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Re: Response to Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (HHS Health Sector AI RFI RIN 0955-AA13)

On behalf of the Long-Term and Post-Acute Care (LTPAC) Health Information Technology Collaborative, we appreciate the opportunity to respond to the Department of Health and Human Services (HHS) Request for Information (RFI) regarding accelerating the adoption and use of artificial intelligence (AI) as part of clinical care. Our collaborative represents providers serving millions of Medicare beneficiaries across skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, hospices, and other LTPAC settings.

The LTPAC sector serves the fastest-growing segment of the U.S. population: adults aged 65 and older, with those over 85 increasing at the most rapid pace. These individuals typically present with multiple chronic conditions (multimorbidity), polypharmacy, cognitive and functional impairments, and complex social determinants of health. Despite serving this critical population, LTPAC providers face significant barriers to technology adoption, data interoperability, and participation in the innovative ecosystem that will shape AI deployment in clinical care.

The LTPAC Collaborative strongly supports the Administration's priority to establish a forward-leaning, industry-supportive, and secure approach to accelerate AI adoption in healthcare. As articulated in the HHS AI Strategy released December 4, 2025, harnessing the transformative potential of AI while upholding patient privacy, civil rights, and civil liberties represents a critical national priority. The LTPAC sector stands ready to partner with HHS to ensure AI-driven innovation benefits all segments of the healthcare ecosystem, particularly the rapidly growing population of older Americans.

We look forward to collaborating with HHS ASTP/ONC to ensure that AI-driven innovation benefits all segments of the healthcare ecosystem, particularly those who have historically been underrepresented in research and technology initiatives. This response addresses the specific questions posed in the RFI and highlights concerns regarding population bias in AI development—risks that could be amplified without intentional policy interventions.

General Comments on Regulation, Reimbursement, and Research & Development

Regulation

The LTPAC Collaborative supports a regulatory framework that is proportionate, transparent, and enables innovation while protecting vulnerable populations. For AI tools deployed in LTPAC settings, regulatory clarity is essential regarding:

- **Clinical Decision Support (CDS) versus Decision Support Interventions (DSI):** Under the HTI-1 Final Rule, distinctions between CDS software and DSI must account for workflow-critical interventions in LTPAC settings, such as glucose monitoring in diabetes management, delirium detection, fall risk assessment, and polypharmacy optimization. Many AI tools operating in these domains directly impact patient safety and outcomes.
- **Algorithmic Transparency and Accountability:** AI tools targeting LTPAC populations must undergo validation against geriatric cohorts and demonstrate transparency in their decision-making logic. Vendor accountability for algorithmic bias affecting safety outcomes should be enforced, particularly for tools addressing conditions prevalent in older adults.
- **Age-Inclusive Standards:** Regulatory frameworks should mandate age-stratified data collection and validation in real-world data (RWD) studies to mitigate age bias in AI algorithms. Current clinical trials frequently underrepresent geriatric patients, leading to biased algorithms that may recommend inappropriate care pathways for older adults.
- **Cybersecurity and HIPAA Compliance:** Accelerating AI adoption must not come at the expense of patient and provider security. AI development guardrails, scaled proportionately to cybersecurity and HIPAA risk, are essential. This is particularly important since LTPAC providers lack the technical expertise to independently assess protections embedded in proprietary, often "black box," vendor technology that handles residents' personally identifiable information (PII) and protected health information (PHI).

Reimbursement

Payment policies significantly influence technology adoption in LTPAC settings. The Collaborative recommends:

- **Value-Based Payment Alignment:** Payment models should incentivize the use of high-value AI interventions that improve outcomes for complex, high-need populations. Alternative payment models (APMs) and value-based care arrangements should explicitly include quality measures and risk-adjustment methodologies that account for LTPAC populations.
- **Coverage for AI-Enabled Remote Monitoring:** Medicare and Medicaid should expand coverage for AI-enabled remote patient monitoring (RPM), ambient AI, and other technologies that support aging in place and reduce preventable hospitalizations and emergency department visits.
- **Infrastructure Investment:** Reimbursement mechanisms should support the underlying infrastructure required for AI adoption, including interoperability investments, workforce training, and technical assistance for small and rural providers.

- **Reduction of Administrative Burden:** AI tools that automate documentation, quality reporting, and administrative tasks should be incentivized through payment policy to offset provider burden and allow clinicians to focus on direct patient care.

Research & Development

HHS should prioritize R&D investments that address the unique needs of aging, geriatric, and LTPAC populations:

- **Inclusion of LTPAC Populations in Research:** NIH, AHRQ, and other HHS research agencies should require inclusion of LTPAC and geriatric populations in AI research funding. Pilot programs should focus on AI applications in nursing homes, home health, assisted living, and other post-acute settings.
- **Interoperability Research:** Support development and validation of Fast Healthcare Interoperability Resources (FHIR) implementation guides that capture geriatric-specific data elements, including functional status, cognitive assessments, social determinants of health, and caregiver support data.
- **Public-Private Partnerships:** Establish cooperative research and development agreements (CRADAs) with LTPAC providers, health IT vendors, and academic institutions to co-develop and validate AI tools in real-world settings.
- **Longitudinal and Multimorbidity Research:** Fund large, longitudinal studies on aging trajectories, multimorbidity trials, polypharmacy optimization, and research on family caregivers and aging in place.

Responses to Specific Questions

Question 1: What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?

For LTPAC providers and the populations they serve, the most significant barriers include:

Population Bias and Data Exclusion: Clinical trials and AI training datasets systematically underrepresent older adults, particularly those in LTPAC settings. This leads to biased algorithms that perform poorly or produce harmful recommendations when applied to geriatric populations. AI models trained predominantly on younger cohorts may recommend inappropriate medication dosages, fail to account for age-related pharmacokinetics, or overlook fall risk factors specific to frail older adults. Multiple studies have documented that older adults, particularly those over 85 or living with multiple chronic conditions, are routinely excluded from AI training data, and models fail to account for complex social needs of aging populations.

Data Interoperability Limitations: LTPAC providers face significant challenges in achieving interoperability with acute care hospitals, primary care providers, specialty clinics, and health information exchanges. The healthcare ecosystem is not designed to be inclusive of LTPAC populations. Limited adoption of standardized data exchange formats, particularly HL7 FHIR implementation guides relevant to LTPAC (such as those developed by the PACIO Project), hinders the flow of critical patient information across care transitions. Statistics demonstrate that while 78% of nursing homes and home health agencies have adopted EHRs, fewer than 40% can easily share structured data with acute care EHRs, with poorly coordinated care transitions associated with hospital readmission, medication errors, and adverse drug events. Without access to longitudinal, interoperable data, AI tools cannot effectively support person-centered, holistic care.

Infrastructure and Resource Constraints: Many LTPAC providers, particularly small, rural, and under-resourced facilities, lack the technical infrastructure, broadband connectivity, and financial resources needed to adopt AI technologies. The digital divide in LTPAC settings creates inequitable access to innovation. Additionally, workforce challenges, including limited health IT expertise and high staff turnover, impede successful AI implementation. LTPAC providers prioritize resources for staffing and regulatory compliance over interoperability, creating structural barriers that federal policy must address.

Regulatory Uncertainty: Lack of clarity regarding liability, indemnification, privacy, and security for non-medical device AI tools creates hesitation among LTPAC providers and AI developers. Questions about who bears responsibility when an AI tool produces an adverse recommendation, how HIPAA applies to AI-generated insights, and what standards govern AI tool validation remain inadequately addressed.

Reimbursement Barriers: Fee-for-service payment structures provide limited incentives for LTPAC providers to invest in AI tools, even when such tools could improve outcomes and reduce costs over time. Coverage and reimbursement decisions for AI-enabled services are slow, and current payment models do not adequately account for the value of AI interventions that prevent adverse events, reduce hospitalization, or improve quality of life.

Lack of Geriatric-Specific Clinical Guidelines Integration: AI-powered clinical decision support tools often lack integration with geriatric-specific clinical practice guidelines. Evidence-based guidelines tailored for older adults, such as those published by the Post-Acute and Long-Term Care Medical Association (PALTmed), address conditions like diabetes management, falls prevention, delirium detection, polypharmacy, and pressure ulcer prevention in geriatric populations. AI tools that do not incorporate these guidelines may produce recommendations that are inappropriate for LTPAC patients.

Question 2: What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why?

The LTPAC Collaborative recommends the following priority changes:

Regulatory Changes

- **Mandate Age-Stratified Validation (42 CFR Part 412, 413, 482, 483, 484, 485):** Require AI tools used in clinical care to undergo validation testing on age-stratified cohorts, particularly for tools intended for use in Medicare populations. Validation should include performance metrics specific to geriatric patients and demonstrate absence of age-based bias.
- **Algorithmic Transparency Requirements (45 CFR Part 170):** Under the ONC Health IT Certification Program, establish certification criteria for AI-enabled clinical decision support tools that require disclosure of training data characteristics, model performance on diverse populations, and explanation of decision logic. FHIR-based event-condition-action rules per HL7 Clinical Reasoning modules should be used to enforce transparency.
- **Interoperability Standards for Geriatric Data (45 CFR 170.315):** Expand the United States Core Data for Interoperability (USCDI) to include geriatric-specific data elements captured in PACIO Project FHIR implementation guides: functional status (ADLs/IADLs), cognitive assessments (PHQ-9, CAM), advance directives, standardized medication profiles, social determinants of health, and caregiver support information. HL7 PACIO frameworks have been validated for functional status, cognitive assessments, transition of care, and clinical conditions prevalent in older adults.
- **Privacy and Security Safeguards (45 CFR Parts 160, 164):** Clarify HIPAA applicability to AI-generated clinical insights and establish standards for de-identification, consent management, and audit trails for AI tools that access or generate protected health information.

Payment Policy Changes

- **Medicare Coverage for AI-Enabled RPM (42 CFR Part 405, 410, 414):** Expand Medicare Part B coverage for AI-enabled remote patient monitoring, ambient AI monitoring, and wearable devices that support aging in place. Evidence demonstrates that RPM in skilled nursing facilities enables real-time alerts and immediate response to abnormal readings, with studies showing significant reductions in Hemoglobin A1c in diabetic patients and decreased need for emergency department visits. Reimbursement should cover device costs, data transmission, clinical interpretation, and care coordination activities.
- **Value-Based Payment Incentives (42 CFR Part 425, 512):** Incorporate AI adoption and outcome metrics into Medicare Shared Savings Program (MSSP), Accountable Care Organization (ACO) models, and other APMs. Quality measures should reward use of AI tools that demonstrate improved outcomes for high-risk, complex patients. Evidence from randomized controlled trials demonstrates that AI-based early warning models significantly reduced hospital and 30-day mortality rates and shortened hospital stays in prospective clinical validation.
- **Infrastructure Investment Payments (42 CFR Part 413, 484, 485):** Create a Medicare/Medicaid infrastructure payment mechanism to support LTPAC providers' investments in interoperability, health IT upgrades, and AI readiness. This could be modeled after the Medicare Promoting

Interoperability Program but tailored for LTPAC settings directly addressing the 15-year technology investment gap created by LTPAC exclusion from Meaningful Use incentives.

- **Documentation Burden Reduction (42 CFR Part 483, 484):** Allow AI-generated documentation to satisfy regulatory documentation requirements in skilled nursing facilities (42 CFR 483.20, 483.21) and home health agencies (42 CFR 484.55, 484.60), provided the AI tool meets transparency and accuracy standards.

Programmatic Design Changes

- **CMMI Innovation Models:** Develop Center for Medicare and Medicaid Innovation (CMMI) models specifically focused on AI adoption in LTPAC settings. Evaluate payment incentives, technical assistance models, and shared savings approach for providers implementing AI tools.
- **LTPAC-Focused FHIR Adoption:** Provide grants and technical assistance through the Office of the National Coordinator (ONC) to accelerate LTPAC provider adoption of PACIO Project FHIR implementation guides and onboarding to Qualified Health Information Networks (QHINs) under the Trusted Exchange Framework and Common Agreement (TEFCA).
- **Geriatric AI Validation Testbeds:** Establish regulatory-science testbeds in partnership with FDA, VA, and CMS to validate AI tools for safety, efficacy, and equity in LTPAC settings. Require real-world evidence from diverse care settings for regulatory approval.

Question 3: For non-medical devices, what novel legal and implementation issues exist related to AI in clinical care, and what role should HHS play?

Liability and Accountability: When an AI tool recommends a clinical intervention that results in patient harm, liability questions arise: Is the provider liable for following the recommendation? Is the AI vendor liable for the algorithm's output? Is the health system liable for deploying an inadequately validated tool? Current medical malpractice frameworks do not clearly address AI-mediated decision-making. HHS should work with state medical boards, professional liability insurers, and legal experts to develop guidance on shared accountability models.

Indemnification Agreements: Many AI vendors require healthcare organizations to sign indemnification agreements that shift liability risk entirely to the provider. This is particularly problematic for under-resourced LTPAC providers who lack the financial capacity to assume such risk. HHS should establish model contract language and standards for equitable risk-sharing between vendors and providers.

Privacy and Security: AI tools often require access to large volumes of patient data for training and operation. Questions remain about:

- Whether AI-generated clinical insights constitute protected health information (PHI) under HIPAA
- How consent should be obtained for AI processing of patient data

- What security standards apply to AI model storage, transmission, and updates?
- How to address privacy risks when AI tools use consumer-generated health data from non-HIPAA-covered wearables and apps

HHS should issue guidance clarifying HIPAA applicability to AI systems and establish security standards for AI tools used in clinical care.

Algorithmic Bias and Discrimination: AI tools that exhibit bias against protected classes (age, race, disability status) may violate civil rights laws. However, detection and remediation of algorithmic bias require technical expertise that many healthcare organizations lack. Research demonstrates that AI often underperforms for older adults due to gaps in training data, leading to misdiagnoses and delayed care, with bias linked to socioeconomic factors carrying high stakes when errors disproportionately affect vulnerable patients. HHS Office for Civil Rights (OCR) should develop guidance on algorithmic equity requirements and establish complaint mechanisms for patients who believe they have been harmed by biased AI tools.

Data Ownership and Control: When AI tools generate clinical insights, predictions, or risk scores based on patient data, questions arise about who owns these outputs and how they can be used. HHS should establish clear data governance frameworks that respect patient autonomy while enabling appropriate secondary use for research and quality improvement.

Workforce Competency: Effective use of AI in clinical care requires workforce education on AI capabilities, limitations, and appropriate supervision. HHS should support development of training programs and competency standards for clinicians, administrators, and health IT professionals who will deploy and oversee AI tools.

Question 4: What are the most promising AI evaluation methods for clinical care, and how should HHS support them?

Pre-Deployment Evaluation Methods

- ***Prospective Validation on Diverse Cohorts:*** AI tools should undergo prospective validation testing on age-diverse, racially diverse, and clinically diverse populations before deployment. For tools intended for geriatric populations, validation cohorts must include adequate representation of older adults with multimorbidity and polypharmacy. External validation studies of mortality prediction models in older adults demonstrate that local refinement and calibration is required to provide direct estimates of prognosis, with validation highlighting the critical role of assessing performance of proprietary models in diverse healthcare settings.
- ***Bias Auditing and Fairness Testing:*** Independent bias audits should assess AI tool performance across demographic subgroups (age, race, ethnicity, sex, disability status) and clinical subgroups (disease severity, functional status, cognitive status). A systematic evaluation sampling 48 studies

across tabular, imaging, and hybrid data models using PRISMA selection strategy provides a framework for bias assessment. Disparities in performance should trigger remediation before approval.

- **Explainability Assessment:** AI tools should be evaluated for their ability to provide clinically meaningful explanations of recommendations. Age-stratified analysis using methods like SHAP (Shapley Additive Explanations) demonstrates that performance improves and models become more interpretable with feature selection processes. Black-box models that cannot explain their reasoning pose risks in clinical settings where clinicians must understand rationale to appropriately supervise AI outputs.
- **Workflow Integration Testing:** Human-centered design evaluations should assess how AI tools integrate into clinical workflows, including cognitive load, alert fatigue, and usability for diverse users (including staff with varying levels of health IT literacy).

Post-Deployment Evaluation Methods

- **Continuous Performance Monitoring:** Real-world performance monitoring should track AI tool accuracy, adoption rates, override rates, and clinical outcomes over time. Performance should be stratified by patient characteristics to detect emerging bias or model drift. FDA guidance emphasizes that AI is never validated once. It requires ongoing lifecycle evaluation with drift monitoring, retraining controls, and change management protocols.
- **Clinical Outcome Studies:** Rigorous implementation science research should evaluate whether AI tools actually improve patient outcomes, reduce costs, or enhance clinician efficiency in real-world settings. Meta-analysis of 116 randomized controlled trials with 204,523 participants demonstrated that EHR-based interventions reduced 30-day all-cause readmission risk by 17% and 90-day readmission risk by 28%, with better performance in study populations composed mostly of older participants.[47] A quasi-experimental study of hospital readmissions demonstrated that AI model implementation decreased readmission rates from 11.4% pre-intervention to 8.1% post-intervention ($p < 0.001$). Studies should include LTPAC sites and geriatric populations.
- **Safety Surveillance:** HHS should establish voluntary or mandatory adverse event reporting mechanisms for AI tools, similar to FDA MedWatch for medical devices. This would enable detection of safety signals and patterns of harm.
- **Equity Monitoring:** Ongoing monitoring should assess whether AI tool deployment widens or narrows health disparities. Particular attention should be paid to access barriers for under-resourced providers and vulnerable populations. The example of Optum algorithm recalibration—which increased high-risk Black patient enrollment from 17.7% to 46.5% after using direct health indicators instead of costs—demonstrates that ongoing surveillance is necessary as reliance on historical data could allow biases to re-emerge.

HHS Support Mechanisms

HHS should support these evaluation methods through:

- ***Contracts and Cooperative Agreements:*** Fund development of standardized evaluation frameworks, toolkits, and benchmarking datasets that include geriatric populations.
- ***Grants:*** Support independent research on AI tool performance, safety, and equity through NIH, AHRQ, and PCORI.
- ***Regulatory-Science Testbeds:*** Establish collaboration among FDA, ONC, CMS, and VA to create shared infrastructure for AI validation.
- ***Prize Competitions:*** Incentivize development of novel evaluation methods, bias detection tools, and explainability techniques through HHS prize competitions.

The most impactful approach would be a combination of contracts (for infrastructure development), grants (for independent research), and cooperative agreements (for multi-stakeholder collaboration).

Question 5: How can HHS best support private sector activities to promote innovative and effective AI use in clinical care?

HHS should adopt a supportive posture toward industry-driven quality assurance mechanisms while establishing baseline standards to protect patients:

Accreditation and Certification

- Support development of voluntary AI tool accreditation programs through organizations like The Joint Commission, NCQA, or URAC that assess AI tools for safety, effectiveness, and equity.
- Expand the ONC Health IT Certification Program (45 CFR Part 170) to include certification criteria for AI-enabled clinical decision support tools, with specific requirements for validation, transparency, and bias testing. The HTI-1 Final Rule's FAVES framework (Fair, Appropriate, Valid, Effective, Safe) provides a foundation for organizational evaluation of Predictive DSIs.
- Recognize and incentivize (through payment policy) use of certified or accredited AI tools in value-based payment arrangements.

Industry-Driven Testing and Standards

- Partner with standards development organizations (HL7, IEEE, ASTM) to create technical standards for AI tool interoperability, data requirements, and performance reporting.
- Support industry consortia (such as the Coalition for Health AI, Partnership on AI) that develop best practice frameworks, model cards, and datasheets for AI transparency.
- Fund development of open-source benchmarking datasets and evaluation toolkits that include geriatric and LTPAC populations.

Professional Credentialing

- Support professional societies in developing AI competency standards and credentialing programs for clinicians and health IT professionals.
- Incentivize AI literacy training through continuing education requirements and Medicare payment bonuses for providers who complete AI training programs.

Market Transparency

- Establish a public registry of AI tools used in clinical care, including information on their intended use, validation evidence, and performance metrics. This would function similarly to FDA's medical device databases but for non-device AI tools.
- Require AI vendors to publish model cards and performance reports that enable informed purchasing decisions by healthcare organizations.

Question 6: Where have AI tools deployed in clinical care met or exceeded expectations, and where have they fallen short? What novel AI tools would have the greatest potential?

AI Tools Meeting or Exceeding Expectations

While robust evidence specific to LTPAC settings remains limited, emerging applications show promise:

- **Fall Risk Prediction:** AI tools analyzing gait patterns, functional status, medication profiles, and environmental factors show potential for identifying high-risk individuals and triggering preventive interventions. Research demonstrates that integrating fall prediction models into real-time human-centered AI decision support systems enables proactive identification of at-risk patients and implementation of preventive measures through valid screening scales and evidence-based interventions.
- **Sepsis and Acute Illness Detection:** Early warning systems analyzing vital signs and laboratory trends may enable earlier identification of acute changes in condition, particularly valuable in nursing home settings where physician presence is intermittent. AI-powered early warning systems in prospective clinical validation studies significantly reduced in-hospital and 30-day mortality rates and shortened overall hospital stays, demonstrating positive impact on patient outcomes in real-world settings.
- **Documentation Automation:** Ambient AI documentation tools that transcribe and structure clinical encounters reduce documentation burden and allow clinicians to focus on patient interaction.
- **Medication Management:** AI-powered polypharmacy optimization tools that flag drug-drug interactions, inappropriate medications for older adults (Beers Criteria), and opportunities for deprescribing show promise for improving medication safety.
- **Remote Patient Monitoring:** Studies in skilled nursing facilities demonstrate that RPM enables real-time alerts and immediate response to abnormal readings, with significant reductions in Hemoglobin A1c in diabetic patients, decreased need for in-person appointments and emergency

room visits. Senior housing programs using RPM have documented reductions in skilled nursing facility placements through 24/7 coverage and real-time situational awareness for care teams.

- **Quality Management:** AI improves diagnostic accuracy, personalizes treatments, reduces recovery times and mortality rates, with automation of documentation and audits reducing administrative burden. Real-time dashboards and predictive analytics enable early risk identification.

AI Tools Falling Short of Expectations

- **Biased Algorithms:** Multiple studies have documented racial, age, and socioeconomic bias in AI tools for risk prediction, resource allocation, and clinical decision support. A systematic review of AI-enhanced interventions for older people in long-term care settings found mixed evidence for effectiveness, with high risk of bias in included studies reducing confidence in results. Tools validated on non-representative populations perform poorly when deployed in diverse real-world settings. An example of an AI sepsis detection tool generated thousands of false positive alerts, with implications for standard of care in skilled nursing and long-term care settings.
- **Alert Fatigue:** Some AI-powered clinical decision support systems generate excessive alerts, leading to override behavior and diminished effectiveness.
- **Lack of Integration:** AI tools that function as standalone systems rather than integrating with existing EHR workflows create additional burden rather than reducing it.
- **Cost Without Demonstrated Value:** High-cost AI tools that lack rigorous evidence of improved outcomes or cost savings fail to deliver promised return on investment.

Novel AI Tools with Greatest Potential for LTPAC Settings

- **Multimorbidity Management:** AI tools that synthesize complex patient data (functional status, cognitive status, social determinants, multiple chronic conditions) to generate holistic care plans tailored to individual goals and preferences.
- **Caregiver Support Tools:** AI-powered virtual assistants that guide family caregivers in medication administration, symptom monitoring, and care coordination for homebound older adults.
- **Delirium Detection:** Continuous monitoring systems using wearables or ambient sensors to detect early signs of delirium, enabling rapid intervention to prevent adverse outcomes.
- **Functional Decline Prediction:** AI tools analyzing longitudinal functional status data to predict risk of hospitalization, nursing home placement, or mortality, enabling proactive care plan adjustments.
- **Social Determinants Screening and Intervention:** AI tools that screen for social needs (food insecurity, transportation barriers, housing instability) and connect patients with community resources.
- **Quality Measure Automation:** AI tools that extract quality measure data from clinical documentation and automate reporting to CMS, reducing administrative burden.

- **AI-Driven Virtual Rehabilitation:** AI algorithms prescribing individualized rehabilitation exercises, providing visualizations and feedback to patients, and generating progress reports to clinicians. Pilot studies demonstrate that AI motion tracking during home rehabilitation for spinal cord injury patients documented significant gains in upper-limb strength versus standard exercise videos. Current research suggests that integrating AI with home-based virtual rehabilitation leads to improved outcomes.

Question 7: Which roles or governing bodies have the most influence on AI adoption in clinical care? What are the primary administrative hurdles?

Influential Decision Makers

In LTPAC settings, the following roles and bodies significantly influence AI adoption:

- **Health System Leadership:** Chief Information Officers (CIOs), Chief Medical Information Officers (CMIOs), and Chief Nursing Information Officers (CNIOs) make strategic technology investment decisions.
- **Facility Administrators:** Nursing home administrators, home health agency directors, and hospice executives determine operational technology priorities within resource constraints.
- **Clinical Champions:** Medical directors, directors of nursing, and other clinician leaders who advocate for specific AI tools and support staff adoption.
- **Corporate Ownership:** For provider organizations owned by larger health systems or private equity firms, corporate-level IT and innovation teams often dictate technology choices.
- **Payers:** Medicare Advantage plans, Medicaid managed care organizations, and commercial payers influence adoption through coverage decisions and value-based contract requirements.
- **Regulatory Bodies:** State health departments, CMS, and accrediting organizations (Joint Commission, ACHC) shape adoption through regulatory requirements and survey processes.

Primary Administrative Hurdles

- **Resource Constraints:** Limited capital budgets, IT staff, and technical expertise in LTPAC organizations constrain ability to evaluate, purchase, implement, and maintain AI tools, challenges exacerbated by 15 years of exclusion from federal health IT investment programs.
- **Competing Priorities:** LTPAC providers face numerous regulatory requirements, quality reporting mandates, and operational challenges that compete with AI adoption for attention and resources. Workforce shortages remain the sector's biggest ongoing challenge, with staffing taking priority over technology investments.
- **Vendor Fragmentation:** Lack of standardization across AI vendors requires providers to navigate multiple contracts, integration requirements, and training programs.
- **Interoperability Barriers:** Difficulty obtaining necessary patient data from hospitals, clinics, and other providers limits AI tools' effectiveness in LTPAC settings.

- **Staff Resistance:** Concerns about job displacement, skepticism about AI accuracy, and technology anxiety among frontline staff create adoption barriers.
- **Unclear Return on Investment:** Lack of robust evidence demonstrating cost savings or outcome improvements makes it difficult to justify AI investments, particularly in fee-for-service payment environments.
- **Procurement Processes:** Complex procurement requirements, particularly for government-funded providers, slow adoption cycles.
- **Training and Change Management:** Insufficient time and resources for staff training, workflow redesign, and change management undermine successful implementation.

Question 8: Where would enhanced interoperability widen market opportunities, fuel research, and accelerate AI development for clinical care?

Critical Data Types Requiring Enhanced Interoperability

- **Functional Status:** Activities of Daily Living (ADLs), Instrumental Activities of Daily Living (IADLs), mobility assessments, and functional trajectories over time.
- **Cognitive and Mental Health:** Cognitive assessments (Mini-Mental State Exam, Montreal Cognitive Assessment), delirium screening (Confusion Assessment Method), depression screening (PHQ-9), and behavioral health diagnoses.
- **Social Determinants of Health:** Living situation, caregiver support, food security, transportation access, housing stability, social isolation, and community resources.
- **Care Goals and Preferences:** Advance directives, goals of care conversations, patient values and preferences, and care plan goals.
- **Medications:** Complete medication lists including over-the-counter medications, supplements, and medication administration records with adherence data.
- **Care Transitions:** Transition of care summaries, discharge instructions, pending tests and follow-up needs, and communication between sending and receiving providers.
- **Quality and Outcome Measures:** Patient-reported outcome measures (PROMs), clinician-reported outcomes, adverse events, and quality metric data.
- **Remote Monitoring Data:** Wearable device data, home monitoring data, continuous vital sign monitoring, and consumer-generated health data.

Data Standards Requiring Broader Adoption

- **PACIO Project FHIR Implementation Guides:** HL7 FHIR profiles for functional status (PACIO Functional Status), cognitive status (PACIO Cognitive Status), advance directives (PACIO Advance Directives), care transitions, and other geriatric-specific data elements. PACIO frameworks have been validated for clinical conditions prevalent in older adults including diabetes management, falls and fall risk, delirium/depression/dementia, heart failure,

osteoporosis, pain management, Parkinson's disease, pressure ulcers, stroke management, and urinary incontinence.

- **USCDI Expansion:** Incorporation of PACIO-developed data elements into the United States Core Data for Interoperability (USCDI) to ensure widespread adoption.
- **FHIR Clinical Reasoning Module:** HL7 FHIR Clinical Reasoning module for representing clinical decision support logic in a transparent, interoperable format.
- **FHIR Subscription and Notification:** Real-time event notification standards to enable timely care coordination and early warning system alerts.
- **SMART on FHIR:** Application programming interface (API) standards that enable third-party AI applications to access EHR data with patient consent.

Benchmarking Tools and Infrastructure

- **Standardized Performance Metrics:** Industry-wide agreement on how to measure AI tool performance, including sensitivity, specificity, positive predictive value, negative predictive value, and calibration across demographic subgroups.
- **Open Benchmarking Datasets:** Publicly available, de-identified datasets representative of diverse populations (including geriatric and LTPAC patients) for AI developers to test and benchmark their tools.
- **Federated Learning Infrastructure:** Privacy-preserving federated learning networks that enable AI training on distributed datasets without centralizing sensitive patient data.
- **QHIN Connectivity:** Universal connectivity to Qualified Health Information Networks (QHINs) under TEFCA to enable seamless data exchange across all care settings.

Market Opportunities Created by Enhanced Interoperability

Enhanced interoperability would create market opportunities for:

- AI tools focused on care transitions and post-acute care optimization
- Predictive analytics for high-risk, complex patients across care settings
- Population health management platforms serving integrated delivery networks
- Real-time clinical decision support tools that leverage longitudinal patient data
- Patient-facing applications that aggregate data from multiple providers and consumer devices
- Quality measurement and reporting automation tools
- Research platforms supporting pragmatic clinical trials and real-world evidence generation

Question 9: What challenges do patients and caregivers wish to see addressed by AI adoption? What concerns do they have?

Challenges Patients and Caregivers Want AI to Address

- **Care Coordination:** Patients and caregivers struggle with fragmented care across multiple providers, specialists, and care settings. They desire AI tools that facilitate seamless information sharing, reduce redundant testing, and ensure all providers have access to complete patient information.
- **Medication Management:** Managing complex medication regimens is challenging for older adults and caregivers. AI tools that identify drug interactions, simplify medication schedules, and provide reminders would be valuable.
- **Early Problem Detection:** Patients and caregivers want systems that detect early signs of health decline (infections, falls, cognitive changes) before they become emergencies, enabling timely intervention.
- **Caregiver Support and Guidance:** Family caregivers often lack medical training but are responsible for complex care tasks. AI-powered guidance tools, educational resources, and decision support would help caregivers provide better care and reduce anxiety.
- **Reducing Hospital Readmissions:** Patients and caregivers fear repeated hospitalizations and desire tools that help manage conditions effectively at home or in LTPAC settings.
- **Transparent Communication:** Patients want clear, understandable explanations of their conditions, treatment options, and prognoses. AI tools that translate medical jargon into plain language and provide personalized education materials would be valuable.
- **Access to Specialists:** In rural and under-resourced communities, access to specialists is limited. AI tools that provide specialized expertise or triage patients for teleconsultation could improve access.
- **Quality of Life:** Patients prioritize maintaining independence, function, and quality of life. AI tools that support aging in place, prevent functional decline, and align care with patient goals and preferences are desired.

Concerns Patients and Caregivers Have About AI

- **Privacy and Data Security:** Patients worry about who has access to their health data, how it will be used, and whether it will be protected from breaches or misuse. Concerns are heightened regarding data from consumer devices and wearables that may not be HIPAA-protected.
- **Algorithmic Bias and Discrimination:** Patients fear that AI tools may perpetuate or worsen health disparities, particularly for underrepresented or marginalized populations. Research documents that without intentional design, AI risks reinforcing inequities rather than reducing them, with models failing to account for complex social needs of aging populations. Concerns about age-based bias are particularly relevant for older adults.
- **Loss of Human Connection:** Patients value relationships with their clinicians and worry that AI will replace human interaction, empathy, and personalized care. A qualitative study of older adults' perspectives on AI-driven healthcare found mixed acceptance levels, with concerns about technology replacing human connection and desire for maintaining patient-provider relationships. Concerns about "dehumanizing" healthcare are common.

- **Accuracy and Reliability:** Patients and caregivers question whether AI tools are accurate and reliable, particularly when recommendations conflict with clinician judgment or seem counterintuitive.
- **Lack of Transparency:** Patients want to understand how AI tools reach conclusions and recommendations. Black-box algorithms that cannot explain their reasoning are concerning, particularly when they influence important treatment decisions.
- **Reduced Clinician Autonomy:** Patients worry that clinicians will blindly follow AI recommendations without exercising clinical judgment, or conversely, that clinicians will ignore valid AI alert fatigue.
- **Access and Equity:** Patients in under-resourced settings worry that AI tools will only be available to wealthy health systems, widening rather than narrowing health disparities.
- **Consent and Control:** Patients want meaningful control over whether AI tools are used in their care and how their data is used to train AI systems. Concerns about informed consent processes that are difficult to understand are common.
- **Job Displacement:** Patients and communities worry about whether AI will displace healthcare workers, particularly in communities where healthcare facilities are major employers.

Question 10: Are there specific areas of AI research that HHS should prioritize to accelerate AI adoption in clinical care?

Priority Research Areas for LTPAC and Geriatric Populations

- **Inclusion of Aging Populations in AI Research:** Establish requirements that NIH, AHRQ, and other HHS-funded research include adequate representation of older adults, particularly those with multimorbidity, polypharmacy, cognitive impairment, and functional limitations.
- **Multimorbidity and Polypharmacy Optimization:** Develop AI tools that can synthesize evidence across multiple chronic conditions and optimize medication regimens for older adults with complex needs.
- **Functional Status and Trajectories:** Research AI applications for predicting functional decline, targeting interventions to prevent disability, and personalizing rehabilitation approaches.
- **Cognitive Assessment and Dementia Care:** Develop AI tools for early detection of cognitive impairment, monitoring dementia progression, and supporting caregivers of persons with dementia.
- **Fall Prevention:** Research AI applications for fall risk assessment, environmental modification recommendations, and real-time fall detection and response.
- **Delirium Prevention and Management:** Develop AI tools for early delirium detection, identification of modifiable risk factors, and guidance on non-pharmacological interventions.
- **Social Determinants of Health:** Research AI tools that screen for social needs, predict social risk, and connect patients with appropriate community resources.
- **Palliative and End-of-Life Care:** Develop AI tools that facilitate goals-of-care conversations, predict prognosis, and ensure care aligns with patient values and preferences.

- ***Bias Detection and Mitigation:*** Research methods for detecting and mitigating age-based, racial, and socioeconomic bias in AI algorithms. Develop fairness metrics and bias audit tools specific to vulnerable populations. Studies demonstrate the need for bias mitigation strategies throughout the AI lifecycle (data collection, model development, deployment, post-deployment monitoring).
- ***Explainable AI:*** Research techniques for making AI recommendations interpretable and actionable for clinicians and patients, particularly for complex clinical decisions.
- ***Implementation Science:*** Study effective strategies for implementing AI tools in LTPAC settings, including workflow integration, training approaches, and change management methods.
- ***Health Equity:*** Research on how AI tools can reduce rather than widen health disparities, including studies of AI deployment in under-resourced and rural settings.
- ***Research:*** Mimic the effort and research prioritization historically offered to acute and primary care but customize to the unique patient population and care needs, and workflow of facility based long-term and post-acute care providers.

Published Findings on Impact of AI Tools

A systematic review and meta-analysis specifically examining AI-enhanced interventions for older people in long-term care settings found mixed evidence for effectiveness across different health outcomes, with AI-enhanced interventions being somewhat acceptable to users but high risk of bias in included studies reducing confidence in results. The review concluded that more high-quality trials are required before widespread implementation, especially in low- and middle-income countries. Additional literature documents:

- Racial and age bias in clinical risk prediction algorithms
- Performance degradation of AI models when applied to populations is different from training data
- Alert fatigue and override behavior with clinical decision support systems
- Challenges with AI tool integration into clinical workflows
- Variable evidence quality for commercially available AI tools

Costs, Benefits, and Transfers of AI in Clinical Care

The literature suggests:

- ***Potential Benefits:*** Improved diagnostic accuracy, earlier disease detection, reduced medical errors, personalized treatment recommendations, workflow efficiency, reduced clinician burden, and cost savings through prevention of adverse events.
- ***Potential Costs:*** High acquisition and implementation costs, ongoing maintenance expenses, training costs, infrastructure requirements, and potential for increased health disparities if access is unequal.
- ***Transfers:*** Shifts in labor from routine tasks to oversight and complex decision-making, redistribution of resources from late-stage treatment to prevention, and potential concentration of benefits in well-resourced health systems.

Critical research gaps remain regarding long-term impact, cost-effectiveness, and equity implications of AI adoption in clinical care, particularly in LTPAC settings.

Conclusion

The LTPAC Health Information Technology Collaborative appreciates the opportunity to provide input on HHS's approach to accelerating the adoption and use of artificial intelligence in clinical care. We emphasize the critical importance of ensuring that AI innovation benefits all Americans, including the rapidly growing population of older adults served by LTPAC providers.

The convergence of demographic trends (10,000 Americans turning 65 daily), workforce crisis (persistent staffing shortages across the LTPAC continuum), and technology exclusion (15 years without federal health IT investment) creates an urgent imperative for strategic federal action. AI technologies offer transformative potential to address workforce constraints, improve care quality, and ensure sustainable care delivery for America's aging population but only if policy frameworks support rather than hinder LTPAC adoption.

Key recommendations from this response include:

1. Mandate age-stratified validation and bias testing for AI tools intended for use in Medicare populations
2. Expand interoperability standards to include geriatric-specific data elements (functional status, cognitive status, social determinants)
3. Align payment policies to incentivize high-value AI adoption in LTPAC settings
4. Provide infrastructure support and technical assistance to enable AI readiness in under-resourced LTPAC providers
5. Prioritize research funding for AI applications addressing multimorbidity, functional decline, and other priorities for aging populations
6. Establish clear regulatory frameworks addressing liability, privacy, and algorithmic transparency for non-medical device AI tools
7. Create validation testbeds and evaluation frameworks that include LTPAC settings and geriatric populations
8. Support the development of AI tools that augment rather than replace healthcare workers, addressing workforce shortages while maintaining the human connection patients' value

We urge HHS to take a comprehensive, equity-focused approach that ensures AI technologies reduce rather than widen health disparities, protect vulnerable populations from algorithmic bias, support the complex care needs of older adults across all care settings, and enable LTPAC providers to leverage AI solutions that address critical workforce constraints.

The Administration's commitment to accelerating AI adoption in healthcare creates a historic opportunity to rectify longstanding inequities in technology investment and support. By including LTPAC providers in AI policy, payment reform, and research priorities, HHS can enable sustainable, high-quality care for



millions of older Americans while demonstrating meaningful return on federal investment through improved outcomes and reduced costs.

The LTPAC Health IT Collaborative is ready to collaborate with HHS ASTP/ONC to advance these priorities. We welcome the opportunity for ongoing dialogue and partnership to ensure that AI policy and programs are inclusive of the needs of LTPAC providers and the millions of older Americans they serve.

For further information or dialogue, please contact Michelle Dougherty, LTPAC Health IT Collaborative Convener, at leaders@ltpachit.org.

Sincerely,

The LTPAC Health IT Collaborative

For a list of LTPAC Health IT Collaborative members, please visit www.LTPACHIT.org.

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