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The Honorable Mehmet C. Oz, MD, FACS
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: RIN 0938-AV82

Dear Dr. Oz:

The Consumer Technology Association (CTA®) appreciates the opportunity to comment on the Calendar Year 2027 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 1200 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 advances consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. The Division includes telehealth providers, personal health wearable companies, digital health technology companies, healthcare payers, health systems, and biopharmaceutical innovators. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and more – and they are poised to lead the next wave of American innovation with cutting-edge health technology.

General Comments

CTA strongly supports the Trump Administration's focus on leveraging technology to improve the health of Americans. From the Kill the Clipboard Initiative, to the Health Tech Ecosystem, to the ACCESS Model, the Department of Health & Human Services (HHS) is taking action, and CTA members are proud to be a part of these critical programs. The Centers for Medicare and Medicaid Services (CMS) has made historic investment in rural health through the Rural Health Transformation Program (RHTP), which includes tech innovation as a strategic goal. Additionally, CMS has a stated goal to use real-time, artificial intelligence (AI)-driven tools to improve fraud detection. Together, these commitments will improve access to care, data interoperability, and program integrity.

However, CTA is concerned that several policies in the proposed rule, particularly those governing remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) services, would undermine rather

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than advance these initiatives and goals. CTA supports CMS's goal of protecting Medicare from fraud and abuse, but the answer is to target bad actors, not make legitimate technology-enabled care harder to deliver. Requiring practices to employ clinical staff furnishing RPM and RTM services, while simultaneously reducing reimbursement, would hit small and rural providers especially hard. Many simply do not have the scale or resources to build these capabilities in-house.

This directly conflicts with the Administration's broader health agenda. Technology should help relieve provider shortages, reduce administrative burden, expand access to care, and allow clinicians to focus their time on patients. CMS should not advance those goals with one hand while adopting policies that make technology-enabled care harder to deliver with the other.

There is a better approach. CMS can strengthen program integrity through targeted safeguards, better data collection, provider enrollment requirements, and AI-enabled fraud detection without limiting legitimate care arrangements or patient access. We therefore urge CMS not to finalize these proposals and instead work with stakeholders on targeted, evidence-based safeguards for CY 2028.

Remote Physiological Monitoring and Remote Therapeutic Monitoring Services

CTA does not support CMS' proposals related to RPM and RTM services, specifically the proposals to:

- Only allow payment for RPM or RTM services when furnished by clinical staff employed by the practice;
- Crosswalk CPT codes 99453 and 98975 to the direct PE inputs from CPT code 99473;
- Crosswalk CPT codes 99445 and 99454 to the direct PE inputs from CPT code 99474;
- Crosswalk CPT codes 98976, 98977, 98978, 98984, 98985, and 98986 to the direct PE inputs from CPT code 93270; and
- Eliminate the PE inputs for CPT codes 99470, 99457, 99458, 98979, 98980, and 98981.

If finalized, these proposals would impose substantial new burdens on providers while severely limiting patient access. Few providers, particularly small and rural providers, have the capacity to build in-house RPM or RTM programs, especially considering the proposed cuts in reimbursement. This outcome is difficult to reconcile with the Administration's own frequent observation that technology's central promise lies in relieving provider burden and mitigating provider shortages. The proposal to limit payment to services furnished by clinical staff employed by the practice compounds the problem: it would exclude not only vendor partners, but also health systems that draw on nursing or provider groups organized as separate legal entities within the same system, as well as 1099 contract staff. These proposals run counter to realizing the full benefit of digital health tools, and we urge CMS not to finalize.

Proven Benefits of Remote Patient Monitoring

Remote patient monitoring (including RPM and RTM services) has proven to both improve patient outcomes and lower costs. For example, one study looking at retrospective Medicare claims data from primary care and cardiology clinics across 15 states found a reduction in cost of care (\$1302 per patient per year), driven by a reduction in inpatient costs (\$1420 per patient per year).¹ Importantly, this study was focused on what the researchers call "remote patient care" – which includes the provision of a remote patient monitoring device, but more importantly a remote clinical team monitoring and triaging vitals and conducting virtual visits driven by clinical guideline-based interventions. Additionally, in the case of this program, artificial intelligence (AI) is helping prioritize patients experiencing high-acuity symptoms, as well as alert physicians when a patient may need clinical intervention. Not only is this important to show the value of virtual staffing, but it also highlights the inappropriateness of the proposed code crosswalks to much lower reimbursed codes.

There are many additional studies highlighting the benefits of remote patient monitoring. A review of studies found remote patient monitoring was associated with early detection of health deterioration, reduced hospital admissions, and improved patient satisfaction.² Similar to the previous study, all the programs included in this review utilized virtual nursing.

¹ <https://www.sciencedirect.com/science/article/pii/S2542454825000906>

² <https://sigmapubs.onlinelibrary.wiley.com/doi/10.1111/wvn.70134>

Alternative Steps

In the proposed rule, CMS points to a 2024 HHS Office of the Inspector (OIG) report on remote patient monitoring which found additional oversight of services is needed.³ However, CMS' proposals are not aligned with the recommendations included in the OIG report.

Putting aside questions around the findings in the OIG report itself – for example, the finding that use of remote patient monitoring increased dramatically between 2019 and 2022 when CMS didn't even start reimbursing for RPM codes until 2018 – OIG recommended steps CMS could take to gather additional information on whether or not there was inappropriate or fraudulent billing. CTA supports alternative guardrails to help address potentially inappropriate or fraudulent billing that have been proposed by the Remote Monitoring Leadership Council, including:

- Additional general supervision criteria
- Adopt HHS OIG recommendations as outlined in the 2024 report, including:
 - Requiring that all remote patient monitoring services be ordered by a Medicare eligible provider
 - Requiring use of an "incident to" modifier
 - Implement methods to collect information about the devices being used and conditions being treated
 - Establish a new provider or supplier enrollment classification for remote patient monitoring companies
- Adopt the proposed initiating visit requirement, but with exceptions for currently enrolled patients, patients with existing provider-patient relationships, and certain post-acute situations
- Build robust pathways to value-based payment

CTA recognizes that many of these suggested policies require additional consideration by CMS and stakeholders; therefore, we urge CMS to not adopt the proposals and instead work with stakeholders on more appropriate and targeted evidence-based safeguards for CY 2028.

Technology and AI-Augmentation in Primary Care via the Medicare AWW

How can CMS improve the effectiveness, efficiency, personalization, and beneficiary experience of the IPPE and Medicare AWW?

CTA agrees with CMS that AI holds great promise in better enabling primary care services, like the Medicare annual wellness visit (AWV). In addition to AI being able to personalize pre-visit health risk assessments for patients, it can help pull relevant existing data from the patient's record and create a clinically meaningful summary for providers instead of taking time to go through each generic question. AI can also ingest the patient's health risk assessment, combine it with past patient data like prior visit notes, wearable data, and test results to flag areas of concern that providers may miss.

Could AI-enabled AWWs improve health outcomes that prior studies have found to be inconclusive?

Qualitative studies have examined how providers perceive the motivation, value, and process of Medicare AWWs. Providers report that AWWs prompt important conversations that might not otherwise arise during a clinical encounter and help strengthen the provider-patient relationship. Many, however, characterize much of the visit as mere "questionnaire administration" that a medical assistant could just as readily perform. AI is well suited to automating that non-clinical intake, freeing providers to concentrate on substantive patient interaction and on concerns that other visits may have overlooked.⁴

How should CMS evaluate whether AI-enabled AWWs are improving outcomes rather than merely increasing AWW volume, documentation completeness, coding intensity, or low-value care follow 'cascades' of services? Specifically, for which outcomes should CMS hold technology companies accountable?

³ <https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/>

⁴ <https://pmc.ncbi.nlm.nih.gov/articles/PMC11520687/>

First, CMS should continue to use AI tools to better detect potential fraud and abuse across services. For example, AI tools should be looking for duplicate/copied documentation from one provider across patients. CMS can also use similar tools to benchmark patients who have had AWWs using AI tools against similar patients who have not to determine if those with AWWs are receiving more low-volume (or not clinically indicated) tests and services. CMS could also require technology companies to submit benchmark data. CMS should not assume that an increase in utilization is automatically inappropriate as use of AI tools can help capture patients who otherwise would not have been seen until they needed to visit an emergency department. While creating outcomes measures and outcomes-based payment specific to AWWs would be difficult given the limitations of these visits and the breadth of unrelated issues covered in an AWW, CMS can and should use AI tools to ensure providers and vendors are providing services appropriately.

Software as a Medical Service (SaMS) Laboratory Analyses

CTA appreciates CMS' growing recognition of the varying functions and intended uses of health technology, including AI. For this reason, we support CMS proposed terminology change from Software as a Service (SaaS) to Software as a Medical Service (SaMS). While we support this proposed change in terminology, we encourage CMS to establish a better framework to define SaMS – such as the relationship to FDA's SaMD definition – while CMS states that not all SaMD is SaMS, it does not state all SaMS is SaMD. CMS should continue to work with stakeholders to create a concrete definition and framework around SaMS that provides more clarity around payment and interaction with other regulatory frameworks, such as FDA's SaMD framework.

Payment for Medicare Telehealth Services

Telehealth Flexibilities and Modifiers

CTA appreciates the clarification from CMS in creating modifiers BB and BC, the statutorily required modifiers for telehealth services furnished through a virtual telehealth platform, that these modifiers do not affect payment. We encourage CMS to issue the referenced subregulatory guidance on modifiers BB and BC swiftly to allow sufficient implementation time before January 1, 2027. The guidance should be clear and straightforward to best allow providers to comply.

Medicare Diabetes Prevention Program

CTA was supportive of many of the changes in the CY26 Medicare Physician Fee Schedule around Medicare Diabetes Prevention Program (MDPP), including the addition of an asynchronous delivery modality and allowing MDPP suppliers to deliver the Set of MDPP services online through December 31, 2029. While this was a positive step, CMS did finalize payment rates that are significantly lower for online suppliers. In future rulemaking, we encourage CMS to take additional steps to improve MDPP, including:

- CMS should limit eligible virtual suppliers to organizations with “Full” or “Full Plus” CDC recognition status. This would expand access while ensuring only high-quality virtual suppliers are eligible to participate.
- CMS should establish a fair pricing structure for online providers, which could include:
 - **Outcomes-based reimbursement vs. completion-based reimbursement:** CMS could base reimbursement on weight-loss outcomes vs. whether or not a beneficiary has completed the program.
 - **Virtual supplier-specific reimbursement:** CMS could re-weight payments to account for virtual suppliers that furnish connected weight scales to MDPP beneficiaries.
 - **Payment parity:** G9886 (In Person) and G9887 (Distance) are both compensated at \$27. G9871 should be compensated at the same rate and allow virtual MDPP suppliers the opportunity to receive the same payment amount as suppliers furnishing services in-person.

- CMS should expand and align weight collection requirements for asynchronous, online modalities to align with CDC DPRM standards. We recommend CMS align with CDC DPRP standards that use the “first and last recorded weights during the Core and Core Maintenance phases” to determine starting and final weight / weight loss during the member’s participation in the program.
- In order to increase participation in MDPP, CMS should update Medicare.gov and other publicly facing beneficiary documents and websites to promote timely access to new virtual MDPP modalities.
- CMS should not require live lifestyle coaching interactions in order to receive payment for asynchronous virtual delivery of MDPP. Virtual providers cannot control whether or not a beneficiary chooses to respond or engage with a coach. Having availability and offering coaching should satisfy this requirement.

Unattended Sleep Testing (CPT Codes 95X18–95X23)

CMS' proposed unattended sleep testing codes for at-home sleep tests are based on the number of channels and types of measurement each device uses. CMS should clarify definitions, counting conventions, and alignment between FDA-authorized capabilities and intended use of home sleep testing devices, thus differentiating devices that are intended to diagnose sleep disorders. Likewise, CPT code descriptors and Medicare payment policies must be aligned to support consistent technology classification, coding, and payment. CMS should also ensure that the labor, equipment-time, and practice expense assumptions underlying the new complexity-based framework accurately reflect current home sleep test technologies and clinical workflows.

Proposals to Adopt New Improvement Activities

CTA supports CMS' proposal to adopt IA_AHW_XX (Clinician Use of Artificial Intelligence (AI) to Improve Patient Care) as a new improvement activity under the Merit-based Incentive Payment System (MIPS). We believe this is aligned with not only the Administration's efforts to leverage technology to improve patient care, but also the historical focus of MIPS improvement activities on encouraging provider use of data and innovative technology.

Conclusion

Technology is and will continue to be critical to achieving the Administration's Make America Health Again goals. While CTA is encouraged by many of the proposals in this final rule, we believe proposals to severely limit remote patient monitoring services would greatly hinder this progress. CTA and its members stand ready to work with CMS to promote policies that protect program integrity, strengthen the health care workforce, and expand access to high-quality, technology-enabled care.

Sincerely,

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