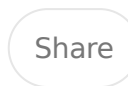
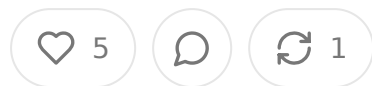


CMS 2026 Physician Fee Schedule: A Paradigm Shift Creating Unprecedented Opportunities for Health Technology Innovation

JUL 15, 2025



Disclaimer: The views and analysis expressed in this essay are my own and do not reflect opinions or positions of my employer or any affiliated organizations.

Table of Contents

1. Abstract
2. Executive Summary
3. The Great Skin Substitute Disruption: A \$9 Billion Market Realignment
4. The Ambulatory Specialty Model: Mandatory Innovation in Chronic Disease Management
5. Digital Health Renaissance: From Experimental to Essential Infrastructure
6. Data Infrastructure and Actuarial Implications
7. Technology Vendor Impact Analysis: Winners and Losers
8. Entrepreneurial Opportunities and Market Entry Strategies
9. Risk Assessment and Implementation Challenges
10. Strategic Recommendations for Health Tech Leaders

Abstract

The Centers for Medicare & Medicaid Services (CMS) Calendar Year 2026 Physician Fee Schedule proposed rule represents the most significant transformation of Medicare payment methodology since the establishment of value-based care initiatives. This analysis examines the profound implications for health technology vendors, with particular focus on:

- Skin substitute market disruption: A proposed 90% payment reduction affecting \$10+ billion market
- Mandatory specialty care model: New Ambulatory Specialty Model targeting heart failure and low back pain
- Digital health expansion: Permanent telehealth flexibilities and ADHD digital therapeutics coverage
- Data infrastructure requirements: Enhanced electronic communication and performance monitoring systems
- Payment methodology evolution: Separation of conversion factors for APM participants vs. traditional fee-for-service providers
- Key Finding: This rule creates an estimated \$15-20 billion market opportunity for health technology solutions while simultaneously disrupting existing vendor relationships across multiple healthcare segments.

Executive Summary

CMS Administrator Dr. Mehmet Oz's first major policy initiative signals a decisive shift toward technology-enabled, outcomes-based healthcare delivery. The proposed rule's four pillars—waste reduction, prevention focus, specialty care accountability, and technology integration—create a complex landscape of opportunities and challenges for health technology entrepreneurs. The implications extend far beyond simple payment adjustments, fundamentally restructuring how healthcare technology vendors are measured and compensated within the Medicare ecosystem.

The Great Skin Substitute Disruption: A \$9 Billion Market Realignment

The Magnitude of Change

The proposed transformation of skin substitute payments from biologicals to incident-to supplies represents one of the most dramatic market corrections in Medicare history. Medicare spending on these products experienced unprecedented growth from \$256 million in 2019 to over \$10 billion in 2024—a nearly 40-fold increase that CMS attributes to "abusive pricing practices" and products with "limited evidence of clinical value."

The proposed payment methodology change would reduce spending by approximately 90%, creating immediate implications for the entire wound care technology ecosystem. This dramatic reduction stems from changing the payment basis from Average Sales Price (ASP) plus percentage markup—which could reach \$2,000 per square inch—to a supply-based payment methodology that fundamentally alters the economic incentives driving product development and market adoption.

Technology Vendor Implications

Incumbent Disruption: Established skin substitute manufacturers face an existential challenge. Companies like Organogenesis, MiMedx, and Integra LifeSciences, which have built business models around premium pricing for biological products, must rapidly pivot to volume-based strategies or risk market exit. The 90% payment reduction makes current cost structures unsustainable for many products.

Innovation Opportunity: This disruption creates space for technology companies developing evidence-based wound care solutions. Digital wound monitoring platforms, AI-driven healing assessment tools, and cost-effective biological alternatives become suddenly attractive to providers seeking to maintain quality while operating under constrained reimbursement. Companies developing solutions that can demonstrate superior clinical outcomes per dollar spent will find unprecedented market receptivity.

Data Requirements: CMS's emphasis on "products with the most clinical evidence success" creates immediate demand for robust clinical data platforms. Technology vendors capable of providing real-time outcome tracking, comparative effectiveness data, and cost-per-healing metrics will become essential partners for wound care product manufacturers seeking to differentiate themselves in a commoditized market.

Actuarial Deep Dive

The actuarial implications extend beyond immediate payment reductions. CMS's decision to categorize products by FDA regulatory status (361 HCT/P, PMA, 510(k)) rather than maintaining uniform biological classification creates three distinct risk pools with different cost structures and outcome expectations. This segmentation enables more sophisticated risk adjustment and outcomes-based payment models.

Actuarial modeling suggests that while overall spending decreases, the cost-per-successful-healing outcome may remain stable or even improve as the market eliminates low-efficacy, high-cost products. This creates opportunities for technology solutions that can predict healing probability, optimize product selection, and monitor outcome progression in real-time.

The Ambulatory Specialty Model: Mandatory Innovation in Chronic Disease Management

Strategic Framework Analysis

The proposed Ambulatory Specialty Model (ASM) represents CMS's most ambitious attempt to mandate value-based care in specialty practice. Beginning January 2025, specialists treating heart failure and low back pain in approximately 25% of Core Based Statistical Areas will be financially responsible for their patients' outcomes over five-year performance periods.

The model's mandatory nature distinguishes it from previous voluntary programs by creating guaranteed market demand for technology solutions that help specialists succeed under two-sided risk arrangements. The focus on heart failure and low back pain—conditions with high variability in care patterns and significant opportunities for upstream intervention—suggests CMS's confidence in technology's ability to standardize and improve care delivery.

Technology Infrastructure Requirements

Communication Platforms: ASM explicitly rewards specialists who "use technology that allows them to communicate and share data electronically with patients and primary care providers." This creates immediate demand for interoperable communication platforms that can seamlessly integrate with existing EHR systems while providing secure, HIPAA-compliant data sharing capabilities.

Predictive Analytics: The model's emphasis on detecting "signs of worsening chronic conditions early" necessitates sophisticated analytics platforms capable of processing multiple data streams—clinical, behavioral, social determinants, and device-generated data—to identify at-risk patients before acute episodes occur.

Care Coordination Technology: With specialists now accountable for reducing "avoidable hospitalizations," technology solutions that facilitate real-time care coordination between specialists, primary care providers, and ACOs become essential infrastructure rather than optional efficiency tools.

Market Sizing and Financial Impact

Conservative estimates suggest that ASM will affect approximately 15,000-20,000 specialists treating an estimated 2.5 million Medicare beneficiaries annually. With heart failure and low back pain representing combined Medicare spending of approximately \$35-40 billion annually, even modest improvements in care efficiency create substantial shared savings opportunities.

The mandatory nature of the program eliminates adoption friction typically associated with value-based care models. Specialists must participate, creating guaranteed

revenue streams for technology vendors capable of demonstrating measurable improvements in the model's four performance categories: Quality, Cost, Improvement Activities, and Promoting Interoperability.

Data Infrastructure Implications

ASM leverages the CMS Merit-based Incentive Payment System (MIPS) Value Pathways framework, creating standardized data requirements and reporting mechanisms. This standardization enables technology vendors to develop scalable solutions rather than custom implementations for each specialty practice.

The model's focus on "factors specialists are better able to control" suggests CMS recognition that traditional quality metrics often reflect patient characteristics beyond provider influence. This creates opportunities for technology solutions that can risk-adjust performance metrics, identify actionable intervention opportunities, and provide real-time feedback on modifiable risk factors.

Digital Health Renaissance: From Experimental to Essential Infrastructure

Permanent Telehealth Infrastructure

CMS's proposal to make COVID-era telehealth flexibilities permanent represent a fundamental shift in healthcare delivery infrastructure. The permanent inclusion of audio-only telehealth services, virtual supervision capabilities, and elimination of geographic restrictions for mental health services creates a stable foundation for digital health innovation.

The permanency eliminates regulatory uncertainty that has constrained digital health investment for the past five years. Technology companies can now develop long-term platform strategies rather than adapting to annual policy changes, enabling more sophisticated integration with existing healthcare systems and more ambitious technological capabilities.

Digital Mental Health Treatment Device Revolution

The expansion of Digital Mental Health Treatment (DMHT) device coverage to include ADHD represents a watershed moment for the digital therapeutics industry. CMS's creation of specific billing codes (G0552, G0553, G0554) and payment methodologies provides the regulatory clarity necessary for sustainable business models.

Market Creation: ADHD affects approximately 4.4% of adults in the United States, with Medicare-eligible populations representing a significant and underserved segment. The creation of specific payment pathways eliminates the primary barrier to digital therapeutics adoption—unclear reimbursement mechanisms.

Technology Requirements: DMHT devices must be FDA-approved and used "in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care." This requirement creates opportunities for technology platforms that can integrate digital therapeutics with traditional care delivery, providing seamless workflows for providers and comprehensive treatment tracking for patients.

Revenue Model Innovation: The payment structure—covering device supply, initial education, and ongoing therapeutic intervention—enables technology companies to develop subscription-based models with predictable revenue streams. This represents a significant departure from traditional medical device payment structures and aligns technology company incentives with patient outcomes.

Interoperability and Data Exchange Requirements

CMS's emphasis on electronic communication and data sharing creates immediate demand for interoperability solutions. The requirement for specialists to "communicate and share data electronically with patients and their primary care providers" under ASM necessitates platforms capable of seamless integration across multiple EHR systems, communication channels, and data formats.

This requirement extends beyond simple messaging to include clinical data exchange, outcome reporting, and care plan coordination. Technology vendors capable of providing comprehensive interoperability solutions—particularly those that can demonstrate improved care coordination and reduced administrative burden—will find significant market opportunities.

Data Infrastructure and Actuarial Implications

Advanced Analytics Requirements

The convergence of value-based payment models, mandatory specialty care accountability, and expanded digital health coverage creates unprecedented demand for sophisticated data analytics capabilities. Organizations must now process and analyze data from multiple data streams simultaneously:

Clinical Data Integration: Traditional EHR data must be supplemented with device-generated data, patient-reported outcomes, social determinants information, and real-time physiological monitoring to support early intervention and risk stratification requirements.

Predictive Modeling: ASM's focus on preventing avoidable hospitalizations requires predictive models capable of identifying at-risk patients weeks or months before acute episodes. These models must integrate clinical, behavioral, and social factors while accounting for specialist-specific risk profiles and intervention capabilities.

Outcome Attribution: With specialists now financially responsible for patient outcomes, technology solutions must provide clear attribution models that distinguish specialist impact from primary care interventions, patient adherence factors, and external variables beyond provider control.

Risk Adjustment and Performance Measurement

The proposed rule's emphasis on "factors specialists are better able to control" necessitates sophisticated risk adjustment methodologies. Technology vendors must develop platforms capable of:

Dynamic Risk Stratification: Real-time adjustment of patient risk profiles based on changing clinical circumstances, treatment responses, and social determinants of health.

Intervention Tracking: Comprehensive monitoring of specialist interventions and their impact on patient outcomes, enabling continuous quality improvement and evidence-based practice optimization.

Comparative Effectiveness Analysis: Platforms that can provide real-time comparative effectiveness data across different treatment approaches, enabling specialists to optimize care delivery within value-based payment constraints.

Actuarial Modeling Sophistication

The separation of conversion factors for APM participants versus traditional fee-for-service providers creates new actuarial complexity. APM participants will receive 3.83% increases (to \$33.59) while non-APM providers receive 3.62% increases (to \$33.42). This differential creates financial incentives for APM participation while requiring sophisticated modeling to predict which providers will transition between payment methodologies.

Technology vendors serving multiple provider segments must develop flexible pricing and feature models that account for these payment differentials while maintaining profitability across different customer segments. The actuarial implications extend to risk-sharing arrangements, outcome guarantees, and shared savings distribution.

Technology Infrastructure Requirements

The ASM model's emphasis on electronic communication and data sharing with primary care providers will require significant investments in interoperability infrastructure. Specialists who have historically operated with limited external connectivity will need to implement systems that can seamlessly exchange clinical

data, care plans, and outcome metrics with other providers. This creates immediate opportunities for health information exchange platforms, clinical data management systems, and interoperability solutions.

Predictive analytics will be particularly crucial for specialist success under ASM. Early detection of clinical deterioration is explicitly rewarded under the model's payment methodology. Specialists treating heart failure patients will need technologies that can identify patients at risk for hospitalizations through remote monitoring, biomarker analysis, or other predictive indicators. Similarly, specialists managing low back pain will need tools to identify patients likely to benefit from conservative treatment versus those requiring more intensive interventions.

The model's focus on reducing avoidable hospitalizations creates demand for sophisticated care management platforms that can track patient status between visits and alert providers to concerning changes. Remote patient monitoring technologies, particularly those focused on heart failure management, are likely to see significant adoption as specialists seek to prevent costly adverse events. The integration of these monitoring systems with electronic health records and clinical decision support tools will be essential for specialists to effectively manage population-level risk.

Technology Vendor Impact Analysis

Immediate Market Winners

Interoperability platform providers will experience immediate demand growth as ASM mandates electronic communication and data sharing between specialists and primary care providers. The mandatory nature of specialist participation eliminates the adoption resistance typically associated with interoperability implementation, creating a favorable environment for companies specializing in healthcare data exchange and integration solutions.

Population health management platform vendors will benefit significantly from specialists' urgent need to identify and manage at-risk patients proactively. Companies offering comprehensive analytics platforms that can stratify patient

predict clinical deterioration, and track population-level outcomes will find increased demand from specialists who must demonstrate improved care coordination and reduced hospitalizations.

Digital mental health technology companies with FDA-approved solutions will gain immediate market access through the new DMHT payment pathways. Companies that have invested in clinical validation and regulatory approval for digital therapeutics targeting mental health conditions will find new revenue opportunities as Medicare removes traditional reimbursement barriers for evidence-based digital interventions.

Wound care technology companies developing evidence-based, cost-effective solutions will gain significant market share as expensive biological products lose reimbursement support. Companies with robust clinical data platforms that can demonstrate superior outcomes at lower costs will be particularly well-positioned to capture market share in the transformed skin substitute landscape.

Market Disruption Challenges

Traditional skin substitute manufacturers face existential threats from the proposed 90% payment reduction. Companies with business models built around high-margin biological products will need to rapidly pivot toward evidence-based, cost-effective solutions or risk significant market share erosion. This disruption will likely drive consolidation in the sector as companies with unsustainable cost structures become acquisition targets.

Legacy electronic health record vendors without robust population health management and care coordination capabilities will face competitive pressure to rapidly develop or acquire these functionalities. The emphasis on electronic communication and data sharing under ASM will require significant platform enhancements that may strain development resources and timelines.

Single-point solution vendors will face challenges as providers increasingly prefer comprehensive platforms that can address multiple aspects of value-based care. Companies offering narrow-focus solutions will need to expand their capabilities or form strategic partnerships to remain competitive in the evolving market landscape.

Significant Challenges

Premium Skin Substitute Manufacturers: Companies with business models based on high-margin biological products face existential threats. Without rapid business model adaptation, many current market leaders may experience significant revenue decline or market exit.

Traditional EHR Vendors: While EHR systems remain essential, vendors that cannot rapidly implement interoperability features and care coordination capabilities may lose market share to more agile competitors offering integrated solutions.

Simple Telehealth Platforms: Basic video calling solutions will become commoditized as permanent telehealth coverage creates market saturation. Platforms without sophisticated care management features, outcome tracking, or integration capabilities will struggle to maintain premium pricing.

Emerging Opportunities

AI-Powered Clinical Decision Support: The need for early identification of worsening chronic conditions creates market demand for AI platforms capable of processing multiple data streams and providing actionable clinical recommendations.

****Social Determinants Integration Platforms:**** ASM's focus on upstream interventions necessitates platforms that can integrate social determinants data with clinical information to provide comprehensive patient risk profiles.

****Outcome Measurement Solutions:**** The shift toward outcome-based payment creates demand for platforms that can accurately measure and report clinical outcomes, patient-reported outcomes, and functional status improvements.

Entrepreneurial Opportunities and Market Entry Strategies

High-Priority Market Segments

Chronic Disease Coordination Platforms: The convergence of ASM requirement expanded telehealth capabilities creates opportunities for platforms that can coordinate care across multiple providers while maintaining compliance with value-based payment requirements. Entrepreneurs should focus on solutions that integrate seamlessly with existing workflows while providing measurable improvements in coordination efficiency.

Evidence-Based Wound Care Solutions: The skin substitute market disruption creates space for innovative wound care technologies that can demonstrate superior clinical outcomes at lower costs. Opportunities exist for AI-powered wound assessment, personalized treatment selection platforms, and outcome prediction models.

Digital Therapeutics Integration Platforms: The expansion of DMHT coverage creates opportunities for platforms that can integrate digital therapeutics with traditional care delivery. Entrepreneurs should focus on solutions that reduce provider administrative burden while ensuring appropriate clinical oversight and outcome monitoring.

Specialty-Specific Value-Based Care Platforms: ASM's focus on heart failure and back pain creates immediate market demand for specialty-specific platforms that help providers succeed under two-sided risk arrangements. Future opportunities as CMS expands the model to additional specialties.

Market Entry Strategies

Partnership-First Approach: Rather than attempting to build comprehensive solutions independently, entrepreneurs should consider partnership strategies with existing healthcare technology vendors. The complexity of regulatory compliance and EHR integration favors collaborative approaches over standalone solutions.

Evidence Generation Focus: CMS's emphasis on "clinical evidence of success" necessitates robust clinical evidence generation capabilities. Entrepreneurs should plan for sophisticated data collection and analysis capabilities from initial product development rather than treating evidence generation as a secondary consideration.

Interoperability-Native Design: New solutions must be designed with interoperability as a core feature rather than an add-on capability. The mandatory nature of electronic communication requirements under ASM eliminates market tolerance for solutions that cannot integrate seamlessly with existing healthcare infrastructure.

Funding and Investment Implications

The proposed rule's emphasis on evidence-based care and outcome measurement creates new investment criteria for healthcare technology ventures. Investors will likely prioritize companies that can demonstrate:

Clear Regulatory Pathway: Understanding of CMS payment methodologies and compliance requirements becomes essential for investment attractiveness.

Scalable Evidence Generation: Capability to generate clinical evidence at scale rather than relying on small pilot studies or anecdotal success stories.

Integration Capabilities: Ability to integrate with existing healthcare infrastructure without requiring significant workflow disruption or additional staff training.

Measurable ROI: Clear demonstration of return on investment for healthcare providers operating under value-based payment constraints.

Risk Assessment and Implementation Challenges

Regulatory Compliance Complexity

The proposed rule creates multiple overlapping regulatory requirements that technology vendors must navigate simultaneously. ASM participation requirements, DMHT device regulations, telehealth compliance standards, and interoperability mandates create a complex compliance landscape that requires significant legal and regulatory expertise.

Technology companies must develop compliance frameworks that can adapt to ongoing regulatory changes while maintaining operational efficiency. The 60-day comment period ending September 12, 2025, provides limited time for final rule modifications, suggesting that technology vendors should prepare for implementation of the proposed requirements rather than anticipating significant changes.

Implementation Timeline Challenges

ASM implementation beginning January 2027 provides approximately 18 months for technology development and deployment. However, the mandatory nature of special participation means that technology solutions must be fully operational and compliant by the implementation date. This compressed timeline favors established technology vendors with existing healthcare infrastructure over startup companies requiring extensive development cycles.

Organizations planning to serve ASM participants must account for:

EHR Integration Requirements: Minimum 12-18 months for comprehensive EHR integration across multiple health systems.

Clinical Validation: 6-12 months for clinical evidence generation and validation studies.

Provider Training: 3-6 months for comprehensive provider training and workflow optimization.

Compliance Certification: 3-6 months for regulatory compliance verification and certification processes.

Market Adoption Risks

While ASM's mandatory participation eliminates traditional adoption resistance, it creates new risks related to provider satisfaction and technology effectiveness.

Specialists required to participate in value-based payment models may resist

technology solutions perceived as increasing administrative burden or reducing clinical autonomy.

Technology vendors must balance comprehensive functionality with workflow simplicity, ensuring that solutions provide clear value to providers while meeting CMS requirements. Early adopter programs and pilot implementations become essential for validating technology effectiveness and optimizing user experience before mandatory implementation.

Financial Risk Considerations

The separation of APM and non-APM conversion factors creates ongoing financial risk for technology vendors serving both market segments. Companies must develop flexible pricing models that account for customer payment capabilities while maintaining profitability across different reimbursement levels.

Additionally, the emphasis on outcome-based payment creates potential liability for technology vendors offering performance guarantees or shared savings arrangements. Companies must develop sophisticated risk assessment capabilities and consider appropriate insurance coverage for outcome-based contracts.

Strategic Recommendations for Health Tech Leaders

Immediate Action Items (Next 90 Days)

Regulatory Analysis and Compliance Planning: Technology leaders should conduct a comprehensive analysis of the proposed rule's implications for their specific products and services. This analysis should include identification of new compliance requirements, potential market opportunities, and necessary product modifications.

Partnership Development: Initiate discussions with potential healthcare partners including health systems, specialty practices, and other technology vendors. The

complexity of ASM requirements and interoperability mandates favors collaborative approaches over independent solutions.

Evidence Generation Strategy: Develop plans for generating clinical evidence supporting product effectiveness and cost-effectiveness. CMS's emphasis on evidence-based care makes robust clinical validation essential for market success.

Medium-Term Strategic Positioning (6-18 Months)

Product Development Alignment: Align product development roadmaps with CMS requirements and market opportunities. Priority should be given to features supporting care coordination, outcome measurement, and provider workflow optimization.

Market Entry Planning: For companies not currently serving Medicare populations, develop market entry strategies that account for regulatory complexity and provider expectations. Consider partnership approaches that leverage existing healthcare relationships and compliance capabilities.

Investment and Funding Strategy: Develop funding strategies that account for longer development timelines and higher regulatory compliance costs. Consider strategic investors with healthcare expertise rather than relying solely on traditional venture funding.

Long-Term Strategic Considerations (18+ Months)

Scalability Planning: Design solutions with scalability in mind, anticipating expansion of value-based payment models to additional specialties and conditions. CMS's success with ASM will likely lead to broader application of similar models across healthcare.

***International Expansion:** Consider how Medicare policy changes may influence healthcare payment models internationally. Technology solutions developed for

regulatory requirements may have application in other markets adopting similar value-based payment approaches.

Acquisition and Consolidation Strategy: The regulatory complexity and investment requirements created by the proposed rule may drive consolidation in the health technology market. Companies should consider both acquisition opportunities and potential strategic partnerships as the market evolves.

Success Metrics and Performance Monitoring

Technology leaders should establish comprehensive performance monitoring systems that track both business metrics and clinical outcomes. Key performance indicators should include:

Regulatory Compliance Metrics: Time to compliance certification, regulatory audit results, and ongoing compliance maintenance costs.

Clinical Effectiveness Metrics: Patient outcome improvements, provider satisfaction scores, and comparative effectiveness against alternative solutions.

Business Performance Metrics: Revenue growth, customer acquisition costs, customer lifetime value, and profitability across different market segments.

Market Impact Metrics: Market share growth, competitive positioning, and strategic partnership development.

The CMS 2026 Physician Fee Schedule proposed rule represents a fundamental transformation of healthcare payment methodology that creates both unprecedented opportunities and significant challenges for health technology entrepreneurs. Success in this evolving landscape requires sophisticated understanding of regulatory requirements, deep integration with healthcare workflows, and unwavering focus on demonstrable clinical and financial outcomes. Organizations that can navigate this complexity while delivering measurable value to providers and patients will find themselves well-positioned for sustained growth in an increasingly technology-dependent healthcare ecosystem.

The convergence of mandatory value-based care, expanded digital health coverage and evidence-based payment methodologies creates a market environment that rewards innovation, efficiency, and measurable impact. For health technology leaders willing to invest in compliance capabilities, clinical evidence generation, and deep healthcare integration, the proposed rule represents the beginning of a new era of opportunity in healthcare technology.



5 Likes • 1 Restack

[← Previous](#)

[Next →](#)

Discussion about this post

Comments

Restacks



Write a comment...