

VIA ELECTRONIC SUBMISSION

June 16, 2025

Secretary Robert F. Kennedy, Jr. U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Steven Posnack
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The Honorable Dr. Mehmet Oz Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-0042-NC P.O. Box 8013 8013, Baltimore, MD 21244-8013

Re: Request for Information on the market of digital health products for Medicare beneficiaries as well as the state of data interoperability and broader health technology infrastructure (File Code: CMS-0042-NC).

Dear HHS, CMS, and ASTP-ONC Leadership,

The Peterson Center on Healthcare (the Center) appreciates the opportunity to respond to your joint Request for Information on building a more seamless, secure, and patient-centered digital health infrastructure for Medicare beneficiaries.

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 to stimulate competitive healthcare markets and to promote the use of high-value health technology, including launching the Peterson Health Technology Institute (PHTI).

PHTI is an independent, self-funded organization dedicated to accelerating the adoption of effective, evidence-backed healthcare technologies that improve patient 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. 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 across four clinical areas (diabetes, hypertension, musculoskeletal disorders, and depression and anxiety), using the ICER-PHTI Assessment Framework for Digital Health Technologies. Each evaluation identifies clinically effective DHTs that 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. 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. 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. The agency 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. Through our work at the Center and PHTI, we appreciate the opportunity to share insights and learnings from our work on digital health technology and data transparency.

Summary of Recommendations

- CMS should leverage PHTI's independent assessment results to ensure digital health tools with demonstrated clinical and economic value can reach Traditional Medicare beneficiaries. Today, very few digital solutions are available to Traditional Medicare beneficiaries. CMS should leverage PHTI's assessments to identify high-value DHTs and then undertake a comprehensive review of the legal and regulatory barriers that exist today that deter companies from entering the Medicare market. Many of the barriers are within policymakers' purview to change, and doing so will help to incentivize their development for and deployment in Medicare. For further detail, see our responses to PC-3, PC-5, PC-7, TD-1, and VB-1.
- CMS should align remote monitoring with clinical value by developing evidence-based, condition-specific remote monitoring duration limits for Traditional Medicare beneficiaries. The Center recommends that CMS encourage providers to use clinically effective remote monitoring tools by tying coverage and reimbursement to condition-specific evidence of clinical effectiveness. Evidence suggests remote monitoring has the greatest impact on a patient's health when used for a focused period of active monitoring and management by the healthcare provider; however, payments can continue in perpetuity. Payment models for remote monitoring services should be limited based on evidence about their duration of benefit. See our responses to PC-3, PR-1, and VB-1.
- CMS should develop value-based payment pathways for digital tools. The CMS Innovation Center should consider testing new outcome-based payment models focused on high-value health technology drawn from PHTI's learnings. Bundled payments and performance-based contracts with downside risk are the most effective at reducing spending in Medicare and incentivizing providers to leverage high-performing DHTs. The way CMS pays for high-performing DHTs, including new applications for AI in healthcare, should mitigate federal health spending growth, not contribute to it. For additional detail, see our responses to PC-5,



PC-7, PR-2, and VB-1.

Improve price transparency and data usability.

Public and private healthcare markets can benefit from greater data transparency to drive market competition and more informed policymaking. HHS can make prices paid transparent by further standardizing data, expanding requirements to other providers and payers, strengthening compliance, and implementing advanced explanation of benefits for patients to understand pricing before consuming care. See our response to TD-19.

The Center appreciates the opportunity to contribute to this important dialogue. We are eager to be a resource and to continue supporting the Departments' efforts to ensure DHTs are accessible, effective, and affordable for Medicare beneficiaries and their families.

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

Carol Peur



Patients and Caregivers

PC-3. Identify health management, care navigation, and personal health record apps that may benefit Medicare beneficiaries and their caregivers.

Over the past two years, PHTI has assessed nearly 50 DHTs¹ across four clinical areas: diabetes,² hypertension,³ musculoskeletal disorders,⁴ and depression and anxiety.⁵ Each evaluation identified some clinically-effective digital health management tools that provide meaningful improvements in primary health outcomes relative to usual care. If these solutions were covered and made available in Medicare, they could deliver clinical benefits for beneficiaries and, if payment incentives are designed correctly, have the potential to reduce Medicare spending.

- Mental Health: Based on PHTI's review of the clinical evidence, 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. The evidence for both self-guided solutions (AbleTo, Dario, Headspace, Learn to Live, Meru Health, SilverCloud, Talkspace, and Teladoc) and prescription digital therapeutics (DaylightRx and Rejoyn) supports broader adoption. Blended-care solutions also appear to have positive clinical outcomes by combining digital content with networks of clinicians that can deliver therapy virtually.
- Hypertension: PHTI's assessment found that DHTs can be used 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, such as Cadence, Ocshner Digital Medicine, and Story Health, were found to reduce systolic blood pressure (by an average of 7.1 mm Hg) faster (typically within 3-6 months) than in usual care.
- Musculoskeletal Conditions: For the treatment of common musculoskeletal conditions, there is
 promising evidence that patients who use physical therapist-guided solutions, such as Hinge,
 Omada, RecoveryOne, Sword, and Vori, experience greater improvements in pain and function
 than those who receive usual care. In fact, these solutions deliver clinical benefits that are

¹ 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).

² Digital Diabetes Management Solutions. PHTI Health Technology Assessment. April 2024. https://phti.org/assessment/digital-diabetes-management-tools/

³ Digital Hypertension Management Solutions. PHTI Health Technology Assessment. November 2024. https://phti.org/assessment/digital-hypertension-management-solutions/

⁴ Virtual Musculoskeletal (MSK) Solutions. PHTI Health Technology Assessment. October 2024. https://phti.org/assessment/virtual-msk-solutions/

⁵ Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. May 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/



comparable to in-person physical therapy with added convenience that can improve access to care because users have better adherence and complete more-frequent exercise sessions. Remote therapeutic monitoring (RTM) based treatments, like Limber Health, are also clinically effective and can improve pain and functional improvements when used in conjunction with inperson physical therapy.

• **Diabetes:** Most digital solutions for adults with type two diabetes offer only small, short-term reductions in HbA1c that do not produce meaningful clinical benefits relative to usual care. The evidence suggests that remote monitoring for diabetes may be most effective when targeting patients with the highest starting HbA1c levels and those who are at critical transition points in their care plan (e.g., for patients newly starting insulin). One solution, Virta, focused on nutritional ketosis delivered substantial, clinically meaningful reductions in HbA1c sufficient to achieve remission of diabetes in some patients.

PHTI's next assessment will focus on the clinical and economic impact of virtual solutions for opioid use disorder (OUD) with additional assessment areas to follow.

Medicare beneficiaries would benefit from access to high-impact DHTs across clinical conditions and certain technologies would be cost-saving for the program; however, very few high-performing DHTs are currently available to Traditional Medicare beneficiaries. High performing DHT companies are often slow to enter the Medicare market or avoid it entirely because:

- Payment rates are typically lower in Medicare than in the commercial market, which is where
 nearly all digital health companies begin targeting sales. Meaning, the vast majority of DHTs are
 initially designed and marketed for commercial users.
- Most DHT companies are paid on a subscription or case rate basis, which can be challenging to align with the fee-for-service payment structure in Traditional Medicare. In particular, coverage for software-based services in Medicare is limited and CPT or HCPCS codes are often difficult for DHT companies to use.
- Many services covered by Medicare have co-pay requirements, which are a hurdle to patient engagement that often does not exist in the commercial market.
- There are constraints in Medicare on provider types. Many DHT companies use licensed or nonlicensed professionals who cannot bill Medicare or cannot do so without meeting specific supervisory or referral requirements.
- Many DHT companies are reticent to enter Medicare given the statutory restrictions on geographic sites of service, originating sites, and the uncertainty regarding the temporary status of telehealth flexibilities in Medicare.
- There are increased compliance costs for participating in Medicare, such as a complex provider enrollment process, needing to file HIPAA-compliant claims, ensuring Stark/Anti-Kickback compliance, and the management of ongoing program integrity exposure.

For a list of policy changes that CMS and its partners should pursue to drive further adoption of high-value DHTs, see our response to PC-5.



<u>PC-5. What CMS and Its Partners Can Do to Encourage Patient and Caregiver Interest in These Digital</u> Health Products.

To drive adoption and impact, CMS should leverage PHTI's independent assessment results to prioritize covering DHTs that demonstrate clear clinical efficacy and positive economic impact for patients in the Medicare program. We recognize the vast potential of DHTs to improve patient outcomes. However, patients, providers, payers, and investors currently struggle to know which DHTs are truly effective. When patients, their caregivers, and family who often have a say in clinical decisions, have confidence that a product will deliver real health benefits, they are far more likely to adopt and engage with it—maximizing both individual and system-wide gains.

PHTI uses the <u>ICER-PHTI Assessment Framework for Digital Health Technologies</u>⁶ to review the clinical efficacy and economic impact of digital health solutions. This framework was developed through a collaborative partnership between PHTI and the Institute for Clinical and Economic Review (ICER), a leader in health technology assessment. It recognizes the unique characteristics of DHTs, such as digital therapeutics, wellness and chronic care management applications, and remote monitoring solutions. It is based on input from employers, health plans, and health systems about their priorities when selecting a new DHT. The framework can guide technology developers and investors about performance standards and evidence required to demonstrate stated clinical and economic benefits.

PHTI identifies evaluation areas based on several factors, including:

- Burden of disease: Conditions that have a significant burden on patients
- Healthcare spending: Areas that are major drivers of healthcare spending
- **Investment and innovation:** Areas that are experiencing rapid growth in digital innovation and investment
- **Evidence and quality availability:** Areas that have a strong evidence base to inform clinical and economic impact assessments.

Through our work at PHTI, we encourage broader evidence generation across the digital health sector, with a focus on clinical outcomes and economic impact. Our assessments prioritize high-quality, comparative studies with appropriate controls—including both clinical trials and real-world evidence designs. We work with clinical advisors and patients to select primary and secondary outcomes of interest, as well as examine the impact of these solutions on access and outcomes for diverse patient populations, such as rural residents.

As described in our response to PC-3, very few digital solutions are available to Traditional Medicare beneficiaries, and many of the barriers are within policymakers' purview to change.

CMS and its partners should implement the following policy changes to encourage health technology companies with strong evidence of clinical and economic benefits to serve Traditional Medicare beneficiaries:

⁶ The ICER-PHTI Assessment Framework for Digital Health Technologies can be found here: https://phti.org/how-we-assess/



- CMS should implement performance-based payment models for high-value DHTs which allow for more flexibility than CPT/HCPCS-based billing yet clearly tie payment to performance. Several high-performing DHTs that PHTI has evaluated offer these arrangements in the commercial market. See our response to VB-1, for examples of outcome-based payment models focused on high-value DHTs drawn from PHTI's learnings that could be tested by the CMS Innovation Center.
- CMS should launch targeted, performance-based payment models in which payment flows directly to digital health technology companies for technologies that achieve pre-defined engagement and clinical targets. Payment would be tied to verified outcomes rather than CPT/HCPCS code-level utilization.
- CMS should consider authorizing zero-or-reduced patient cost-sharing for DHTs that meet a defined evidence threshold through a CMS Innovation Center demonstration.
- CMS should modernize provider participation rules around value-based payment models by
 expanding the roster of eligible practitioners and loosening direct-supervision and referral
 requirements. Expanding the types of health care providers eligible to provide services in the
 context of performance-based models will increase the ability of high-performing digital health
 companies to deliver services to Traditional Medicare beneficiaries.
- CMS should streamline provider/supplier enrollment for DHT companies to participate in Medicare. Additionally, creating an expedited provider-supplier enrollment track for digital health companies that have external evidence of safety and effectiveness will increase participation of high performing digital health companies in Traditional Medicare.
- CMS should re-evaluate how Medicare pays for software-only services in the Medicare Physician Fee Schedule to strengthen the link between payment levels and value delivered—especially for AI-based technologies which are primarily or exclusively software-based. This would allow reimbursement rates to scale with independently demonstrated value, rather than by the clinician minutes an algorithm replaces.

<u>PC-7. Steps CMS Can Take to Collect and Evaluate Real-World Data on the Impact and Cost of Digital</u> Health Tools.

Peterson Health Technology Institute (PHTI) is currently convening a multi-stakeholder working group of national payors, self-insured employers, and leading DHT developers to accelerate the use of performance-based contracts (PBCs). 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 DHT performance in Medicare.

Our research—slated for publication in early 2026—aims to (1) pinpoint the clinical and operational scenarios in which PBCs 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 PBCs 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 DHT or drawn from EHRs and health information exchanges.

CMS has the opportunity to collect real-world data at scale to better understand and deploy high-value digital tools in Medicare. For example, CMS could explore certification of a lightweight, FHIR-based reporting standard to allow DHT-generated clinical metrics (e.g., blood-pressure readings, functional scores) to flow automatically into a secure federal data enclave. This would allow CMS to understand real world performance and facilitate the adjudication of performance-based contracts with high-performing DHTs.

Providers

PR-1. What CMS and Its Partners Can Do to Encourage Provider Use of Approved Digital Health Products (Including in Rural Areas) and Address Related Obstacles and Responsibilities.

CMS should encourage the availability and adoption of high-impact DHTs, especially in rural areas. To do this, purchasers, providers, and patients must first understand which DHTs are high-performing and for whom. One study found that 80 percent of digital health products had little or no published clinical evidence. As discussed in our response to PC-3 and PC-5, CMS should leverage PHTI's independent assessments of DHTs to ensure tools with demonstrated clinical and economic value can reach Traditional Medicare beneficiaries. PHTI delivers rigorous, evidence-based evaluations of DHTs to help purchasers, providers, and patients make informed decisions.

While adoption of digital tools is growing, adoption is still concentrated among a relatively small number of providers' offices and health systems. This has implications for the distribution of digital solutions: For example, our <u>analysis</u> of billing patterns for remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) across Traditional Medicare, Medicare Advantage, and Medicaid found that a smaller proportion of Medicare beneficiaries living in rural America receive RPM and RTM services compared to those living in urban areas. Given that rural residents face higher rates of chronic disease, experience more provider shortages, and often travel twice as far to receive care, the availability of high-impact remote monitoring services may be even more important for rural populations.

CMS can better encourage providers to leverage high-impact DHTs for their patients by aligning coverage and reimbursement for remote monitoring services to clinical value. 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. For instance, providers may use remote patient monitoring tools to track the blood pressure of patients with hypertension while they are adjusting medications; 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. Payers and policymakers should develop evidence-based, condition-specific remote monitoring duration

⁷ Assessing the Clinical Robustness of Digital Health Startups: Cross-sectional Observational Analysis. J Med Internet Res. 2022. https://www.jmir.org/2022/6/e37677/

⁸ Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Peterson Center on Healthcare. April 16, 2025. https://petersonhealthcare.org/news/evolving-remote-monitoring-report/



limits and require an active redetermination of medical necessity to continue coverage for these services beyond those limits—for example, the available clinical evidence supports monitoring the blood pressure of patients with hypertension for up to an initial six months.

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 codes**. This could include reduced monthly payments plus a larger outcome-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 (for more information, see our response to VB-1).

PR-2. Obstacles That Prevent Development, Deployment, or Effective Utilization of Digital Applications for Physician Workflows —and Ways to Mitigate Them.

Physician burnout remains at unsustainable levels and one of the primary contributors is administrative burden. PHTI recently published a <u>report</u> on the adoption of AI in health care systems with a focus on ambient scribes—technology solutions that convert verbal patient-provider interactions into structured notes for clinical documentation and, eventually, medical billing. There is no technology in recent memory that has been adopted more enthusiastically by clinicians or has scaled so uncharacteristically fast, absent a regulatory mandate. Ambient scribes offer the promise of streamlining clinical documentation, billing, and eventually quality measurement reporting.

Based on early evidence, ambient scribes can reduce clinician cognitive load, reduce burnout and improve the patient experience. The available data around clinician productivity is mixed. Some health systems and studies report minor time savings and others do not. However, as the technology and implementation processes improve, time savings may become more apparent.

Though ambient scribes (and other AI technologies) offer great promise, we encourage CMS to also consider the impact of rapid adoption on overall health care spending. Many ambient scribe companies are extending into coding with the promise of optimizing evaluation and management (E&M) and hierarchical condition category (HCC) coding. It is not yet known what the downstream impact will be, though it is reasonable to expect that given existing incentive structures, ambient scribes will support higher level coding, which will increase healthcare spending and the costs of care.

Technology Vendors, Data Providers, and Networks

TD-1. Steps CMS Can Take to Spur Developer Interest in Digital Health Tools for Medicare Beneficiaries and Caregivers: Near-Term and Long-Term Opportunities.

One of the primary goals of PHTI is to improve transparency for purchasers – making it clear as to what digital health tools work, for whom they work best, and what tools are worth paying for. By publishing independent assessments of clinical and financial value, digital health technology companies will have

⁹ Adoption of Artificial Intelligence in Healthcare Delivery System: Early Applications and Impacts. Peterson Health Technology Institute. March 2025. https://phti.org/ai-adoption-early-applications-impacts/



increasing clarity on what purchasers are looking for, creating a feedback loop between purchasers and companies around where technology innovation is needed and what products and business models are required to meet purchaser needs. PHTI frequently hears from DHT developers after we publish an assessment about their plans for future evidence generation to meet purchaser needs.

As mentioned in PC-3, few of the highest-value tools across diabetes, hypertension, musculoskeletal disorders, and depression and anxiety, are available to Medicare beneficiaries today.

As PHTI is providing clarity to the market on what purchasers need and what DHTs work best, Medicare, as the largest purchaser of health care in the US, should pursue the policy changes articulated in PC-5 to encourage health technology companies with strong evidence of clinical and economic benefits to serve Traditional Medicare beneficiaries.

Value-Based Care Organizations

VB-1. Incentives to Encourage APMs—Including ACOs and MSSP Participants—to More Effectively Leverage Digital Health Management and Care Navigation Products, and the Obstacles Preventing Broader Adoption.

The main barrier to bringing high-performing digital tools to Medicare beneficiaries is that high-performing digital health companies are often slow to enter the Medicare market or avoid it entirely for reasons outlined in PC-3. Some Medicare Advantage plans have adopted digital solutions. As noted in PC-5, if CMS wants to encourage the best health technology companies to enter Traditional Medicare, it must address fundamental barriers. CMS should execute policy changes outlined in PC-5 to encourage health technology companies with strong evidence of clinical and economic benefits to serve Medicare beneficiaries.

Bundled payments and performance-based contracts with downside risk are the most effective at reducing spending in Medicare and incentivizing providers to leverage high-performing DHTs. If revenue can be derived by perpetual use of a DHT, providers will not be motivated to avoid tools that produce little-to-no-clinical value. Bundle-like models or higher-risk 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.

The CMS Innovation Center should consider the following three concepts for outcome-based payment models focused on high-value health technology drawn from PHTI's learnings.

1. Outcome-based payments for high-impact remote monitoring services.

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. ¹⁰ One of the highest-impact use cases of DHTs 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

¹⁰ Evolving Remote Monitoring: An Evidence-Based Approach to Coverage and Payment. Peterson Center on Healthcare. April 16, 2025. https://petersonhealthcare.org/news/evolving-remote-monitoring-report/



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.

Payers and policymakers should develop evidence-based, condition-specific remote monitoring duration limits and require an active redetermination of medical necessity to continue coverage for these services beyond those 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 Peterson Center on Healthcare recommends that CMS limit remote monitoring codes to 6 months with the opportunity to extend if there is continued medical necessity.

The Innovation Center could test an outcome-based payment model for remote monitoring codes where there is good clinical evidence, such as hypertension. For example, the Innovation Center could test reduced monthly payments for RPM and RTM paired with larger outcome payments tied to patient outcomes. This model would better support high-performing providers who already prioritize shorter, clinically appropriate duration episodes. It would also strengthen the financial incentives of companies and providers to prioritize patient outcomes over duration of service. The Innovation Center could test an outcome-based payment model for remote monitoring codes by adding an RPM/RTM set of G-codes (or similar structure) with an outcome-based component.

2. Integrated behavioral health model that leverages virtual behavioral health tools, enabling primary care providers to address the mental health needs of their patients at a lower price point.

PHTI's review of the clinical evidence finds that virtual solutions for depression and anxiety can meaningfully improve outcomes for people with mild to moderate symptoms, especially for those not already receiving therapy. ¹¹ Evidence supporting both self-guided digital solutions and prescription digital therapeutics suggests these solutions merit broader adoption. Blended-care solutions, which combine digital content and clinician-led care, showed the strongest clinical effectiveness and if prices for these tools were lower, they could show net savings. While virtual solutions for depression and anxiety are shown to work, they are not yet well integrated into clinical workflows.

Many primary care providers recognize the importance of meeting the behavioral health needs of their patients and understand that integration of behavioral health care into primary care improves overall patient outcomes. Yet doing so remains operationally challenging for many primary care providers. Current payment mechanisms for behavioral health integration, such as the Collaborative Care Model,

¹¹ Virtual Solutions for Depression and Anxiety. PHTI Health Technology Assessment. May 2025. https://phti.org/assessment/virtual-solutions-anxiety-depression/



require embedding behavioral health providers as part of the care team. This is challenging for many practices, especially given behavioral health provider workforce shortages and high practice expenses.

The Innovation Center could test the effectiveness of leveraging digital mental health tools to expand behavioral health services as part of an existing or new advanced primary care model. The Innovation Center could test the effectiveness of these tools to meet the mental health needs of patients at a lower price point than alternative integrated models of care. The goal should be to create flexible, scalable pathways that begin with lower-intensity behavioral health support in primary care settings that can adjust as needed based on symptom severity. Given the cyclical nature of depression and anxiety, virtual solutions are good at seamlessly stepping up or down treatment to align with patients' changing needs.

3. Embed high-value virtual physical therapy tools into new or existing models for Medicare beneficiaries.

PHTI found that virtual physical therapy holds immense promise in improving clinical outcomes, enhancing access to care, and reducing costs. ¹² For the treatment of common musculoskeletal conditions, patients who use physical therapist-guided solutions experience greater improvements in pain and function than those who receive only in-person physical therapy. These improvements are likely because users have better adherence and complete more-frequent exercise sessions. On average, patients complete eight in-person physical therapy sessions, and physical therapists track improvements using validated measures of pain and function until symptoms reduce. The Innovation Center could test the integration of high-value digital tools for physical therapy into new or existing care models. High performing virtual physical therapy tools could be purchased directly by CMS and access passed through to participating providers.

TD-19. Actions to Improve Price Transparency Implementation: Addressing Shortcomings in Content, Format, Delivery, and Timeliness—and Unlocking Solutions that Add Value for Patients, Providers, Payers, and CMS.

The Center believes that transparency is foundational to competitive healthcare markets, smart policies, and accessible, quality care. The Center and its partners seek to equip healthcare purchasers and federal and state policymakers with the necessary price, utilization, quality, and financial data to inform their decision-making and promote competitive, productive negotiations between providers and payers.

The Center's transparency grantmaking focuses largely on equipping employers with the price data they need to be more effective managers of healthcare benefits for their employees. For example, a <u>project</u> led by the Purchaser Business Group on Health (PBGH) is finding that employers' access to claims data and price comparisons is restricted by insurers and third-party administrators due to the data gaps and complexity of price transparency files. ¹³ A <u>policy brief</u> recently published by the Peterson-KFF Health Tracker provides examples of health plan data that is incomplete, missing, and—when available—

¹² Virtual Musculoskeletal (MSK) Solutions. PHTI Health Technology Assessment. October 2024. https://phti.org/assessment/virtual-msk-solutions/

¹³ Purchaser Business Group on Health Receives Funding to Launch CAA Data Demonstration Project. Press Release. June 18, 2024. P https://www.pbgh.org/caa-data-demonstration-project-2/



unstructured and confusing. ¹⁴ Meanwhile, <u>research recently published by David Muhlestein in Health</u> <u>Affairs</u> shows that while insurers' price data could provide employers with insights into their spending, preparing that data for analysis takes months of painstaking work. ¹⁵

System-wide price transparency is important to increase market competition to enhance the quality of patient care and reduce healthcare spending. Therefore, we offer the following input, which can inform transparency efforts for both private and public payers. The recommendations we offer below will improve the usability of data for intermediaries, who then in turn can make use of the data to negotiate on behalf of patients, make better public policy, and reduce the financial friction so many patients experience today when interacting with the health system.

Standardize how data is shared:

- Develop standard data schema for releasing healthcare price data. Data should be released in relational files, instead of JSON format, to make it more usable and eliminate the need for separate reference files.
- Require organizations that report price data to submit the hosting location to CMS. CMS should publicly release a consolidated list of hosting locations.
- Require reporting organizations to post plain language instruction manuals and contact information for people or departments who can answer questions about data.

Enhance hospital and payer data:

- Require reporting organizations to report the volume of services delivered and paid for. In the
 Transparency in Coverage (TiC) files that commercial market payers are currently required to
 release, an estimated 96.5% of prices are ghost codes, i.e., prices for services that providers never
 perform. Reporting volumes would help eliminate ghost codes, making data easier to use.
- Ensure datasets include negotiated rates, average paid amounts, and cash prices. Paid amounts vary based on factors such as contractual allowances, discounts, and reimbursement ceilings. Including average paid amounts alongside negotiated rates would provide a more accurate picture of spending.
- Link price data to standardized plan information such as plan name, benefit design, co-pays, and deductibles. This information is already required for plans sold on Marketplaces.
- In the Transparency in Coverage (TiC) files that commercial market payers are currently required to release, data is currently reported using NPIs and TINs, which must be painstakingly linked to other

¹⁴ Challenges with Effective Price Transparency Analyses. *Peterson-KFF Health System Tracker*. February 25, 2025. https://www.healthsystemtracker.org/brief/challenges-with-effective-price-transparency-analyses/.

¹⁵ Muhlestein, David. Improving Transparency Data: Recommendations From Practice. Health Affairs Forefront. March 19, 2025: https://www.healthaffairs.org/content/forefront/improving-price-transparency-data-recommendations-practice



information to identify providers and sites of care. Requiring that datasets link TINs or NPIs to basic information such as provider names and addresses would simplify data use.

Expand the entities that must report price and payment data:

- Require all health plans to report price data, including Medicare Advantage, traditional Medicare, Medicare Part D, Managed Medicaid, Tri-Care, and retiree plans. Currently the Transparency in Coverage regulation only requires commercial plans to report. Meanwhile, hospital price transparency requires hospitals to report prices across all of their payer contracts. While Medicare pays on a prospective fee schedule, actual payment varies due to characteristics and classifications of the provider billing Medicare for the service and whether they qualify for supplemental payments such as disproportionate share, graduate medical education or other add-on payments. Having traditional Medicare report what it pays hospitals, physicians and other providers, supplemental and add-on payments included, along with reporting data on utilization, would bring tremendous clarity to the marketplace of innovators leveraging pricing and quality data across payers to drive competitive market behavior.
- Expand price transparency requirements to ambulatory surgery centers (ASCs), imaging centers, and labs. Expansion to additional providers may also be justified based on their contributions to healthcare costs and the ability of patients and employers to shop for the best value.

Increase compliance:

- Encourage payer compliance by requiring executives at reporting organizations to attest to their organizations' compliance and by publicly reporting enforcement actions.
- Establish clear definitions of compliance with TiC rules, perhaps denoting two or three levels of compliance (e.g., full, partial, non-compliant) to focus enforcement priorities and reduce public and media confusion over the progress of the Administration's initiative.
- Increase enforcement activity and penalties, which could include moving quickly towards enforcement actions in lieu of warning letters; increasing civil and monetary penalties; proposing escalating penalties for persistent noncompliance; and publicly reporting enforcement actions.

Use transparency to encourage competition and consumer choice:

- Implement and enforce the rules around hospital and payer consumer-facing price tools, including the Advanced Explanation of Benefits provisions of the No Surprises Act to help consumers understand price implications of their provider selection decisions prior to receiving care.
- Require hospitals to post the data that feeds into Hospital Compare and the CMS's quality payment program (QPP) to enable employers and consumers to consider both price and quality information.

¹⁶ Muhlestein, David. Improving Transparency Data: Recommendations From Practice. Health Affairs Forefront. March 19, 2025: https://www.healthaffairs.org/content/forefront/improving-price-transparency-data-recommendations-practice