HiLabs

Response to Request for Information: Health Technology Ecosystem

To: Centers for Medicare & Medicaid Services (CMS)

From: HiLabs, Inc.

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We thank CMS for the opportunity to submit public comments on their Health Technology Ecosystem Request for Information. CMS, as the nation's largest payer and regulatory authority, holds a unique and critical position to significantly enhance the healthcare experience for millions of patients and their caregivers. By strategically operationalizing foundational workflows and embracing the transformative potential of Artificial Intelligence (AI) technology, specifically leveraging advanced AI models, CMS can ensure high-quality data, streamline operations, and foster true interoperability across the healthcare ecosystem. This response emphasizes how sophisticated AI, in synergy with existing and proposed CMS initiatives, can directly empower all stakeholders across the healthcare ecosystem: 1) patients and caregivers, 2) providers, 3) technology vendors, 4) payers, and 5) value-based care organizations in their daily health management and care coordination efforts, leading to improved access, transparency, and outcomes.

The opportunity to leverage advanced AI models, including agents, LLMs, VLMs, and sophisticated ML and NLP techniques, to fundamentally transform healthcare for all stakeholders is immense. By proactively addressing data fragmentation, championing interoperability, and establishing robust AI governance, CMS can cultivate an environment where individuals are empowered with actionable health information, enabling them to make informed decisions, coordinate care effectively, and ultimately achieve better health outcomes. This proactive approach will not only enhance the patient and caregiver experience but also drive greater efficiency and equity throughout the entire healthcare system.

HiLabs as a healthcare technology vendor can support CMS's efforts in ensuring greater care efficiency and equity through our MCheck Provider Product Suite and MCheck Clinical Product Suite. The former offers a comprehensive Provider Network Lifecycle Management solution, whereas the latter offers a complete Clinical Data Management solution. Both have been proven through partnerships with national and regional health plans across all 50 states and lines of business (Medicare, Medicaid, and Commercial). Our technology, regulatory expertise, and client collaboration automate upstream processes (e.g., roster ingestion and clinical file ingestion) to improve and enable downstream operations, including by resolving inaccurate provider data across 260+ elements and processing ~3.6B clinical records.

Our Provider Data Accuracy solution is based on our proprietary AI algorithm (R3: Reliability, Relevance, Recency), featured in the Journal of the American Medical Association (JAMA) article which was also mentioned in the **June 2024 Medicare Payment Advisory Commission's (MedPAC) report to Congress**. This algorithm scores record confidence from thousands of sources, achieving 90%+ accuracy for trusted automation, well above the 52% industry average. HiLabs' NetworkIQ Module provides advanced network coverage calculation and high-performing provider identification. Our market-leading Roster Automation Module delivers a true end-to-end processing experience. Our Contracts AI solution automates provider contract configuration for claims pricing and supports compliance monitoring through AI-driven contextual reasoning of contractual outcomes, contract language comparison, across both fee-for-service (FFS) and Value-Based Care agreements. It also enables contract standardization, change management, longitudinal analysis and generates compliance report aligned with PADU and other regulatory frameworks. In short, our MCheck Provider solutions ensure compliance, significantly reduce regulatory risk and improve patient access.

Our MCheck Clinical is an AI-powered data harmonization solution that revolutionizes healthcare data through automating the classification and transformation of clinical files (i.e. Excel, CSV, CCDA, etc.) with 90% accuracy and accelerating external data onboarding. For example, our SmartOCR solution extracts unstructured data from medical charts twice as fast as traditional tools with high precision, even when the clinical terms are abbreviated or aliased. CodEx, our AI-powered clinical code extractor, significantly increases throughput and improves coding accuracy from 91% to 99%. Finally, our Term Mapping Engine standardizes clinical terms into vocabularies like ICD-10, SNOMED, and LOINC, creating clean, interoperable datasets for enhanced research, analytics, and care coordination.

HiLabs' integrated data management approach, spanning both provider and clinical data, delivers an unparalleled, comprehensive perspective across the healthcare ecosystem. This singular advantage fosters enhanced care delivery and equitable outcomes for every participant, from patients to healthcare organizations and insurers.

Patients & Care Givers

I. Empowering Patients and Caregivers through AI-Enhanced Workflows

Patients and caregivers constantly navigate complex healthcare journeys. AI offers a powerful opportunity to alleviate administrative burdens and provide actionable insights at critical decision points, directly supporting their workflows in several key areas:

- A. Streamlined Provider Discovery and Access (AI-Powered End-to-End Provider Data Management):
    - Current Workflow Challenge: Patients and caregivers frequently struggle to locate accurate, up-to-date provider information (e.g., in-network status, specialty, contact details), leading to "ghost networks," wasted appointments, and delayed care. The current landscape's reported 55% inaccuracy rate in provider directories creates significant patient abrasion and inability to determine true patients' geo-access to care.
    - AI-Enabled Solution: CMS can leverage various AI techniques to develop and maintain national, authoritative provider rosters.
        - Machine Learning (ML) Models (e.g., Random Forests, Gradient Boosting Machines): Can be trained on existing provider data to identify patterns, detect anomalies, and predict potential inaccuracies, flagging entries for human review.
        - Large Language Models (e.g., T5, BERT): Our sequence-to-sequence models are used in a variety of natural language processing tasks such as named entity recognition, data paraphrasing and retrieval augmented generation. They are crucial for processing unstructured data from diverse sources like provider websites, faxes, and free-text fields in enrollment applications. NLP can extract, standardize, and reconcile provider demographics, specialties, and credentialing information, significantly improving data quality and reducing manual data entry.
        - Semantic Knowledge Graphs: Can model relationships between providers, organizations, and locations to identify inconsistencies or redundancies that might indicate "ghost networks" or outdated information.
        - Vision Models and Image-to-Text Models (e.g. RCNN, SigLIP): For parsing images of unstructured text and tables in complex, multi-page layouts.
    - For patients and caregivers, this translates to: Reduced search time, improved network navigation, correctly processed claims, and enhanced trust in provider information.
- B. Personalized Health Information Access (AI-Enhanced Personal Health Records):
    - Current Workflow Challenge: Aggregating a complete personal health record (PHR) remains a significant burden. Critical information like medication lists, visit summaries, immunization histories, and especially clinical notes (often unstructured and siloed in EMRs) are difficult for patients and caregivers to obtain and synthesize, hindering informed decision-making.
    - AI-Enabled Solution: Expanding Blue Button 2.0 with sophisticated AI agents will revolutionize patient access to their comprehensive health data.
        - Orchestration Agents within Patient-Facing Applications: Embed context-aware, reinforcement-capable orchestration agents to normalize and validate heterogeneous data across systems (i.e. EHR, imaging, billing).
        - Temporal Clinical Context Engine: Maps all the patient's records to a temporal graph of clinical concepts to support longitudinal queries for the patient to ask questions, such as "How many times have I been to the ER in the last 1 year?"
        - Disease Progression Modeling Agents: Each clinical agent is scoped to a specific disease or condition family (i.e. CKD, heart failure, etc.) and identifies when a patient is off the expected trajectory, such as missing exams or appointments (i.e. retinal exam in diabetics), and proactively recommend follow-ups as needed.

  - This means truly understanding diagnoses, treatments, next steps, and proactive care follow-up, without deciphering medical jargon.

- C. Transparent Cost and Coverage Understanding (AI for Price and Benefit Clarity):
  - **Current Workflow Challenge:** The opacity surrounding healthcare costs, deductibles, co-pays, and prior authorization status creates immense anxiety and financial strain. Patients and caregivers often face unexpected bills and delays in care due to a lack of real-time visibility.
  - **AI-Enabled Solution:** CMS can utilize various AI techniques to create a unified and transparent view of healthcare costs and benefits.
    - **ML Models (e.g., Regression Models, Forecasting Models):** Can analyze historical claims data, price transparency data, negotiated rates, identify misclassification of nonpar claims and benefit design details to provide highly accurate, personalized cost estimates for specific procedures, medications, or visits.
    - **NLP Models:** Crucial for parsing complex insurance policy documents, explanation of benefits (EOBs), and prior authorization requests to extract key terms, coverage rules, and approval statuses, standardizing data from various payer formats (e.g., SERFF filings).
    - **Rule-Based AI Systems combined with ML:** Can automate the processing and tracking of prior authorization requests, providing real-time updates on approval status, identifying potential bottlenecks, expediting the resolution of legal workflows for claims disputes and flagging cases for expedited review based on clinical urgency or payer patterns. Additionally, ML models can analyze patient data (with consent) to identify individuals who would benefit most from care management programs or to predict the likelihood of a prior authorization approval, streamlining processes for payers and reducing delays for patients.
  - This empowers patients and caregivers to make informed financial decisions and avoid surprise bills.

- D. Seamless Care Coordination and Transitions (AI-Driven Alerts and Longitudinal Records):
  - **Current Workflow Challenge:** Transitions between care settings (e.g., hospital discharge to home) are often fraught with communication gaps, leading to fragmented care and preventable readmissions. Caregivers frequently lack timely alerts about critical patient events.
  - **AI-Enabled Solution:** AI can power national workflows for robust care coordination and transition alerts.
    - **Predictive Analytics (ML Models, e.g., Survival Analysis, Deep Learning):** Can analyze integrated patient data (clinical, claims, SDoH) to identify patients at high risk for readmission, adverse events, or care gaps, enabling proactive interventions.
    - **Real-time Event Processing (Stream Processing AI):** Monitors incoming data streams (e.g., ADT feeds for hospital admissions/discharges) and immediately triggers alerts to relevant care teams, patients, and caregivers via secure channels (e.g., FHIR subscriptions).
    - **Knowledge Graphs combined with LLMs:** Can synthesize information from disparate EHRs, HIEs, and payer systems to create a unified, navigable longitudinal patient record. LLMs can then summarize transition of care documents and highlight critical follow-up actions for patients and caregivers.
    - **Information Extraction from Free Text:** NLP can extract key entities (diagnoses, procedures, medications) from unstructured clinical text, even from scanned documents, and normalize them for structured use. This is crucial for filling gaps in longitudinal records and improving the clarity of billing and referral information.
  - This minimizes care gaps and reduces the need for duplicate tests.

- E. Addressing Social Determinants of Health (AI for Holistic Support):
    - Current Workflow Challenge: Non-clinical barriers like housing insecurity, food access, and transportation significantly impact health outcomes, yet data on these Social Determinants of Health (SDoH) is rarely structured or consistently integrated into care plans.
    - AI-Enabled Solution: AI can play a pivotal role in identifying and addressing SDoH.
        - Geospatial AI/ML: Can combine patient location data with publicly available SDoH indices (e.g., poverty rates, food desert maps, transportation access) to identify potential social barriers.
        - Consolidated Longitudinal Record: AI can digitize and structure fragmented data (scanned documents, EMRs, flat files, unstructured intake forms, social worker assessments) to extract SDoH information, providing patients and caregivers with a complete view of care history across various providers and platforms and refer patients to the most appropriate health equity program.
        - Population Health Modeling Agents: Each agent is scoped to specific SDoH needs, leveraging predictive models (i.e. Markov, causal models for intervention impact), deviation detection, and proactive recommendation engine to guide patients to relevant local community resources (e.g., food banks, transportation services, housing assistance programs), providing personalized referrals to patients and caregivers.
    - This means more tailored care and support that addresses all aspects of a patient's well-being.

II. Strategic Imperatives for CMS with AI Integration:

To effectively harness these advanced AI capabilities for patient and caregiver empowerment, CMS should focus on the following strategic imperatives:

- A. Robust AI Governance for Healthcare Data Use: Establish comprehensive standards for AI in regulated healthcare workflows, focusing on auditability, explainability (e.g., explainable AI/XAI techniques to understand model decisions), and fairness (e.g., bias detection and mitigation in model training and deployment). This is paramount to building public trust and ensuring equitable outcomes as AI adoption grows. CMS must define clear guidelines for how AI models are developed, validated, and monitored to prevent bias and ensure transparency in their decision-making processes, especially when impacting patient access to care or financial obligations.
- B. Expanding and Standardizing Data Scope via FHIR and APIs: Accelerate the expansion of data available through Blue Button 2.0, prioritizing clinical data (lab results, vitals, care plans), comprehensive benefit design details, and real-time prior authorization and pricing information. All data should be standardized in FHIR-compliant formats to maximize usability for developers and innovators building patient-facing applications. This structured data is foundational for training and deploying effective AI models.
- C. Unified Authentication and Authorization: Implement a unified authentication and authorization framework (e.g., leveraging OAuth 2.0 and OpenID Connect) across all CMS APIs. This will significantly simplify integration for third-party developers, reducing development burden and accelerating the creation of innovative tools for patients and caregivers, allowing seamless access to data that fuels AI-powered applications.
- D. Enhanced Developer Support and Ecosystem: Provide robust sandbox environments with realistic, de-identified test data and comprehensive documentation, including detailed API specifications and AI model outputs. Clear guidelines for third-party app certification and secure patient consent flows are essential to foster a thriving ecosystem of patient-centric digital health solutions leveraging CMS data and AI capabilities.
- E. Accelerating TEFCA Implementation for Patient Access: Expedite the rollout of Individual Access Services (IAS) through Qualified Health Information Networks (QHINs) under TEFCA. This will directly enable patients to request and receive their complete longitudinal health records, breaking down silos and supporting seamless care coordination across the continuum. This integration is crucial for empowering

patients and caregivers to be central participants in their own health data exchange, providing the rich, diverse datasets necessary for training advanced AI models.

Providers

I. Understanding and Addressing Provider Barriers to Digital Health Adoption

For providers, the decision to adopt new digital health products is multifaceted, impacting their daily practice, patient care, and compliance. Understanding these barriers is crucial for CMS to facilitate widespread adoption:

- A. Technical Barriers (Workflow Impact: Operational Friction):
    - **Provider Perspective:** Many providers, especially in rural or under-resourced areas, face fundamental limitations like unreliable broadband, outdated hardware, or incompatibility between new tools and existing EHR systems. Introducing a new digital health product when the underlying technical infrastructure is fragile feels like adding another layer of complexity rather than a solution.
    - AI-Enabled Mitigation:
        - **Network Optimization AI: Machine Learning (ML) models** can analyze network performance data to identify connectivity bottlenecks in specific geographic areas, guiding CMS's investments in broadband expansion.
        - **Compatibility Check AI: Automated testing frameworks driven by ML** can assess the compatibility of new digital health products with diverse EHR systems and hardware configurations, providing immediate feedback to vendors and providers.
        - **Intelligent Device Provisioning: Reinforcement Learning (RL) agents** could optimize the allocation and deployment of necessary devices (e.g., tablets for patient intake) to provider practices based on need, patient volume, and existing infrastructure, ensuring providers have the physical tools.
- B. Personal Barriers (Workflow Impact: Resistance to Change, Fear of the Unknown):
    - **Provider Perspective:** Adopting new technology often involves overcoming technophobia, anxiety about disrupting established routines, or skepticism about perceived benefits. Providers fear a steep learning curve that detracts from direct patient care, especially given varying comfort levels with technology across different age groups and professional experiences.
    - AI-Enabled Mitigation:
        - **Personalized Training LLMs: Large Language Models (LLMs)** can power adaptive training modules that dynamically adjust to a provider's existing digital literacy and learning pace. These LLMs can offer on-demand, conversational support for specific workflow questions, reducing anxiety.
        - **Workflow Simulation AI: Simulation models driven by AI** can create realistic, low-stakes virtual environments for providers to practice using new digital health tools within their simulated daily workflows, minimizing fear of disruption to actual patient care.
        - **Benefit Communication with NLP: Natural Language Processing (NLP)** can analyze provider feedback and common concerns, enabling CMS to tailor educational content that directly addresses specific anxieties and clearly articulates the time-saving or quality-of-care benefits of adoption.
- C. Workload Barriers (Workflow Impact: Perceived Increased Burden, Disruption):
    - **Provider Perspective:** The paramount concern for providers is often the fear that new digital tools will increase administrative burden, extend working hours, or disrupt existing, finely tuned

clinical workflows, particularly during a "ramp-up" period. They need assurance that these tools will truly save them time or improve care without adding to their already demanding schedules.

- AI-Enabled Mitigation:
  - **Workflow Automation AI: Intelligent Process Automation (IPA) solutions incorporating ML and NLP** can auto-populate intake forms from patient portals, retrieve relevant patient history for appointments, and automate routine administrative tasks (e.g., appointment reminders, referral generation), directly reducing provider and staff workload.
  - **Predictive Scheduling AI: Optimization algorithms and ML models** can analyze provider availability, patient demand, and procedure duration to optimize appointment schedules, minimizing "no-shows" and maximizing efficiency, thus reducing unexpected disruptions.
  - **Real-time Workflow Integration AI: FHIR-based APIs combined with real-time AI models** (e.g., event stream processing) can ensure digital health products seamlessly integrate into existing EHR workflows, minimizing context switching and additional clicks for providers. AI can intelligently route relevant patient data from digital health apps directly into the correct fields in the EHR.

- D. Legal/Ethical Barriers (Workflow Impact: Compliance Anxiety, Liability Concerns):
  - **Provider Perspective:** Providers are acutely aware of HIPAA, privacy, and security regulations. The adoption of new digital tools raises concerns about potential breaches, unknown compliance requirements, and increased legal liability or reputational risk if patient data is mishandled. Clear guidance and robust safeguards are essential.
  - AI-Enabled Mitigation:
    - **Automated Compliance Auditing AI: ML models** can continuously monitor data access logs and usage patterns of digital health products, flagging potential privacy or security violations in real-time, providing proactive alerts to providers and compliance officers.
    - **Consent Management with LLMs: LLMs** can help generate clear, concise, and legally compliant consent forms that are easily understood by patients, facilitating transparency and minimizing provider liability related to data usage.
    - **Secure Data Exchange AI: Homomorphic encryption or federated learning techniques** within AI systems can enable data analysis and insights generation across diverse datasets without exposing raw patient data to providers or third parties, enhancing privacy.

II. CMS Strategies to Empower Providers through AI-Infused Interoperability

To proactively address these concerns and drive adoption, CMS must implement a layered strategy combining policy, workflow integration, and intelligent automation:

- A. Enhancing Technical Standards and Policy Frameworks for Administrative Workflows:
  - **FHIR API Expansion with AI:** Mandate and promote wider adoption of FHIR-based APIs (e.g., FHIR Scheduling, FHIR Questionnaire, FHIR Appointment) beyond clinical data to cover administrative functions. **AI models (e.g., NLP for schema matching, ML for data mapping)** can facilitate the mapping and transformation of legacy administrative data into FHIR standards, reducing the technical burden on EHR vendors and providers.
  - **Policy Enforcement via AI:** Integrate CMS price transparency and provider directory rules into standardized APIs. **AI-driven validation engines** can enforce these rules by automatically flagging non-compliant data submissions from health plans, ensuring real-time, accurate provider and network information is available to third-party apps for patient use.
  - **Guidance on Consent and Data Sharing:** Provide clear guidance on consent models and develop reference APIs for administrative interoperability. **LLMs** can assist in generating context-specific consent dialogues for patient-directed data sharing (e.g., for pre-filling forms), ensuring providers remain compliant with HIPAA.

- B. Aligning Interoperability with Provider Value-Based Care Workflows:
    - **AI for Workflow Integration:** Instead of a separate burden, interoperability requirements should seamlessly integrate into existing provider workflows. **AI tools (e.g., NLP for extracting structured data from unstructured clinical notes during Clinical Documentation Improvement (CDI) efforts)** can transform routine tasks like submitting risk adjustment data or care coordination documentation into high-quality, interoperable data for broader exchange, reducing duplicate effort.
    - **Smart Metric Integration:** Embed interoperability metrics within existing Promoting Interoperability and MIPS programs. **ML models** can analyze provider data submission patterns to identify areas for improvement in interoperability, providing targeted feedback and technical assistance.
    - **Delegated Access Models with AI:** Encourage and provide guidance for delegated access models where trusted third-party vendors, utilizing **AI for data normalization, de-duplication, and quality checks**, manage data exchange on behalf of providers. This offloads significant operational burden while maintaining data integrity and security through **secure multi-party computation (MPC)** or **federated learning** to protect sensitive PHI during data processing.
- C. Institutionalizing Roster-Based Interoperability with AI:
    - **Centralized Roster Management with AI:** CMS should standardize and publish centralized provider rosters. **Advanced NLP and ML models** can continuously aggregate, de-duplicate, and validate roster data from multiple sources (e.g., health plans, state licensing boards, credentialing organizations), ensuring a single, authoritative source of truth.
    - **Automated Flagging and Validation:** Allow provider rosters to carry Value-Based Care (VBC) participation flags and credentialing data. **AI-driven validation engines** can automatically check these flags against VBC program requirements and credentialing statuses, streamlining administrative processes for providers.
    - **Workflow Reuse through AI:** Enable the reuse of roster submissions for network validation, directory updates, and attribution logic. **Graph Neural Networks (GNNs)** can model the complex relationships within provider networks, helping CMS and health plans identify network adequacy gaps and streamline attribution processes automatically.

Payers

I. Accurately Auditing Payers with an AI-Powered Nationwide Provider Directory

A nationwide provider directory that is enriched with FHIR endpoints and leverages robust digital identity credentials would deliver transformative value to payers by fundamentally enhancing data interoperability, optimizing provider network management, and achieving substantial operational efficiencies. This centralized, authoritative resource, significantly augmented by Artificial Intelligence (AI) capabilities, would redefine how payers interact with and utilize provider information.

I. Core Value Propositions for Payers:

- A. Single Source of Truth for Provider Data Accuracy:
    - **Current State:** Payers currently grapple with fragmented, often inconsistent, and outdated provider data across multiple internal systems and external sources. This leads to costly manual reconciliation, claim denials due to inaccurate network participation, and patient abrasion from incorrect directory information.
    - **Proposed Value:** Such a directory would serve as the definitive single source of truth for real-time, validated provider information, including demographics, specialties, network participation, and digital communication endpoints. This drastically reduces redundancy and inconsistencies.
- B. Enhanced Interoperability and Automated Workflows:

- **Current State:** Administrative workflows like prior authorization, referrals, and care coordination are often manual, reliant on faxes, phone calls, or proprietary portals, leading to significant delays and administrative burden for both payers and providers.
- **Proposed Value:** Integrating **FHIR (Fast Healthcare Interoperability Resources) endpoints** directly into the directory enables automated, standards-based data exchange. This facilitates seamless, programmatic workflows for:
  - **Automated Prior Authorization:** Payers can query through third-party EMRs/EHRs or integrations directly for necessary clinical documentation via FHIR, streamlining approvals and reducing manual chase.
  - **Efficient Referrals:** Automated exchange of referral requests and confirmations between primary care providers and specialists.
  - **Optimized Care Coordination:** Real-time exchange of patient summaries and care plans (i.e. structured and unstructured data—EMR, lab feeds, clinical notes) as patients transition between providers or care settings.
  - **Real-time Provider Availability and Feedback:** Future integration of FHIR Scheduling and EMR APIs could allow payers to verify provider availability for appointments directly, enhancing patient navigation and reducing "ghost networks" and feed quality flags back to providers (e.g. "Patient is overdue for HbA1C test" at the point of care)

- **C. Streamlined and Secure Provider Authentication:**
  - **Current State:** Payers typically manage a multitude of proprietary login credentials for their provider portals, creating security vulnerabilities and administrative overhead for credential management. Providers face "password fatigue" and fragmented access to payer systems.
  - **Proposed Value:** Incorporating trusted **digital identity credentials (e.g., Login.gov, ID.me)** would standardize and streamline provider authentication and access control across the entire payer ecosystem. This minimizes reliance on disparate, proprietary logins, enhancing security through robust multi-factor authentication and reducing administrative costs associated with identity management for both payers and providers.

- **D. Accelerated Compliance and Reduced Costs:**
  - **Current State:** Compliance with evolving CMS interoperability mandates (e.g., Patient Access Rule, Provider Directory Rule) requires significant internal resources and often involves manual data compilation and validation.
  - **Proposed Value:** A centralized, FHIR-enabled, and digitally credentialed directory would significantly accelerate compliance efforts. It would improve provider search and verification processes, reduce costs associated with maintaining fragmented and inaccurate directories, and mitigate regulatory risks.

II. The Role of AI in Maximizing Value for Payers:

AI will be instrumental in realizing the full value proposition of a nationwide provider directory for payers:

- **A. Data Ingestion and Normalization (NLP, ML):**
  - **AI Function: Natural Language Processing (NLP) models (e.g., BERT, specialized clinical NLP models)** can automatically ingest, extract, and normalize provider and clinical data from diverse, unstructured sources (e.g., websites, PDFs, legacy systems, faxes, EHRs) that are currently burdensome to process. **Machine Learning (ML) models (e.g., clustering algorithms, unsupervised learning)** can identify and reconcile duplicate provider entries, resolve discrepancies, and standardize various data fields (e.g., specialty nomenclature, address formats) into a consistent FHIR-compliant schema. **Data Hygiene Agents** can also check for possible data integrity issues (i.e. missing labs, coding errors) and flag records for human review.
  - **Payer Value:** Drastically reduces manual data entry and reconciliation costs, ensuring a high-quality, normalized dataset for all payer operations.

- B. Real-time Data Validation and Anomaly Detection (ML, Anomaly Detection Models):
    - AI Function: Orchestration agents and ML-driven anomaly detection models can continuously detect and resolve data hygiene issues in real-time, such as inconsistencies, outdated information, or potential fraud. The agents will learn from discrepancies and resolutions via active or reinforcement learning. For example, the system could flag sudden changes in a provider's network status that don't align with historical patterns or identify providers listed at addresses with no corresponding practice.
    - Payer Value: Ensures the provider directory is always current and reliable, minimizing the risk of claim denials due to incorrect network data and improving fraud detection capabilities. This reduces administrative churn related to provider data maintenance.
- C. Smart Provider Search and Matching (Semantic Search, Knowledge Graphs):
    - AI Function: Semantic search engines powered by LLMs and Knowledge Graphs can enable payers to conduct highly precise queries beyond simple keyword matching. For example, a payer could search for "pediatric endocrinologists accepting new Medicaid patients in rural [County Name] with virtual visit capabilities."
    - Payer Value: Improves the accuracy of network adequacy assessments, facilitates rapid identification of appropriate providers for complex cases, and enhances patient routing to in-network providers, optimizing resource utilization.
- D. Automated Network Adequacy Analysis (Predictive Analytics, Optimization Models):
    - AI Function: Predictive analytics models can analyze provider distribution, patient demographics, and access to care metrics. Optimization models can identify network gaps and recommend strategic provider recruitment or telehealth expansion to meet regulatory requirements and patient needs.
    - Payer Value: Proactively identifies and addresses network deficiencies, ensuring compliance with state and federal regulations, improving member access to care, and optimizing network design for cost-effectiveness.
- E. Automated API Integration and Monitoring (RPA, Observability AI):
    - AI Function: Robotic Process Automation (RPA) integrated with ML can automate the setup and monitoring of FHIR API connections between the nationwide directory and payer internal systems. Observability AI tools can continuously monitor API endpoints for performance, security, and data integrity, flagging any issues in real-time.
    - Payer Value: Streamlines the technical implementation of interoperability, reduces reliance on manual IT intervention, and ensures the continuous flow of accurate data.

Technology Vendors, Data Providers, and Networks

I. Stimulating Market Demand for Digital Health Products (Vendor Perspective)

Technology vendors are driven by market opportunity. CMS can create this demand by directly influencing provider behavior and alleviating their key concerns:

- A. Short-Term: Financial Incentives for Provider Adoption:
    - Vendor Workflow Impact: A clear financial incentive for providers to adopt digital health products and interoperability standards and provides a tangible "pull" for vendors to develop targeted solutions (i.e. faster risk adjustment and quality reporting, cohort monitoring, etc.). This reduces sales cycle friction and provides a clear ROI for vendor R&D.

- **CMS Action & AI Role:** Adjust incentive structures of existing programs (e.g., MACRA, MSSP) to include metrics for digital health products and interoperability standards (i.e. bulk FHIR) adoption.
    - **Machine Learning (ML) Models:** Can analyze provider data submissions to accurately track and verify adoption metrics of certified digital health products, ensuring fair and objective incentive distribution. This allows CMS to dynamically adjust incentive levels based on aggregated adoption trends.
    - **Explainable AI (XAI):** Provides transparency into how adoption metrics are calculated, building trust with providers and helping them understand how their digital health usage contributes to financial incentives.
    - **Comprehensive Data Sharing:** Encourage the inclusion of both structured and unstructured (e.g., scanned documents, clinical notes) data in Bulk FHIR exports, potentially through standardized extensions or linked binary resources, with AI-ready formats.

- **B. Longer-Term: "Meaningful Use"-Type Program for Digital Health:**
    - **Vendor Workflow Impact:** A long-term, sustained commitment from CMS, similar to the HITECH Act's Meaningful Use program for EHRs, would signal a stable and substantial market, encouraging significant private sector investment in novel digital health solutions. This stability allows vendors to plan long-term R&D roadmaps and attract venture capital.
    - **CMS Action & AI Role:** Consider a comprehensive program that defines progressive stages of digital health utilization.
        - **Predictive Analytics (ML Models):** Can forecast potential adoption rates, identify likely barriers, and model the impact of different incentive structures based on historical data from Meaningful Use and other programs, guiding program design.
        - **Economic Modeling AI:** Can assess the overall market size and potential ROI for vendors, justifying long-term R&D investments.

- **C. Proactive Policy Addressing Provider Concerns:**
    - **Vendor Workflow Impact:** Providers' technical, personal, workload, and legal/ethical concerns directly impact their willingness to purchase and implement digital health products. Clear policies reduce provider hesitation, thereby increasing market receptiveness for vendor solutions. Vendors spend less time on customer education regarding compliance and more on product innovation.
    - **CMS Action & AI Role:** Clarify and strengthen privacy, security, and liability policies.
        - **Natural Language Processing (NLP) / Large Language Models (LLMs):** Can analyze complex regulatory texts (e.g., HIPAA) to identify ambiguities, suggest clearer language, and automatically generate plain-language summaries of provider responsibilities and patient consent requirements.
        - **Automated Compliance Monitoring (ML/Rule-Based AI):** Vendors can integrate **AI-powered compliance checks** directly into their products, providing real-time alerts to providers regarding potential privacy or security risks based on updated CMS guidelines. This minimizes provider liability fears and builds trust in vendor solutions.

II. Unlocking Innovation through Comprehensive Data Access (Vendor Perspective)

Developers are eager to build more robust and patient-centric applications, but they are currently constrained by limited access to critical healthcare data beyond Blue Button 2.0:

- **A. Expanded Data Scope for Richer Applications:**
    - **Vendor Workflow Impact:** Access to a broader range of data enables vendors to build more sophisticated, clinically relevant, and financially transparent digital health products, moving beyond basic claims analysis to true decision support and care management.

- **CMS Action & AI Role:** Expand Blue Button 2.0 to include:
  - **Clinical Data (Lab results, Vitals, Immunizations, Problem Lists, Care Plans): ML models** can process this data for trend analysis, risk stratification, and anomaly detection for chronic disease management tools. **LLMs** can generate personalized patient summaries and care plans.
  - **Real-time Prior Authorization Data (Approval Status, Documentation Requirements): Rule-based AI and NLP models** can automate status checks and documentation guidance within vendor workflows, reducing manual effort for both providers and patients.
  - **Benefit Design Data (Co-pays, Deductibles, Out-of-Pocket Limits): ML regression models** can use this data with pricing information to provide highly accurate, real-time cost estimations to patients and providers within vendor apps.
  - **Formulary Data, Tiered Drug Pricing, Provider Network Participation Knowledge Graphs:** can model complex network relationships for optimal patient navigation, while **ML models** can predict drug affordability and suggest alternatives.
  - **Complementary Datasets (Medicare Advantage Encounter Data, Medicaid Data for Dual-Eligibles, SDOH, Public Health Datasets): Multi-modal AI models** can integrate and analyze these diverse datasets (structured, semi-structured, unstructured) to create holistic patient profiles, enabling vendors to build inclusive, risk-aware, and preventive care solutions. For SDOH, **NLP** can extract needs from free text, and **Recommendation Engines** can suggest community resources.

- B. Addressing Data Access Barriers (Silos, Inconsistent Standards, Availability):
  - **Vendor Workflow Impact:** Current data silos, inconsistent standards (beyond USCDI), and varying authentication protocols create significant development overhead, requiring custom integrations for each data source. This stifles innovation and increases time-to-market.
  - **CMS Action & AI Role:**
    - **Standardized API Expansion:** Require support for FHIR Bulk Data API (Flat FHIR) for population health, FHIR Scheduling API for appointment management, FHIR Questionnaire API for intake, and Provider Access API for real-time eligibility/utilization. **AI-powered data mapping tools (NLP, ML-based schema alignment)** can help vendors translate data from legacy systems into these standardized FHIR formats, reducing integration complexity.
    - **Unified Identity Framework:** Mandate a unified authentication and authorization framework (e.g., leveraging OAuth 2.0 with digital identity credentials like Login.gov/ID.me) across all CMS-related APIs. This drastically simplifies vendor integration efforts. **Behavioral AI** can monitor for suspicious login patterns across these unified frameworks, enhancing security and enforcing identity access management through novelty detection.
    - **Enhanced Developer Resources:** Provide comprehensive implementation toolkits, robust testing sandboxes with realistic test data generated by **Generative AI**, and extensive sample code repositories. This lowers the technical barrier to entry for vendors and accelerates development cycles.

- C. Nationwide Provider Directory with FHIR Endpoints & Digital Identity:
  - **Vendor Workflow Impact:** This is a foundational element for seamless interoperability. Vendors currently struggle to maintain accurate provider directories for their apps, leading to frustrated users. A centralized directory reduces this burden.
  - **CMS Action & AI Role:** Establish a centrally published and maintained directory by a trusted national entity.

- **AI for Directory Maintenance (NLP, ML, GNNs):** As previously discussed, AI will be critical for real-time data validation, de-duplication, and ensuring the accuracy and completeness of provider demographics, network participation, and FHIR endpoint addresses.
- **Automated Discovery:** Vendors can leverage **AI-powered discovery services** to automatically find and connect to certified provider FHIR endpoints listed in the directory, enabling seamless data exchange for workflows like prior authorization, referrals, and scheduling.
- **Digital Identity Integration:** The inclusion of digital identity credentials streamlines secure API access for vendors, reducing the overhead of managing multiple proprietary authentication mechanisms for providers.

III. Redefining Health IT Certification for an API-First Ecosystem (Vendor Perspective)

Current certification criteria often focus on traditional software functionalities, not true interoperability. An API-first approach benefits vendors directly:

- **A. Mandating FHIR-Based API Support:**
  - **Vendor Workflow Impact:** This creates a consistent playing field, allowing vendors to focus on building innovative applications on top of standardized interfaces rather than spending resources on custom integrations for each client. It drives product scalability.
  - **CMS Action & AI Role:** Mandate FHIR-based API support as part of federal programs (Medicare Promoting Interoperability, Medicare Advantage). Require certified health IT systems to support a baseline set of public, standards-compliant APIs for patient access, provider directories, scheduling, and prior authorizations.
    - **Automated Conformance Testing (AI-driven): ML models** can automate the testing of vendor API implementations against FHIR specifications and CMS compliance rules, significantly speeding up the certification process.
    - **Performance Monitoring AI: AI-powered tools** can continuously monitor API performance (e.g., response times, uptime) in certified systems, ensuring vendors meet usability and reliability standards.
- **B. Expanding USCDI with AI-Enhanced Flexibility:**
  - **Vendor Workflow Impact:** The current USCDI's narrow clinical focus limits the scope of digital health products, particularly for administrative, financial, and holistic care management solutions. Expanding it unlocks new product categories.
  - **CMS Action & AI Role:** Expand USCDI to include elements like prior authorization status, network participation, benefit design, formulary tiers, and SDOH data.
    - **Hybrid Data Processing (NLP/LLMs):** Endorse the inclusion of non-proprietary, semi-structured or unstructured data (e.g., narrative clinical notes) in interoperability frameworks. **LLMs and NLP** are essential for vendors to extract structured insights from this rich contextual data, providing a comprehensive patient view even when full structured data isn't available. This means vendors can offer solutions that analyze *all* relevant patient information, not just structured fields.
    - **Tiered Adoption Model with AI Guidance:** Introduce a tiered USCDI adoption model (core, extended, optional) to manage implementation complexity, especially for smaller vendors. **AI-driven tools** can help vendors assess their current data capabilities against these tiers and provide clear pathways for phased compliance.
- **C. API-First Certification Paradigm:**
  - **Vendor Workflow Impact:** Shifting certification emphasis from proprietary software functionality to API-enabled capabilities encourages modular development, reduces vendor lock-in, and fosters

innovation through open standards. This allows vendors to develop best-of-breed solutions for specific problems that seamlessly integrate into a broader ecosystem.

- **CMS Action & AI Role:** Revise certification criteria to require APIs to support access to all key data domains (structured, unstructured, legacy formats).
  - **Automated API Testing (ML-driven):** Automated platforms can test API performance, security, and data coverage across various data types (including those derived from **NLP** processing of unstructured data) in real-world scenarios, ensuring reliability.
  - **Continuous Compliance Monitoring: AI models** can continuously monitor certified products' API usage post-certification to ensure ongoing compliance and optimal performance, minimizing the risk of vendors implementing "bare minimum" APIs.

Value-Based Care Organizations (VBCO)

I. Overcoming Patient Digital Health Adoption Barriers (VBCO Perspective)

VBCOs are incentivized by patient engagement in their care and digital health tools are key enablers. However, several patient-facing challenges impede widespread adoption, directly impacting VBCOs' ability to meet performance metrics:

- **A. Digital Literacy & Usability (Workflow Impact: Low Patient Engagement, Missed Opportunities):**
  - **VBCO Perspective:** When digital health tools are complex or non-intuitive, patients, particularly older adults or those less comfortable with technology, disengage. This leads to lower adherence to care plans, missed opportunities for remote monitoring, and a reduced ability for VBCOs to proactively manage their attributed populations.
  - **CMS Action & AI Role:** CMS should partner with digital health vendors and APM participants to mandate user-centric design, prioritizing intuitive interfaces based on extensive patient input and testing.
    - **User Experience (UX) Analytics AI (ML models for behavioral analytics):** Can track patient engagement patterns, identify friction points in user interfaces, and predict where users might abandon a digital tool. This data can inform iterative product design to enhance simplicity.
    - **Adaptive Learning AI (LLMs):** Can power personalized in-app tutorials or conversational chatbots that provide step-by-step guidance, answer user questions in plain language, and offer "just-in-time" support, making complex tasks approachable for users with varying digital literacy levels.
- **B. Health Literacy & Contextualization (Workflow Impact: Patient Anxiety, Poor Adherence):**
  - **VBCO Perspective:** Patients with low health literacy struggle to understand complex medical terminology or contextualize test results, leading to unnecessary anxiety, misinterpretation of health information, and reduced likelihood of adhering to digital health tool recommendations. This directly impacts VBCOs' ability to drive positive health outcomes.
  - **CMS Action & AI Role:** CMS should mandate features that simplify health information and foster effective patient-provider communication.
    - **Large Language Models (LLMs) (e.g., fine-tuned clinical LLMs):** Can translate complex medical terminology in test results, diagnoses, and care plans into easy-to-understand language. These LLMs can provide contextual explanations for abnormal findings, mitigating patient anxiety and empowering informed decision-making.
    - **Natural Language Generation (NLG) AI:** Can automatically generate personalized summaries of visits or test results for patients, highlighting key actions and explanations in a clear, concise format.

        - **Sentiment Analysis AI (NLP):** Can monitor patient feedback (e.g., through surveys, free-text inputs) within digital tools to gauge comprehension and identify areas where health information is causing confusion or stress, allowing VBCOs to intervene with tailored support.

- **C. Privacy & Security Concerns (Workflow Impact: Data Sharing Hesitation, Limited Insights):**
    - **VBCO Perspective:** Patient reluctance to share sensitive health data due to privacy fears (misuse, breaches) directly limits the comprehensive data VBCOs need to identify at-risk members, personalize interventions, and measure population health outcomes. Lack of trust undermines the core of VBC.
    - **CMS Action & AI Role:** CMS must clarify and strengthen regulatory policies, defining clear provider and vendor responsibilities and liabilities, while ensuring transparency with patients.
        - **Explainable AI (XAI) for Data Governance:** Can provide transparent explanations to patients (and providers) about *what* data is being collected, *how* it's being used, and *who* has access, building trust.
        - **Homomorphic Encryption/Federated Learning (Advanced Cryptography & Distributed AI):** These techniques allow **ML models** to train on distributed patient data without the raw data ever leaving its source or being exposed to third parties, minimizing privacy risks while still enabling powerful analytical insights for VBCOs.
        - **Automated Consent Management (Rule-Based AI):** Can ensure patient consent protocols are clearly communicated and strictly enforced within digital health products, tracking and auditing data access permissions.

II. Empowering Providers and Enhancing VBCO Workflows through Data and AI

For VBCOs to succeed, providers need timely, comprehensive data and performance insights. This is critical for assessing performance, identifying at-risk populations, and driving targeted interventions:

- **A. Comprehensive Patient Data for Proactive Management (Workflow Impact: Identifying At-Risk Members):**
    - **VBCO Perspective:** VBCOs require a holistic view of each patient to identify at-risk members, target interventions (e.g., for non-adherence), and ensure seamless transitions of care. Fragmented data leads to missed opportunities for proactive management and care coordination.
    - **Essential Data Types & AI Role:**
        - **Patient Demographics (age, sex, race, ethnicity), Clinical Data (EHR/EMR), Claims Data, Pharmacy Data, Disease Registries, SDoH Data, Geographic Data, Self-Reported Data:** These are all essential.
        - **Multi-Modal AI Models:** Can integrate and harmonize these diverse data types (structured, semi-structured like clinical notes, and unstructured like patient surveys), creating a comprehensive, longitudinal patient profile.
        - **Predictive Analytics (ML models, e.g., gradient boosting, deep learning):** Can analyze this integrated data to identify patients at high risk of developing certain conditions, readmissions, or medication non-adherence, enabling VBCOs to deploy targeted interventions proactively.
        - **Natural Language Processing (NLP) / Large Language Models (LLMs):** Can extract SDoH data from unstructured notes, enabling VBCOs to understand non-clinical barriers (e.g., transportation constraints, housing insecurity) and connect patients to appropriate resources.

- **B. Performance Insights and Benchmarking for Continuous Improvement (Workflow Impact: Driving Quality & Cost Efficiency):**

- **VBCO Perspective:** Providers need clear, real-time feedback on their performance against VBC metrics, how they compare to peers, and specific opportunities for improvement to optimize care delivery and financial outcomes.
- **CMS Action & AI Role:** Arm providers with data and insights around their performance.
  - **Automated Performance Dashboards (BI/Analytics AI):** Can aggregate and visualize provider performance on VBC metrics, benchmarking them against aggregated, de-identified data from similar providers using **ML-powered comparative analysis**.
  - **Prescriptive Analytics (Reinforcement Learning/Optimization Models):** Can identify specific opportunities for improvement (e.g., "Patients with X condition show better outcomes if Y intervention is applied earlier") and recommend actionable strategies to providers based on their attributed population's data and best practices from top performers.
  - **Data Quality AI (ML for anomaly detection):** Can flag gaps or inconsistencies in provider-submitted data for quality reporting (e.g., missing diagnoses codes, incomplete encounter data), ensuring the accuracy of performance metrics.

III. Modernizing VBCO Workflows through Modular Standardization and AI Automation

To balance innovation with consistency across APMs and minimize operational burden, CMS should adopt a modular standardization approach, heavily augmented by AI:

- **A. Standardizing Core Data Elements & APIs:**
  - **VBCO Workflow Impact:** Fragmentation in data elements and API standards across APMs creates significant integration burden. Standardization reduces this complexity, allowing VBCOs to scale their IT infrastructure across multiple models.
  - **CMS Action & AI Role:** Mandate core data elements (e.g., USCDI, FHIR, CCDA) and FHIR-based APIs for key workflows (roster exchange, risk attribution, outcomes reporting).
    - **AI Agents (ML/NLP):** Can automate data normalization, fill data gaps, and harmonize provider and clinical records from disparate sources (e.g., EHRs, claims systems, registries) into standardized formats.
    - **API Monitoring AI (ML for log analysis):** Can monitor API traffic, identify data quality issues in real-time, and suggest corrections for FHIR submissions.
- **B. Reusable Components & Smart Attribution:**
  - **VBCO Workflow Impact:** Duplicative development for each APM is inefficient. Reusable components and standardized attribution logic reduce development costs and accelerate implementation for VBCOs.
  - **CMS Action & AI Role:** Promote reusable components (e.g., SMART on FHIR apps, HL7 profiles) and standardize attribution/roster reconciliation workflows.
    - **Pre-trained AI Models:** Can power common VBC functions like patient attribution logic, utilization prediction, and outcomes scoring across various programs, providing off-the-shelf capabilities for VBCOs.
    - **Conflict Resolution AI (Optimization Models):** Can automatically detect misalignments or conflicts in patient attribution based on care patterns and recommend corrections, streamlining reconciliation.
- **C. Digitizing & Codifying VBC Contracts & Registries:**
  - **VBCO Workflow Impact:** Manual review of VBC contracts is time-consuming and prone to error. Maintaining participation registries is an administrative burden.

- **CMS Action & AI Role:** Digitize VBC contract terms into machine-readable formats (JSON, XML). Allow provider rosters to include VBC participation flags. Centralize VBC participation registries.
    - **Natural Language Processing (NLP) / LLMs:** Can parse and codify VBC contract terms from unstructured documents (e.g., PDFs), identify deviations from standard templates, and flag non-compliant or high-risk clauses for payers and CMS.
    - **Reconciliation AI (ML for data matching):** Can reconcile provider rosters with claims, enrollment data, and contract terms to detect mismatches, fill data gaps, and ensure consistency for automated attribution tracking and payment eligibility checks.
    - **Knowledge Graph AI:** Can build a dynamic, interconnected registry of VBC participation, continuously updated by triangulating data from contracts, rosters, claims, and provider directories, ensuring real-time accuracy and reducing manual attestation burdens for VBCOs.