The following Comment Letter includes AugMend Health's recommendations and comments regarding RFI Notice CMS-0042-NC.

Letter:

June 16, 2025

Submitted Via Electronic Delivery to Regulations.gov

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave SW Washington, DC 20201

Re: Request for Information; Health Technology Ecosystem

Dear Administrator Oz:
AugMend Health appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Request for Information (RFI): Health Technology Ecosystem published in the May 16, 2025, Federal Register.

As a developer of integrated AI and virtual reality (VR) behavioral health software specifically designed for specialty medical clinics, we offer unique insights into the billing code framework needed to support innovative digital health technologies that serve Medicare beneficiaries with chronic conditions.

Our platform addresses the critical shortage of behavioral health professionals by embedding AI-guided VR assessments and interventions directly into oncology and chronic pain specialty care workflows, serving the 79% of these patients who experience mental health disorders but cannot access traditional behavioral health services.

Company Background and Technology Overview

AugMend Health Inc. uses AI and VR technology to enable clinical care teams to provide more effective and accessible behavioral healthcare for all people. Our technology includes the following four core components:

- AI-powered conversational avatars conducting comprehensive biopsychosocial assessments in immersive VR environments.

- EHR-integrated clinical interface providing insurance-compliant documentation and insights.
- Evidence-based VR behavioral exercise modules for psychoeducation, stress reduction, and pain management.
- Multi-modal data collection including physiological measurements and conversational analysis.

Initially and currently we are serving multidisciplinary specialty clinics with a focus on oncology and chronic pain management, where behavioral health needs are highest but access is most limited.

Key Responses to CMS Questions

PC-8 & PC-9: Data Access and Blue Button 2.0 API Enhancement

Current Value: The Blue Button 2.0 API provides essential foundation data, but additional data sources would significantly enhance digital health product capabilities:

Recommended Additions to Blue Button 2.0:

- **Provider quality metrics and outcomes data** to support care navigation
- **Real-time medication adherence data** from pharmacy benefits managers
- **Social determinants of health indicators** for personalized interventions
- **Care coordination data** including specialist referrals and care plan updates
- **Patient-reported outcome measures (PROMs)** for chronic disease management

PR-2: Digital Health Application Development Obstacles

Current Obstacles Preventing Innovation:

1. **Billing Code Uncertainty:** Limited clarity on appropriate CPT codes for AI-assisted digital interventions
2. **Integration Complexity:** Varying EHR certification requirements across health systems
3. **Regulatory Ambiguity:** Unclear FDA oversight requirements for AI-driven clinical decision support
4. **Reimbursement Gaps:** Insufficient coverage for innovative delivery modalities

Recommended Mitigations:

- Establish clear guidance on existing code utilization for digital health platforms
- Create streamlined certification pathways for EHR-integrated digital tools
- Develop specific billing codes for AI-assisted clinical assessments

TD-2: Additional CMS Data Sources for Developer Innovation

Most Valuable Data Sources:

1. **Hierarchical Condition Categories (HCC) data** for risk stratification
2. **Quality measure performance data** at provider and facility levels
3. **Prior authorization patterns** to predict coverage decisions
4. **Medication therapy management data** for comprehensive care coordination
5. **Social vulnerability index data** by geographic region

Billing Code Framework Recommendations

Currently Supported Codes (Requiring Enhanced Guidance)

1. HCPCS Code E1905 - VR Cognitive Behavioral Therapy Device

- **Current Status:** Established March 2023 by CMS ($549-$646 reimbursement)
- **Enhancement Needed:** Clarify applicability beyond RelieVRx to other VR platforms meeting general requirements
- **Recommendation:** Publish clear criteria for platforms eligible under E1905

2. Psychotherapy Codes (90832, 90834, 90837)

- **Current Challenge:** Unclear guidance on "face-to-face" requirements for AI-facilitated sessions
- **Our Use Case:** Licensed clinician oversight of VR sessions with AI avatars
- **Recommendation:** Clarify that clinician "facilitation and oversight" qualifies for psychotherapy billing

3. Health Behavior Assessment/Intervention (96156, 96158)

- **Current Application:** Behavioral factors affecting physical health
- **Our Enhancement:** AI-powered comprehensive biopsychosocial assessments
- **Recommendation:** Explicit guidance on AI-assisted assessment billing

4. CPT Category III Code 0770T - Therapeutic Virtual Reality Platform

- **Current Status:** Emerging technology code for VR-based therapeutic interventions
- **Our Application:** AI-guided VR behavioral health assessments and interventions integrated into specialty care workflows
- **Key Advantages:**
    - Recognizes VR as distinct therapeutic modality requiring specialized billing
    - Allows tracking of outcomes data for future permanent code development
    - Provides pathway for innovative VR platforms beyond single-device models
- **Enhancement Needed:**

- ○ Clear guidance on clinical supervision requirements for AI-facilitated sessions
  - ○ Documentation standards for multi-modal VR interventions (assessment + treatment)
  - ○ Integration with existing behavioral health codes for comprehensive care billing
  - ○ Shift 0770T from Category III code to an established Category I or II code
- **Recommendation:** Expand 0770T guidance to include AI-enhanced VR platforms that provide clinical decision support alongside therapeutic interventions

New Code Categories Needed

1. AI-Assisted Clinical Assessment

- **Rationale:** Traditional assessment codes don't capture the enhanced data collection and analysis capabilities of AI platforms
- **Proposed Structure:** Tiered codes based on assessment complexity and AI involvement
- **Patient Benefit:** More comprehensive, consistent assessments leading to better treatment planning

2. Digital Therapeutic Monitoring

- **Current Gap:** Remote monitoring codes (99453-99458) focus on device data, not therapeutic engagement
- **Proposed Solution:** Codes specifically for digital therapeutic platforms that combine monitoring with active intervention
- **Example Application:** VR-delivered behavioral exercises with real-time biometric feedback

3. Integrated Behavioral Health Technology

- **Rationale:** Current behavioral health integration codes (99484, 99492-99494) don't account for technology-enhanced delivery
- **Proposed Enhancement:** Add-on codes for technology platforms that extend behavioral health capacity
- **Cost Efficiency:** Enables one provider to effectively manage multiple patients simultaneously

Value-Based Care Integration

Enhanced HCC Documentation Support

- **Current Challenge:** Under-documentation of behavioral health conditions in specialty care
- **Our Solution:** AI-powered identification and documentation of qualifying conditions

- **Billing Impact:** Improved risk adjustment accuracy, supporting value-based care initiatives

---

Recommendations for CMS Action

Short-Term (Next 2 Years)

1. **Publish Comprehensive Guidance** on existing code utilization for digital health platforms
2. **Establish Clear Criteria** for HCPCS E1905 eligibility beyond original applicant
3. **Clarify "Face-to-Face" Requirements** for psychotherapy codes in technology-assisted settings
4. **Create Fast-Track Review Process** for innovative digital health billing scenarios

Medium-Term (2-5 Years)

1. **Develop Technology-Specific Code Categories** for AI-assisted clinical services
2. **Establish Digital Therapeutic Monitoring Codes** distinct from basic remote monitoring
3. **Create Incentive Structure** for digital health adoption in underserved specialties
4. **Implement Outcome-Based Billing Models** for digital behavioral health interventions

Long-Term (5+ Years)

1. **Integrate Digital Health Quality Measures** into MIPS and value-based care programs
2. **Establish Technology Certification Standards** for billing code eligibility
3. **Create Population Health Digital Intervention Codes** for preventive behavioral health
4. **Develop AI Transparency Requirements** for billing compliance

---

Patient and Provider Benefits

For Medicare Beneficiaries:

- **Increased Access:** Digital platforms extend behavioral health services to underserved specialty care settings
- **Improved Outcomes:** AI-powered personalization enhances treatment effectiveness

- **Cost Reduction:** Technology-assisted care reduces per-encounter costs while improving quality
- **Convenience:** VR-delivered interventions reduce travel burden for patients with chronic conditions

For Healthcare Providers:

- **Enhanced Capacity:** Technology platforms enable providers to serve more patients effectively
- **Improved Documentation:** AI-assisted clinical note generation ensures complete, compliant billing
- **Better Outcomes:** Data-driven insights lead to more effective treatment planning
- **Revenue Optimization:** Clear billing pathways support sustainable digital health adoption

---

Implementation Considerations

Regulatory Framework:

- **FDA Oversight:** Software-based clinical decision support tools operating under existing clinical workflows
- **HIPAA Compliance:** Full encryption and security standards for patient health information
- **EHR Integration:** HL7 FHIR-based APIs ensuring seamless clinical workflow integration

Quality Assurance:

- **Clinical Validation:** Evidence-based interventions with demonstrated efficacy
- **Provider Training:** Comprehensive onboarding ensuring appropriate technology utilization
- **Outcome Monitoring:** Built-in quality metrics tracking for continuous improvement

---

The integration of AI and VR technologies into behavioral healthcare represents a critical opportunity to address the growing mental health crisis among Medicare beneficiaries with chronic conditions. However, realizing this potential requires a supportive billing framework that recognizes the unique value proposition of these innovative platforms.

We thank CMS for taking the initiative on this critical care issue, and trying to get in front of the future of technology in the health care delivery system. In summary we urge CMS to to the following:

1. Provide immediate clarity on existing code utilization for digital health platforms
2. Develop new billing categories that capture the enhanced capabilities of AI-assisted care
3. Create incentive structures that encourage adoption of innovative technologies in underserved care areas
4. Establish outcome-based payment models that reward improved patient outcomes

AugMend Health stands ready to collaborate with CMS on pilot programs, outcome studies, and regulatory framework development to ensure that Medicare beneficiaries can access the full benefits of innovative digital health technologies.

Contact Information: Sacha Moreau, CEO, AugMend Health Inc. One Broadway, 14th Floor, Cambridge MA 02142; 617-693-5727; smoreau@augmend.health.

Supporting Documentation:

- Clinical efficacy data from pilot implementations
- Detailed billing code analysis and recommendations
- Technology architecture and security documentation
- Provider workflow integration specifications

This response represents AugMend Health's perspective based on our experience developing and deploying AI/VR behavioral health technology in specialty care settings. We welcome the opportunity to provide additional detail or participate in follow-up discussions regarding these recommendations.