers. CMS itself has stated "that as the data used in our PE methodology have aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology." Medical devices are not an "other expense" akin to "administrative labor" or "office expenses." Neither is SaMD an "other expense" because SaMD is, by law, a medical device SaMD is subject to the same regulatory oversight by the Food and Drug Administration (FDA) as hardware medical devices. The legal, regulatory, and financial burdens incumbent of a SaMD manufacturer (i.e., developer) are no less stringent than those of hardware medical device manufacturers. Under the law, SaMD is a medical device no different than hardware, thus it's incorrect to consider SaMD as an "other expense" and not "medical equipment" (which need not be physical hardware) a direct practice expense. CMS must distinguish and appropriately categorize SaMD away from mere "computer software" indirect PE but properly categorize and account for SaMD as direct PE under "medical equipment."

Telehealth

Telehealth, including audio-only telehealth, is a critical tool to increase access to care for Medicare beneficiaries and CTA supports CMS uses its authority under existing law. CTA strongly supports CMS' proposal to:

> *"include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology."*

CTA also supports CMS' proposal to extend through CY 2025 the flexibility for providers to use their enrolled practice location instead of their home address when providing telehealth services from their home. As the agency notes in the proposed rule, this is an important safety and privacy protection for Medicare providers.

Remote Patient Monitoring

CTA continues to urge CMS to remove the 16-day data collection requirement on remote patient monitoring to reflect new services and expanding use cases for RPM. While some RPM services benefit from more days of data collection, there are many treatments that benefit from monitoring for fewer than 16 days of time.

The agency has requested feedback on RPM reimbursement as part of various global payment packages. We are supportive of the agency's consideration of future revisions to remote patient monitoring (RPM) reimbursement as part of a global payment package intended to better capture provider expenditures and make reimbursement more viable for the tools and services intended to improve access to comprehensive care modalities.

Digital Mental Health Services

CTA supports CMS' proposal to reimburse, for the first time, DMHT devices furnished incident to professional behavioral health services. This is an important first step towards broader Medicare recognition and reimbursement of prescription digital therapeutics, which are evidence-based, FDA-cleared or approved software products that treat various mental and physical health diseases and disorders.

Specifically, CTA supports CMS' proposal to establish three new HCPCS codes: GMBT1 (onboarding, education, and supply of the DMHT device); GMBT2; and GMBT3 (treatment management services that support DMHT device use). While CTA supports the establishment of these codes, we are concerned with the agency's proposal to use contractor pricing for GMBT1. Delegating determination of the payment rates to Medicare Administrative Contractors (MACs) can cause confusion and unnecessary delays in payment, and often initial payment rates are set artificially low. This poses barriers to provider adoption until there is confidence the codes will be adequately reimbursed in a timely manner. Instead, CTA urges CMS to set a national rate for GMBT1. The agency says in the proposed rule that invoices were provided. We encourage CMS to use these invoices to develop a national payment rate.

Further, CTA recommends CMS adopt technical corrections related to specific proposals:

- CMS proposes to define the term "digital CBT" as "software devices cleared by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health." FDA cleared devices refers to devices that have gone through the 510k process; however, given digital therapeutics are still an emerging technology, it would be more appropriate to use the term "FDA cleared or approved" to include devices who go through the FDA *de novo* approval process.

- In the code descriptors for GMBT2 and GMBT3, there is reference to "professional time reviewing data generated from the DMHT device." However, DMHT devices, as defined in the proposed rule, generally do not generate data from patient observations or patient specific inputs. Instead, CMS should use "reviewing information *related to* the DMHT device."

CMS also posed specific questions for commenters regarding DMHT and below CTA responds to questions 1, 2 and 4 in the proposed rule:

1. Whether payment should be made if the practitioner furnishes a digital device that has not been cleared by FDA for mental health treatment for a specific use, even if the digital device has been cleared by the FDA for another specific use
    i. CTA supports payment for DMHT devices under GMBT1 if a digital device has been cleared or approved for mental health treatment. While this is an important first step, we also encourage CMS to continue to develop codes for digital therapeutics that have proven safe and effective in other clinical areas.

2. Whether payment should be made for DMHT devices cleared by the FDA not only under 21 CFR 882.5801 but also under other regulations
    i. Yes, CMS should consider broadening to DMHT devices cleared under other regulations. 21 CFR 882.5801 is a very narrow category of computerized behavioral therapy for psychiatric disorders. CMS should consider other categories of computerized behavioral therapy for mental health disorders. Further, as this is an evolving category, the agency should provide flexibility for new FDA regulatory categories as long as safety and effectiveness have been determined and which are appropriate for use as a part of a behavioral therapy plan for

mental health disorders.

4. Whether and how payment might be limited to a set number of DMHT devices per calendar month per patient
    a. It may be appropriate to limit a patient to one DMHT device for one indication of use (e.g. one device to treat schizophrenia); however, given many patients experience more than one mental health condition, it may be appropriate to allow for use of more than one DMHT in a calendar month (e.g. one device to treat schizophrenia, one device to treat generalized anxiety disorder, if a patient has both diagnoses).

Conclusion

CTA appreciates the opportunity to comment on the Calendar Year 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies proposed rule. We urge CMS to finalize proposals related to telehealth and DMHT and we look forward to continuing to work with CMS to increase access to quality health care by leveraging technology.

Sincerely,

Michael Petricone
Senior Vice President, Government Affairs
Consumer Technology Association

René Quashie
Vice President, Digital Health
Consumer Technology Association

Catherine Pugh
Director, Digital Health
Consumer Technology Association