PETERSON CENTER ON HEALTHCARE

VIA ELECTRONIC SUBMISSION

September 12, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1832-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz,

The Peterson Center on Healthcare (the Center) appreciates the opportunity to submit comments on select provisions of CMS' CY 2026 Medicare Physician Fee Schedule proposed rule.

The Center is a nonprofit, nonpartisan organization dedicated to making higher-quality, more affordable healthcare a reality for all Americans. We are working to create a more efficient and cost-effective healthcare system in the United States by finding and promoting innovative solutions that improve quality and lower costs. To advance these goals, we have prioritized efforts to improve data transparency, stimulate competitive healthcare markets, and promote the use of high-value health technology—including launching the Peterson Health Technology Institute (PHTI), which is an independent, self-funded organization dedicated to accelerating the adoption of healthcare technologies that improve health and lower costs.

There is currently no recognized regulatory authority responsible for assessing the clinical efficacy and economic impact of digital health technologies (DHTs). As a result, DHTs are often adopted without clear evidence of their ability to improve patient outcomes, leading to wasteful spending and missed opportunities to improve care. The lack of evidence regarding what works also obscures our ability to drive the adoption of high-value digital tools. PHTI fills this critical gap by providing rigorous assessments of DHTs to inform purchasing decisions by health plans, health systems, and employers. As an independent evaluator engaging with purchasers, providers, innovators, and patients, PHTI has unique cross-sector insights that are valuable for policy development.

Over the past two years, PHTI has assessed nearly 50 DHTs, including most recently for depression and anxiety, giving us unique insights into the critical questions that CMS is grappling with in this year's proposed rule regarding valuation for digital mental health treatment and remote monitoring services.[1] PHTI's upcoming assessments will focus on the clinical and economic impact of virtual solutions for opioid use disorder and gastrointestinal conditions.[2,3] PHTI is also currently working on pinpointing the clinical and operational scenarios in which performance-based contracts add the greatest value and will recommend a core set of contractual and measurement standards that would streamline administration across the industry.

The DHTs that are available today for Traditional Medicare beneficiaries typically leverage remote monitoring codes that can be billed indefinitely, regardless of whether they generate clinical benefits for the patient. In a report released in April 2025, the Center found that remote monitoring is used by a relatively small subset of beneficiaries, but use – and duration of use – is growing rapidly.[4] Absent policy change, future spending potential on these codes is enormous and not tied to the demonstration of clinical value.

We share CMS's commitment to ensuring that technology enhances rather than hinders the patient and provider experience and applaud CMS's recent efforts to secure commitments from major healthcare and information technology firms to promote interoperability. The Center submitted comments this past June in response to CMS' Health Technology Ecosystem RFI and we believe CMS has an important role to play in stimulating ongoing digital health innovation to ensure that older Americans have access to tools that improve their lives, enhance their care experiences, and reduce costs.[5]

We appreciate the opportunity to share insights and learnings from our and our grantees' vast work across digital health technology evaluation and payment policy. Our enclosed comments focus on select provisions of the proposed rule including the coding and valuation of remote monitoring services, updates to payment for digital mental health treatment, and the new ambulatory specialty model.

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[1] Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. September 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/

[2] Virtual Opioid Use Disorder Solutions. PHTI Health Technology Assessment. March 2025. https://phti.org/assessment/virtual-opioid-use-disorder-solutions/

[3] Virtual Solutions for Gastrointestinal Conditions. PHTI Health Technology Assessment. July 2025. https://phti.org/assessment/virtual-solutions-gi-conditions/

[4] Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Peterson Center on Healthcare. April 2025. https://petersonhealthcare.org/news/evolving-remote-monitoring-report/

[5] Center Responds to RFI on Modernizing the Medicare Digital Health Ecosystem. PHTI Health Technology Institute. June 2025. https://petersonhealthcare.org/news/center-responds-to-medicare-digital-health-rfi/

Summary of Recommendations

Coding and Valuation for Remote Monitoring Services

- Modify coding for remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) services—including new codes for 2-15 days of data collection and 10-minute increment treatment management services—to support targeted, high-value interventions.
- Pair proposed coding changes with requirements for greater specificity on RPM and RTM claims and encounters in order to evaluate and direct high-value use of remote monitoring codes.
- Base reimbursement for RPM and RTM codes on their clinical value, rather than physician work time or equipment expense.
- Develop evidence-based, condition-specific remote monitoring duration limits for Traditional Medicare beneficiaries and require an active redetermination of medical necessity to continue coverage beyond service duration limits.
- Test an outcome-based payment model for remote monitoring, which could include reduced monthly payments plus a larger payment tied to patient outcomes, through the CMS Innovation Center.

Updates to Valuation for Digital Mental Health Treatment

- Leverage PHTI's budget impact models to inform a national coverage decision for prescription digital therapeutics (PDTs) for anxiety and depression. If payment rates for the device supply code were set at or below $270 per device, these solutions could have the potential to reduce net spending in Medicare.
- Expand coverage for a broader set of digital tools for anxiety and depression that do not require FDA clearance, as proposed by CMS. This aligns with PHTI's findings that virtual solutions for depression and anxiety can meaningfully improve outcomes for people with mild to moderate symptoms, especially if they are not already receiving therapy.[6]

Ambulatory Specialty Model

- Finalize the model, as proposed by CMS, as a mandatory program that requires participants to assume two-sided risk.
- Hold specialists financially accountable for upstream chronic condition management, as currently proposed, rather than past approaches that have relied more exclusively on primary care to reduce spending and improve outcomes.
- Publish a list of preferred, high-value digital tools that would support treatment for low back pain and heart failure. PHTI's evaluations of virtual musculoskeletal

[6] Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. September 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/

solutions and digital hypertension management solutions give providers insight into what digital tools may support beneficiary engagement and outcomes.[7]

- Provide technical assistance to support implementation of high-value digital tools, including best practices for providers and templates for contract and financing structures that allow solution vendors to be included in value-based contracts.

We appreciate the opportunity to comment on this proposed rule and welcome opportunities to support CMS on any aforementioned topics. For any questions or follow-up, please contact Natalie Joyce, Vice President of Advocacy at njoyce@petersonsolutions.org.

Sincerely,

Caroline Pearson

Executive Director, Peterson Center on Healthcare

[7] Virtual Musculoskeletal (MSK) Solutions. PHTI Health Technology Assessment. October 2024. https://phti.org/assessment/virtual-msk-solutions/

Coding and Valuation for Remote Monitoring Services

RPM and RTM coding revisions

CMS proposes adopting several recommendations of the Current Procedural Terminology (CPT) Editorial Panel related to remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) including, adding codes to denote RPM and RTM services that supply data for 2-15 days in a 30-day period (valued separately from supplying 16-30 days of data in a 30-day period.) Additionally, CMS proposes new codes and code revisions to report RPM and RTM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter.

CMS' proposed coding modifications have the potential to improve the evidence base and increase the availability of targeted, high-value applications of remote monitoring services, especially if paired with more specificity on RPM and RTM claims and encounter submissions. PHTI's research has identified the need for additional evidence on how RPM and RTM work, for whom, in which clinical settings, and over what duration to deliver meaningful clinical benefits to patients. Additionally, the amount of data that providers need to treat a condition varies widely by condition. The impact of RPM and RTM on clinical outcomes has less to do with the volume of data collected, and more to do with how it is used by providers and care teams to prompt timely interventions.

We urge CMS to pair increased flexibility in remote monitoring codes with requirements for greater specificity on RPM and RTM claims and encounter submissions. To continue to make evidence-based coverage and reimbursement decisions for remote monitoring services, payers and policymakers need clear data. Currently, it is difficult to know what patient health data are being collected and what conditions are being managed.

Improving the quality of remote monitoring claims and encounter data

Over the past few years, the Center has funded multiple research projects examining the utilization of RPM and RTM codes across Traditional Medicare, Medicare Advantage, Medicaid, and commercial insurance. Researchers faced significant challenges answering basic questions about remote monitoring services, including what digital solutions are used, what physiological data are being collected (e.g., blood pressure, blood glucose), and what condition the RPM and RTM is being used to treat and monitor. In August 2025 and September 2024, the HHS Office of Inspector General raised concerns about possible fraud and abuse of RPM codes and pointed to numerous gaps in data collection, including not knowing what specific health data were being collected for patients, what devices were being used, or what provider was

ordering the service.[8,9] Such data are needed to help payers evaluate the use of these solutions and help manage their distribution to patients.

We strongly recommend that CMS consider improving the quality of RPM and RTM claims and encounter data by requiring procedure modifiers to provide additional information about the services being provided including the condition being treated and monitored and the physiologic data being collected (e.g. blood pressure, blood glucose). Without this data, it is difficult for researchers to definitively know what physiological data are being collected or what condition the RPM and RTM is being used to treat and monitor. Currently, providers rarely attach modifiers. For example, less than 5% of commercial claims for RPM have a modifier attached within a large claim warehouse.

Valuation of RPM and RTM services

CMS disagreed with several recommendations of the CPT Editorial Panel regarding the valuation (relative value units) of RPM and RTM services. In lieu of their recommendations, CMS proposes utilizing hospital outpatient (OPPS) data to set rates and inform cost assumptions for some remote monitoring services to promote price transparency, offer more predictable rate setting, and limit the influence of AMA's physician survey data.

While the Center strongly agrees with CMS that now is the time to rethink how we value RPM and RTM services, we believe reimbursement for remote monitoring should be based more on *clinical value* rather than differences in clinician staff time, levels of intensity, supplies, or equipment expense.

To better align coverage and reimbursement to clinical benefits for patients, CMS should do more to tie coverage of remote monitoring and reimbursement rates to clinical effectiveness by condition. Providers are using remote monitoring for patients with a wide variety of conditions, despite varying evidence about the benefit of RPM and RTM to treat and monitor different diseases.[10] Ultimately, clinical value should drive physician payment, not cost. To move towards that goal, CMS should establish data-driven guardrails around reimbursement, such as implementing duration limits, and constructing reimbursement for remote monitoring as an outcome-based payment depending on the impact to a patient's health.

With CMS' proposal to use hospital outpatient data to value remote monitoring codes rather than limited RUC survey data, CMS should consider that RPM services are most

[8] Billing for Remote Patient Monitoring in Medicare. Health and human Services-Office of the Inspector General. August 2025. https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/

[9] Additional Oversight of Remote Patient Monitoring in Medicare Is Needed. Health and human Services-Office of the Inspector General. September 2024. https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/

[10] Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Peterson Center on Healthcare. April 2025. https://petersonhealthcare.org/news/evolving-remote-monitoring-report/

often delivered in lower-cost settings (e.g., physician offices) and using hospital cost data may increase the rates beyond actual costs, potentially risking overpayments. We recognize that there are several instances where CMS is proposing to use OPPS data and valuations are lower for CY 2026 than what the CPT Editorial Panel recommended. Additionally, CMS will need to correct for year-to-year cost fluctuations in the OPPS data which, if RPM is infrequently used in hospital settings, may fluctuate, be non-representative of remote monitoring services delivered, or distorted by outliers.

We previously commented on the CPT Editorial Panel's meeting regarding remote monitoring codes and agreed with the decision to reject consolidating RPM and RTM codes.[11] This would have made it more difficult to continue to evaluate the performance of these services by condition, solution, and patient group.

Duration limits for RPM and RTM services

PHTI provides independent health technology assessments that compare clinical performance across digital health solutions. We believe baseline research is necessary to inform both public and private purchasers of health care about which remote monitoring services are effective—for which populations, and over what time period. Evidence about clinical outcomes, which may vary by condition and solution, should guide decisions about what level and duration of reimbursement are justified. As evidence about the value of these services grows, payers should consider restricting coverage to those conditions that demonstrate clinical value, as some commercial payers are already doing. A 2023 report from the American Medical Association on commercial payer coverage of digital medicine codes includes a review of private health plans' policies compared to Medicare—some pay for time-limited episodic care and several limit coverage to specific conditions.[12]

CMS should align remote monitoring with clinical value by developing evidence-based, condition-specific remote monitoring duration limits for Traditional Medicare beneficiaries. In a report released in April 2025, the Center found that remote monitoring is used by a relatively small subset of beneficiaries, but use—and duration of use—is growing rapidly.[13] Additionally, the benefits of remote monitoring vary substantially by condition and duration of use. Evidence suggests that remote monitoring has the greatest impact on a patient's health when used by a healthcare provider for a focused period of active monitoring and management.[14]

[11] RE: Interested Party Comments on Tab 50 – Remote Monitoring. Peterson Health Technology Institute. January 2024. https://phti.org/wp-content/uploads/sites/3/2024/02/AMA_PHTI_Interested-Party-Comments.pdf
[12] Future of Health: Commercial Payer Coverage for Digital Medicine Codes. American Medical Association. 2023. https://www.ama-assn.org/system/files/issue-brief-commercial-payer-coverage-digital-care.pdf
[13] Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Peterson Center on Healthcare. April 2025. https://petersonhealthcare.org/news/evolving-remote-monitoring-report/
[14] Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Peterson Center on Healthcare. April 2025. https://petersonhealthcare.org/news/evolving-remote-monitoring-report/

One of the highest-impact use cases for digital health technologies is leveraging digital solutions to onboard, adjust, and stabilize patients with high blood pressure to their medication regimen. Some digital solutions for the management of hypertension integrate dedicated virtual care teams to monitor patients' blood pressure and adjust medications quickly, which helps achieve faster blood pressure control than usual care. Digital remote monitoring solutions focused on medication management were found to meaningfully reduce systolic blood pressure more quickly than in usual care. However, once patients stabilize on their new medication regimen and have lowered their blood pressure, ongoing monitoring becomes less valuable. This suggests that remote monitoring codes should be time-limited to the period where the evidence supports active management of a patient.

Remote monitoring should require an active redetermination of medical necessity to continue coverage for services beyond service duration limits. For example, the available clinical evidence supports monitoring the blood pressure of patients with hypertension for up to an initial six months. Because there is currently no incentive for a provider to end a patient's remote monitoring after stabilization is achieved (or even to use digital solutions to ensure appropriate patient outcomes), the Center recommends that CMS limit remote monitoring codes to 6 months with the opportunity to extend if there is continued medical necessity. There are precedents for medical necessity verification for durable medical equipment that can be analogues to this approach. For example, CMS requires provider attestation to continue Continuous Positive Airway Pressure (CPAP) therapy coverage past the initial 12-week trial period. Providers must confirm the patient is using and benefiting from CPAP and CMS may request compliance data from the device to verify adherence. Additionally, attestation and an in-person visit are required for continuous glucose monitor (CGM) use. CMS requires follow-up visits every 6 months to maintain CGM coverage. The provider must document that the patient is adhering to use, continues to meet eligibility criteria, and is benefiting from the CGM. CMS may also request usage data from the CGM to verify compliance.

As PHTI's work proceeds to evaluate condition-specific applications of digital tools, we envision our assessments, and their conclusions will continue to support CMS' coverage and adoption decisions.

Outcome-based payment for RPM and RTM services

Currently, there is no financial incentive for a provider to end a patient's remote monitoring. **The CMS Innovation Center should consider testing an outcome-based payment model for remote monitoring**. A new outcome-based payment model for remote monitoring could include reduced monthly payments plus a larger payment tied to patient outcomes. This model would better support high-performing remote monitoring solution providers who already prioritize shorter, clinically appropriate duration episodes of care. It would also strengthen the financial incentives for more companies and providers to prioritize patient outcomes when choosing to leverage a digital health tool. Such a model would also enable CMS to collect more detailed

information about RPM and RTM services to inform future changes to payment and coverage policies.

Bundled payments and performance-based contracts with downside risk incentivize providers to leverage high-performing digital health tools. If revenue can be derived by perpetual use of a digital health tool, providers will not be motivated to avoid tools that produce little-to-no-clinical value. Bundle-like models or models with downside risk are better suited to reimburse for digital health tools and incentivize providers to leverage technology in ways that allow them to deliver care more effectively and improve patient outcomes.

PHTI is currently convening a multi-stakeholder working group of national payers, self-insured employers, and leading digital health technology developers to accelerate the use of performance-based contracts. Collecting real-world data is a central component of this work. The best practices identified by PHTI in the commercial and employer markets will provide useful insights into how to structure incentives for digital health technology performance in Medicare.

Our research—slated for publication in early 2026—aims to (1) pinpoint the clinical and operational scenarios in which performance-based contracts add the greatest value, (2) surface the practical barriers that inhibit their uptake today, and (3) recommend a core set of contractual and measurement standards that would streamline administration across the industry.

Early findings suggest that performance-based contracts are most appropriate when product performance is uncertain in the real world, benefit is likely to accrue only to well-defined sub-populations, and sustained patient engagement is required to realize the intended clinical effect. All three situations demand timely, high-quality real-world evidence on outcomes and costs—data that are frequently absent from claims files and often must be captured directly by the digital technologies or drawn from electronic health records and health information exchanges.

Updates to Payment for Digital Mental Health Treatment (DMHT)

Over the past two years, PHTI has assessed nearly 50 digital health technologies across four clinical areas: diabetes, hypertension, musculoskeletal disorders, and depression and anxiety.[15,16,17,18,19] PHTI's upcoming assessments will focus on the clinical and economic impact of virtual solutions for opioid use disorder and gastrointestinal conditions.[20,21] PHTI uses the ICER-PHTI Assessment Framework for Digital Health Technologies to review the clinical efficacy and economic impact of digital health solutions.[22]

Every PHTI evaluation to date has identified clinically effective digital tools that provide meaningful improvements in primary health outcomes relative to usual care and could be valuable for Medicare beneficiaries. However, current coverage and payment rules mean that many of these solutions are not available for beneficiaries enrolled in Traditional Medicare. If these solutions were covered and made available in traditional Medicare, they could deliver clinical benefits for beneficiaries and, if payment incentives are designed correctly, they have the potential to reduce Medicare spending.

To drive adoption and impact, CMS should leverage PHTI's independent assessment results to prioritize covering digital health technologies that demonstrate clear clinical efficacy and positive economic impact for patients in the Medicare program. Below we outline opportunities for CMS' consideration given our recent evaluation of digital mental health tools for depression and anxiety.[23]

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[15] PHTI uses FDA's definition of digital health technologies: DHTs use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). Additionally, PHTI includes Software as a Medical Device (SaMD) and excludes Software in a Medical Device (SiMD).

[16] Digital Diabetes Management Solutions. PHTI Health Technology Assessment. April 2024. https://phti.org/assessment/digital-diabetes-management-tools/

[17] Digital Hypertension Management Solutions. PHTI Health Technology Assessment. November 2024. https://phti.org/assessment/digital-hypertension-management-solutions/

[18] Virtual Musculoskeletal (MSK) Solutions. PHTI Health Technology Assessment. October 2024. https://phti.org/assessment/virtual-msk-solutions/

[19] Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. September 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/

[20] Virtual Opioid Use Disorder Solutions. PHTI Health Technology Assessment. March 2025. https://phti.org/assessment/virtual-opioid-use-disorder-solutions/

[21] Virtual Solutions for Gastrointestinal Conditions. PHTI Health Technology Assessment. July 2025. https://phti.org/assessment/virtual-solutions-gi-conditions/

[22] The ICER-PHTI Assessment Framework for Digital Health Technologies can be found here: https://phti.org/howwe-assess/

[23] Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. September 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/

Pricing FDA-Cleared Digital Mental Health Treatments

To date, CMS has not assigned reimbursement for the digital therapeutic device supply code to be used with DMHT, deferring to regional Medicare Administrative Contractors (MACs) to establish contractor pricing for each device. In this proposed rule, CMS acknowledges that claims volume for DMHTs remains low. In the absence of a national rate, DMHTs are logistically difficult for providers to navigate and the pathway to reimbursement is opaque. CMS proposes retaining the contractor-based pricing status for CY 2026, citing diversity of technologies in this market and the challenges of establishing a uniform national rate at this stage.

CMS should leverage PHTI's independent budget model outputs for prescription digital therapeutics (PDTs) for anxiety and depression to inform a national coverage decision for DMHTs. Below we include detailed results from the PHTI budget impact analysis on the impact of virtual solutions for depression and anxiety on healthcare spending in Medicare.

PDTs are FDA-cleared, software-based digital therapies that are sold to providers and must be prescribed to patients. These solutions deliver digitized behavioral interventions, which can be used in conjunction with clinician-supervised outpatient treatment. When used alongside therapy or medication, PDTs produce clinically meaningful improvements in depression and anxiety symptoms that exceed outcomes with usual care alone. Because these solutions are expected to be reimbursed on a per user basis (estimated at $280 per episode), they have the potential to generate net savings of $1.3 million per million Medicare beneficiaries. This estimates $200 for the device supply code (G0552) plus $80 for two months of billing for treatment management at $40 per month (G0553 and G0554). According to PHTI's model, reimbursement of the device supply code could be set up to $270 per device (plus $80 for two months of billing for treatment management) and still have the potential to reduce net spending in Medicare. PDTs could deliver additional savings if used to reduce the frequency or duration of patients' therapy sessions.

Coding and Payment for a Broader Set of Digital Mental Health Tools

CMS is requesting public comments on the potential to establish separate coding and payment for a broader set of digital tools that help maintain or encourage healthy lifestyle habits as part of a mental health treatment plan of care.

The Center supports CMS' proposed expansion to a broader set of digital tools for anxiety and depression—this aligns with PHTI's findings that virtual solutions for depression and anxiety can meaningfully improve outcomes for people with mild to moderate symptoms, especially if they are not already receiving therapy.[24]

[24] Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. September 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/

Two of the three categories of digital tools in PHTI's assessment fall outside of current FDA-cleared pathways and demonstrate clinically meaningful improvements in symptoms of depression and anxiety, as measured by the PHQ-9 and GAD-7—two widely used, clinically validated tools to measure symptom severity.

- **Self-Guided Solutions** offer a range of digital content, including lessons and activities, that users can access anytime and select topics that meet their needs. Some also offer coaching support to reinforce skills and increase engagement. Today these solutions are typically sold directly to employers or health plans. For people not otherwise receiving psychotherapy, self-guided solutions demonstrate clinically meaningful improvements in depression symptoms (6.9-point reduction in PHQ-9) that significantly outperform control conditions (3.9-point difference). In most studies, these solutions also deliver clinically meaningful improvements in anxiety symptoms for people not receiving therapy. Improvements in depression and anxiety symptoms were more modest for people receiving usual care.
- **Blended-Care Solutions** build on the self-guided digital content by integrating virtual care teams with licensed therapists and psychiatrists who can deliver comprehensive mental health treatment, including psychotherapy and medication management when appropriate. These solutions are also primarily sold to employers or health plans. Blended-care solutions that combine digital content and clinician-led care appear to have the greatest clinical effectiveness, particularly for depression (average 7.7-point reduction in PHQ-9 for people not previously receiving psychotherapy), compared with the other categories of solutions; however, the evidence supporting these findings is less rigorous and more limited with most solution-specific findings come from single arm studies.

CMS should leverage PHTI's budget impact model outputs as a reference for setting appropriate payment rates for a broader set of digital tools for anxiety and depression for Medicare beneficiaries. Below are detailed results from PHTI's budget impact analysis that demonstrate the impact of virtual solutions for depression and anxiety on healthcare spending in Medicare. As with our remote monitoring recommendations, we believe that reimbursement of these tools should reflect their clinical value.

CMS should also consider implementing an appropriate symptom severity threshold score using clinically validated tools such as the PHQ-9 and GAD-7 for Medicare beneficiaries to gain access to such a set of digital tools for mental health. All of the digital tools for anxiety and depression that PHTI evaluated used clinically validated measurements to assess users' symptoms.

Using PHTI's budget impact model – described in greater detail below – to assess the impact of virtual solutions for depression and anxiety, we find:

- Self-guided solutions increase total Medicare spending by $1.09 PMPM, or $13.1 million per million Medicare beneficiaries. If rates for self-guided solutions were set on a per user basis rather than across all Medicare beneficiaries, they would

have the potential to save $350 per user in Medicare because the health benefits would offset the solution price.

- Blended-care solutions increase total spending because of the high PMPM charges for nonusers. In total, PMPM costs would increase spending by $5.34 PMPM, or $64.1 million per million Medicare beneficiaries. If PMPM rates for blended-care solutions were set at less than $4, these solutions would have the potential to reduce net spending in Medicare because the health benefits would offset the solution price.
- With an estimated device cost of $200, prescription digital therapeutics could save Medicare $0.11 PMPM across all beneficiaries, or $1.3 million per million Medicare beneficiaries. If payment rates were set even higher, for example, at $270 per device, these solutions would still reduce net spending in Medicare. According to our budget impact model, PDTs would begin to *increase* total Medicare spending if the price was set higher than $270 per device.

See PHTI's assessment of digital mental health tools for the full results and methodology.[25]

[25] Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. September 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/

Table 1. PHTI Budget Impact Model for Anxiety and Depression Key Inputs per 1 Million Medicare Beneficiaries

Category	Parameter	Medicare
Eligible Population	No Psychotherapy	50,391
	Usual Care	66,665
Usual Care Costs	Psychotherapy Sessions (annual average)	4.7
	Annual Cost (CPT code 90791, CPT code 90834)	$657
Health Savings (No Psychotherapy)	Self-Guided Solutions	$441
	Blended-Care Solutions	$574
Health Savings (Usual Care)	Self-Guided Solutions	$324
	Blended-Care Solutions	$536
	Prescription Digital Therapeutics	$358
Technology Price	Self-Guided Solutions	$24 per member per year ($2 per member per month)
	Blended-Care Solutions	$72 per member per year ($6 per member per month); additional $792 per engaged user per year for therapy
	Prescription Digital Therapeutics	$280 per user per year
Participation Rate	Self-Guided Solutions	25%
	Blended-Care Solutions	50%
	Prescription Digital Therapeutics	25%

PHTI Budget Impact Model Parameters:

Population: The model estimates the spending impact for individuals receiving usual care, those not engaged in psychotherapy, and those enrolled in a virtual solution program. The model estimates that about 12% of Medicare beneficiaries are estimated to have either depression or anxiety, with 6.7% receiving usual care psychotherapy and 5% not receiving psychotherapy, and both groups eligible to use self-guided or blended-care solutions. Based on the literature, the model assumes 25% would elect to use a self-guided solution for their care and 50% would elect to use a blended-care solution, with greater participation since these solutions may include some therapy visits at no cost to the user and therefore patients are more likely to engage in therapy as part of a blended-care solution. Because PDTs require a prescription from a clinician, users are assumed to be only those already receiving usual care, and therefore the model assumes that 25% of people would receive a PDT prescription through their provider.

Intervention: The interventions in the budget impact analysis were hypothetical virtual solutions for treating depression and anxiety based on the three solution categories: self-guided solutions, prescription digital therapeutics, and blended care solutions. The

solutions vary in the composition of the solution offerings and the primary purchaser of the solution: (1) CBT-based digital programs sold directly to employers or health plans, (2) FDA-approved digital therapies sold to providers and must be prescribed to patients, and (3) integrated clinician-guided care, including one-on-one therapy, with digital programs sold directly to employers or health plans.

Comparator: The comparators for this analysis were usual care defined as a typical treatment episode of CBT psychotherapy or no psychotherapy treatment. For patients receiving usual care psychotherapy, the model assumes 4.7 sessions (50%) per person based on an average of 9.4 psychotherapy sessions from a typical CBT treatment episode and clinical evidence about virtual solutions that showed half of patients receive psychotherapy at baseline. For self-guided and PDT solution users, the model assumes the cost of usual care psychotherapy is added to the cost of the solution. Whereas all users of blended-care solutions are assumed to switch to receiving psychotherapy within the solution. Reimbursement for people receiving usual care psychotherapy was estimated at an annual cost of $657 based on Medicare 2024 reimbursement rates for the initial diagnostic evaluation (CPT code 90791) and a 45-minute psychotherapy session (CPT code 90834).

Healthcare Costs: Annual healthcare spending estimates for anxiety and depression draw on published studies linking PHQ-9 and GAD-7 scores to commercial healthcare costs that are converted to Medicare rates using Medicare to commercial cost ratios for outpatient services and inflated to 2024 US dollars. From the systematic literature review conducted by PHTI, the model estimates the expected per person decrease in healthcare spending that results from improved mental health outcomes for those using virtual solutions. For those not receiving psychotherapy that engage with a self-guided solution the model predicts that per user Medicare spending would decrease by $441 per year before accounting for solution costs. When comparing virtual solutions to usual care, patients with Medicare coverage who use self-guided solutions to augment their current treatment are estimated to spend $324 less than those receiving usual care. For blended-care solutions, health improvements for people not receiving psychotherapy are estimated to reduce spending by $574. For people who have usual care and begin using a blended-care solution, their annual spending is expected to decrease by $536. For patients using PDTs to augment usual care, health improvements using just the comparative evidence available for PDTs are estimated to decrease per user healthcare spending by $358.

These results demonstrate that virtual solutions—self-guided, PDTs, and blended-care—have the potential to reduce healthcare utilization and spending in Medicare. Benefits are greatest for patients who are not otherwise receiving psychotherapy but virtual solutions also reduced costs for patients receiving usual care. However, while self-guided and blended care solutions decrease total health spending on a per user basis, since these solutions are charged for all plan enrollees, regardless of whether they use the solution or not, these solutions increase total net spending in Medicare. To estimate the net spending impact of virtual solutions for depression and anxiety, the

model offsets the price of the virtual solution provided from the estimated healthcare savings.

Virtual Solution Program Costs: Self-guided solutions for depression and anxiety are typically sold at a low price directly to employers as supplements to or replacements for elements of Employee Assistance Programs (EAPs), or to health plans through the medical benefit. Pricing information from a variety of sources (e.g., market analysis reports, vendor-supplied pricing, published economic studies, industry experts) estimated these solutions cost approximately $2 PMPM or less. The model assumes an average monthly solution price of $2 PMPM, or $24 per member per year, with no variation across plan type and covered for the entire one-million-member plan.

Blended-care solutions for depression and anxiety may be sold as EAP packages to employers or as “buy up” to health plans as part of their medical benefit. The model estimates total healthcare spending, inclusive of medical benefit spending and EAP costs. Based on reviewed sources, PMPM prices average about $6 across the entire plan membership. Companies report that those who engage with the solution typically use 6–8 sessions, including a mix of coaching and therapy. Prices for coaching sessions average $84 and therapy sessions average $143. Therefore, for blended-care solutions, the model assumes an average monthly solution price of $6 PMPM, or $72 per year, and an added cost of $792 per engaged user per year, based on an average utilization of seven sessions, with no variation across plan type and covered for the entire one-million-member plan.

For PDTs, beginning January 1, 2025, CMS established three new payment codes that will enable reimbursement for FDA-cleared PDTs. The initial code covers the supply of the device (i.e., software). Medicare contractors have not yet established reimbursement rates for PDTs; however, publicly available pricing for PDTs currently range between $200 and $400. The subsequent two codes will cover reimbursement to the provider for treatment- management services on a monthly basis. There are no limits on the number of times a provider can prescribe a PDT for an individual during a given year. Medicare administrative contractors, Medicare Advantage plans, and commercial plans may establish their own coverage policies regarding the frequency of coverage. The model assumes the low end of the range at an annual reimbursement rate of $200 for the device supply and $40 per month for two months of billing of treatment management per user for a single treatment episode of depression and anxiety. The cost impact of these solutions could be higher, however, if providers prescribe PDTs multiple times per year to the same patient.

Results: The model combines the solution price charged for all plan enrollees with the savings from users who experience lower healthcare spending resulting from improved depression and anxiety symptoms.

Ambulatory Specialty Model

CMS proposes to implement the Ambulatory Specialty Model (ASM), a new mandatory Center for Medicare and Medicaid Innovation (CMMI) model that will run for five years, starting January 1, 2027 and ending on December 31, 2031. The model aims to test whether adjusting payment for specialists based on their performance on select measures will encourage more effective upstream chronic condition management and care coordination with primary care providers, resulting in improved quality of care and reduced costs. ASM targets specialists who commonly treat people with Traditional Medicare for heart failure or low back pain in an outpatient setting, given these are two areas of high spending with significant potential for cost savings.

ASM participants' performance across quality, cost, care improvement activities, and promoting interoperability would determine whether they receive positive, neutral, or negative payment adjustments on future Medicare Part B claims for covered services. Notably, ASM is the first CMMI model to leverage the Merit-based Incentive Payment System (MIPS) Value Pathway framework, which is one MIPS reporting option that allows providers to select a smaller set of measures most relevant to a condition or specialty.

We strongly support CMMI introducing a model that is mandatory and requires participants to assume two-sided risk, both of which are critical to minimizing selection bias and increasing the likelihood of a model test yielding generalizable results. CMMI models can only be expanded if CMS' Chief Actuary certifies that expansion would reduce (or not increase) net program spending – or CMMI must return to the drawing board and undergo another multi-year process to make modifications to the model or to develop a different model drawing on lessons learned. Thus, it is prudent to design the initial test to optimize for sufficient volume and a statistically robust evaluation that can reliably inform certification and future rulemaking to improve quality and reduce spending across larger swaths of the program population.

Additionally, we are pleased to see CMS directly engaging specialists in this model and holding them financially accountable for upstream chronic condition management—a welcome shift from past approaches that placed the burden largely on primary care providers to reduce spending and improve outcomes. While CMMI has historically tested multiple models that seek to integrate primary care and specialty care for chronic conditions, these models have mainly focused on primary care providers and have offered specialists limited financial incentives to prevent and manage these conditions. ASM tests payment incentives for specialists that encourages them to prioritize prevention and disease management, reduce spending on low-value and high-cost interventions, and improve coordination with primary care providers. Targeting specialists will be important for building the evidence base on how to improve quality and reduce unnecessary Medicare spending in a fee-for-service chassis, and it will impart valuable lessons across the healthcare system and other payers.

Given CMMI's strategic pillars of promoting evidence-based prevention and empowering people to achieve their health goals, we recommend that CMMI strongly encourage ASM participants to deploy high-value digital health technologies for low back pain and heart failure. As described earlier in our comments, PHTI has evaluated the clinical and economic benefits of virtual musculoskeletal solutions and digital hypertension management solutions, including identifying specific tools with the strongest evidence base.[26,27] These assessments may provide valuable insights to ASM participants as they assess potential digital tools to help improve beneficiary engagement and the outcomes on which ASM participants will be evaluated.

For example, PHTI's assessment of virtual musculoskeletal solutions found that virtual physical therapist-guided solutions can deliver similar clinical benefits as in-person physical therapy (PT) at the time and place a patient chooses, potentially broadening access and improving outcomes. Although early assessment and use of PT have been shown to improve health outcomes and avoid unnecessary spending for acute musculoskeletal disorders, such as low back pain, access to timely, high-quality, and consistent PT can be challenging and costly for patients. Evidence-based virtual solutions can be an effective tool in ASM participants' toolkit for improving their treatment and management of low back pain, particularly for older adults, people who live in rural areas, and people with mobility limitations who may have difficulty accessing in-person PT.

For ASM participants treating patients with heart failure, PHTI's evaluation of digital hypertension management solutions may support performance on one of the proposed quality measures in the heart failure measure set, Controlling High Blood Pressure (MIPS Q236).[28] Notably, PHTI's evaluation highlighted strong evidence for broader adoption of digital hypertension solutions that included embedded medication management services.

Specifically, CMS should publish a list of preferred, high-value digital tools that would support treatment for low back pain and heart failure. Given the plethora of digital tools in the market that are not easily differentiated or supported by clear evidence, it can be challenging and inefficient for providers to select which ones to adopt into their practice. We recommend that CMS leverage PHTI's work to develop a list of vetted tools and vendors to support ASM participants to deploy tools with stronger evidence of their ability to improve patient outcomes.

CMS could go even further to establish vendor enablement guidance and allow vendors

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[26] Virtual Musculoskeletal (MSK) Solutions. PHTI Health Technology Assessment. October 2024. https://phti.org/assessment/virtual-msk-solutions/

[27] Digital Hypertension Management Solutions. PHTI Health Technology Assessment. November 2024. https://phti.org/assessment/digital-hypertension-management-solutions/

[28] Digital Hypertension Management Solutions. PHTI Health Technology Assessment. November 2024. https://phti.org/assessment/digital-hypertension-management-solutions/

to self-certify key capabilities such as interoperability, data sharing, and performance reporting— enabling providers to choose tools that align with their workflows and patient needs. Similar to its approach with CPC+, CMS could develop technical requirements and guidance documents to shape vendor behavior, and share a list of health IT vendors that voluntarily sign MOUs with model participants.[29] For example, CMS may consider a technical requirement for the tool to be integrated into the primary care providers' practice, the specialist practice, and the patient's interface to support maximum coordination between the three entities.

CMS could also provide additional technical assistance to support ASM participants in incorporating digital tools into their practice. ASM participants may benefit from a list of best practices for providers to ensure high-value implementation of these tools and templates for contract and financing structures that allow solution vendors to be included in value-based contracts. As described earlier in our comments, PHTI is convening a working group of payers, employers, and digital health technology developers to accelerate the use of performance-based contracts, which will provide useful insights into how to structure incentives for digital health technology performance in Medicare. This research, which will include a recommended core set of contractual and measurement standards, is slated for publication in early 2026.

Finally, we appreciate ASM's use of the existing MIPS Value Pathway (MVP) framework, which will allow CMS to more seamlessly expand this payment approach to other specialties if the evidence from this initial phase supports it. This will benefit both CMS and the stakeholder community by streamlining the number of unique models CMMI must design, request comments on, and implement for each specialty or condition. It will also potentially create a standard process for adding new specialty types to the mandatory model and soliciting feedback through the regular PFS rulemaking schedule.

[29] The Health IT Vendors in CPC+ list can be found here: https://www.cms.gov/priorities/innovation/files/x/cpcplus-hittracker.pdf