Request for Information; Health Technology Ecosystem [CMS-0042-NC]
Submitted by: Adherium
Contact: Luke Allera, lukea@adherium.com
Date: June 16th, 2025

Executive Summary

Adherium is an FDA-cleared digital health company focused on improving medication adherence and respiratory care management through remote monitoring and connected inhaler technology. Our Hailie® SmartInhaler® platform integrates directly into clinical workflows and collects physiologic and usage data that enables timely, proactive care.

From our experience deploying real-world remote monitoring programs with large provider networks, we believe that CMS and ONC have laid a critical foundation for a patient-centered digital health ecosystem. However, to make digital health truly scalable for Medicare beneficiaries, several infrastructure gaps must be addressed, particularly around pharmacy data access, interoperability standards for device data, and certification criteria that support modular, open platforms.

This response provides input from the perspective of a digital health technology vendor with on-the-ground experience implementing interoperable solutions and engaging providers, payers, and patients. Our recommendations aim to advance CMS's goals of increasing beneficiary access to digital tools and enabling data-driven care.

Ecosystem & Data Access (TD-1, TD-2)

Scaling remote patient monitoring (RPM) across Medicare populations—particularly those with chronic respiratory conditions like COPD and asthma—requires frictionless, bi-directional access to real-time and historical data, including pharmacy fills, claims, and prior authorizations.

Recommendations:

- CMS should incentivize bi-directional data exchange between RPM vendors and Fee-for-Service (FFS) providers to support collaborative, patient-centered care models.
- Expand the Blue Button 2.0 API to include:
    - Prior authorization status and denial history
    - Medicare Part D refill and adherence gap indicators
    - RTM/RPM billing code submission and reimbursement visibility (e.g., CPT 98976, 98980, 99454, 99457)
- Enable payer-provider-patient shared APIs so that patient-generated data (e.g., inhaler usage patterns, symptom reports) can flow upstream to both providers and CMS.

Digital Identity (TD-3)

Many Medicare beneficiaries, especially older adults, struggle with fragmented digital identity

systems. Multiple portals and inconsistent verification processes create barriers to accessing digital tools that manage their care.

Recommendations:

- CMS should support federated digital identity infrastructure (e.g., Login.gov, ID.me) that enables patients to log in once and grant access across all certified applications.
- Require OpenID Connect compatibility across ONC-certified health IT platforms to support secure, scalable identity federation.
- Enable patients to delegate access to caregivers or family members via consent-based proxy tools that allow RPM platforms to be administered on their behalf. This will be particularly impactful for older adults managing multiple chronic conditions.

Standards, APIs & Certification (TD-4 to TD-11)

Despite policy advancements, RPM vendors still face integration barriers due to inconsistent API exposure by EHR vendors, even among those with ONC certification. This limits the impact of digital tools that rely on timely, contextual data.

Recommendations:

- Strengthen ONC Health IT Certification Program to:
    - Prioritize API-readand write access for external systems, including RPM platforms
    - Ensure certification covers bidirectional exchange of patient-reported outcomes (PROs) and sensor-derived data
- Expand the USCDI (United States Core Data for Interoperability) standard to include:
    - Device use data (e.g., dose counts, inhaler adherence trends, usage timestamps)
    - Passive physiologic measures (e.g., inspiratory flow rate, technique analysis)
    - Behavioral outcomes (e.g., engagement with reminders or nudges)
- Update EHI export criteria to include structured sensor data collected by certified RPM platforms. This ensures longitudinal care records are complete, portable, and patient-owned.
- Support bulk FHIR export of RPM patient cohorts to reduce provider burden in quality reporting and care coordination.
- Create a new "Patient-Reported Data Bundle" under FHIR to enable structured intake of device and behavioral data into both payer and provider workflows.

Standardizing Patient-Generated Health Data (TD-8 Enhancement)

Medicare beneficiaries use diverse RPM devices—inhalers, glucose monitors, blood pressure cuffs—that currently generate siloed data. The existing OpenMHealth-to-FHIR specification provides a proven framework for standardizing this data flow.

Recommendation: CMS should mandate OpenMHealth-to-FHIR compliance for all RPM devices seeking Medicare reimbursement under CPT codes for RPM and RTM.

Implementation Pathway:

- Phase 1 (6 months): Update ONC certification criteria to require OpenMHealth schema support
- Phase 2 (12 months): Pilot with 5 health systems using certified OpenMHealth-compliant devices
- Phase 3 (18 months): Mandate for all new RPM billing

Evidence: Our Hailie platform supports OpenMHealth data schema, enabling seamless integration with FHIR.

Data Exchange Infrastructure (TD-12 to TD-17)

The lack of a unified FHIR endpoint directory and inconsistent network interconnection policies create operational drag for RPM vendors and digital health innovators. Scaling depends on reliable routing and search capabilities.

Recommendations:

- CMS or ONC should develop and maintain a national FHIR endpoint directory, indexed by NPI and organizational ID, to support patient-matching and data routing.
- Encourage adoption of FHIR bulk APIs for:
    - Population-level adherence and intervention monitoring
    - Aggregated risk stratification based on device usage
- Support TEFCA-aligned modular networks that accommodate both traditional EHR architectures and modern app-based digital health tools.
- Offer implementation grants or reimbursement flexibility for providers adopting certified RPM tools that integrate via open FHIR APIs.
- Reduce administrative burden on participants in APMs or value-based care programs who use standards-compliant RPM systems for chronic condition monitoring.

Conclusion

Adherium appreciates the opportunity to contribute to this RFI and commends CMS and ASTP/ONC for engaging stakeholders in shaping a more open, interoperable, and patient-centered digital health ecosystem. We believe that meaningful progress will depend on continued collaboration across agencies, providers, developers, and patients. We welcome further dialogue and are committed to supporting CMS's long-term goals to enhance care, reduce costs, and expand access for Medicare beneficiaries.