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U.S. Department of Health & Human Services
330 C St., SW, Floor 7
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5, RIN 0955-AA09)

The Long Term & Post-Acute Care (LTPAC) Health IT Collaborative, whose members include provider and professional associations and national experts in post-acute care settings, nursing homes, senior living communities, assisted living, home health care, physicians, nursing, pharmacists, rehabilitation, and healthcare information systems, appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) for Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity.

The Collaborative was formed in 2005 to advance health IT issues by encouraging coordination among LTPAC provider organizations, policymakers, vendors, payers, and other stakeholders. Since that time, we have been actively involved in commenting to federal agencies, including the Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) and the Centers for Medicare & Medicaid Services (CMS), on concerns with funding and policies related to developing the national health information technology (HIT) framework for implementing secure access of electronic health information to support the care journey for all patients and improve their health outcomes.

The LTPAC sector stands ready to be an active partner in advancing ASTP/ONC's vision for innovation, transparency, and a healthier America including reducing the chronic disease burden and expanding meaningful patient engagement across all care settings. Yet these goals cannot be fully realized if federal technology policy systematically bypasses the high-need, high-cost populations that LTPAC providers serve every day. We are already on the front lines, delivering around-the-clock care to the older adults with multiple chronic conditions, cognitive impairment, and functional limitations whom these policies ultimately aim to benefit. Our goal is not to slow the pace of innovation, but to ensure that LTPAC is brought along as a full and supported participant. A national health IT strategy that leaves behind the sector caring for America's most medically complex and costliest population cannot achieve sustainable, equitable, or fiscally sound healthcare for any of us.

We appreciate ASTP/ONC's efforts to streamline certification requirements and reduce regulatory burden. However, we have significant concerns that several proposed removals and

revisions may disproportionately impact LTPAC providers and the vulnerable populations they serve, particularly given the foundational role that certification criteria play in ensuring baseline capabilities for cross-setting care coordination.

Summary of Key Recommendations:

The LTPAC HIT Collaborative recommends ASTP/ONC:

- Retain or phase more gradually the removal of privacy and security certification criteria, establishing clear baseline expectations for vendor capabilities that protect vulnerable LTPAC populations
- Maintain transitions of care and clinical information reconciliation criteria critical for cross-setting handoffs and medication safety
- Preserve patient engagement features including view, download, and transmit (VDT) and patient health information capture that support resident and family caregiver involvement
- Ensure AI-enabled decision support transparency through meaningful oversight mechanisms including audit trails and AI model cards for algorithm governance and safety
- Clarify the impact of information blocking revisions on LTPAC participation in TEFCA and health information exchange networks, with specific guardrails against third-party access abuse
- Clarify that "Third Party Seeking Modification" provisions do not permit RPA-driven agents to alter patient records without provider-supervised authorization, require certified health IT vendors to implement and document technical controls governing automated and AI-directed workflows, and ensure that "without limit" access modalities incorporate reasonable constraints to prevent system performance degradation that could compromise clinical safety
- Provide sufficient transition timelines and implementation guidance for LTPAC providers and their technology vendors
- Develop model contract language that LTPAC providers can use in vendor agreements to ensure essential capabilities remain available when certification requirements are removed

Comments on Specific Provisions

1. Removal of Privacy and Security Certification Criteria (§ 170.315(d))

Our Concern: The proposal to eliminate all privacy and security certification criteria (pp. 60989-60990) creates substantial uncertainty for LTPAC providers regarding baseline security expectations for certified health IT. While ASTP/ONC asserts that HIPAA Security Rule and other federal frameworks provide sufficient coverage, the removal of these certification

requirements eliminates a critical verification mechanism that LTPAC providers have relied upon when evaluating and procuring health IT systems.

The removal of event logging and audit trail criteria is particularly concerning in light of the increasing use of robotic process automation (RPA) and asynchronous, AI-directed workflows in LTPAC settings. These automated tools may enable third-party actors to access EHR systems on a continuous basis and unilaterally write to or modify patient records often without accounting for HIPAA's minimum necessary, access control, and accountability requirements. When bots inherit broad end-user permissions and operate without clear role-based constraints or human-readable audit trails, LTPAC providers cannot reliably distinguish bot-generated entries from clinician documentation, reconstruct who or what made a given change, or verify that appropriate clinical judgment was applied. This exposes providers to litigation, reimbursement denials, and enforcement risk and, most critically, to patient safety events stemming from inaccurate or inaccessible clinical information — while simultaneously obscuring accountability for inappropriate access to protected health information.

LTPAC settings serve highly vulnerable populations—including residents with cognitive impairments, complex medical needs, and limited ability to advocate for their own privacy rights. These populations are at heightened risk for privacy breaches and identity theft. The certification criteria provided LTPAC providers with assurance that vendors had demonstrated baseline technical capabilities for authentication, access control, auditing, encryption, and integrity protection.

The removal of audit trail, authentication, access control, and integrity certification requirements eliminates critical capabilities for investigating security breaches, validating data provenance for secondary use (quality reporting, legal proceedings, regulatory compliance), and protecting vulnerable residents. When privacy breaches occur, providers cannot track or support investigations without robust audit functions. The removal also lowers barriers to entry for new vendors that may offer insufficient baseline protection, while shifting the burden of ensuring security capabilities entirely to contractual negotiations where LTPAC providers have limited leverage. Existing vendors who have already invested in these security capabilities will retain them, but new market entrants will face no requirement to build these protections.

As a reminder, LTPAC providers were excluded from HITECH Act funding and current Promoting Interoperability programs, resulting in persistently low certified health IT adoption and limited resources to independently assess and negotiate vendor security capabilities.

Our Recommendation: We urge ASTP/ONC to retain core privacy and security certification criteria or, at least, establish clear guidance on alternative mechanisms through which LTPAC providers can verify that health IT vendors meet baseline security expectations. If removal proceeds, we recommend:

- Publishing comprehensive guidance on how LTPAC providers should evaluate vendor security capabilities in the absence of certification requirements, including model language for vendor agreements and Business Associate Agreements (BAAs) addressing privacy and security requirements, audit trail preservation, breach notification obligations, and data use restrictions

- Clarifying how HIPAA Security Rule requirements apply to health IT vendors when privacy and security certification criteria are removed, and providing guidance on contractual provisions that ensure vendor compliance with applicable federal security frameworks, especially given that vendors may not be direct HIPAA covered entities
- Establish safeguards for automated and RPA-driven access to EHR Certification Criteria. Require that certified health IT vendors implement and document technical controls to govern RPA and other automated or AI-directed workflows, including:
  - Role-based access constraints that prevent automated agents from inheriting broad end-user permissions or overriding EHR-documented patient consent indicators
  - Audit trail functionality that uniquely identifies and distinguishes bot-generated entries from human clinician documentation, preserving a reliable chain of custody in the medical record; and
  - System performance protections that prevent continuous, high-volume automated access from degrading end-user functionality in ways that could compromise clinical safety.
  - Further clarify that information blocking safe harbors and manner exceptions do not require LTPAC providers to permit unbounded automated access that creates unreasonable compliance, liability, or patient safety risk and should develop model contract language LTPAC providers can use to hold vendors accountable for these protections in the absence of certification requirements.
- Requiring vendors to maintain transparent documentation of security controls and testing results accessible to prospective LTPAC purchasers
- Establishing a voluntary security attestation framework that vendors can use to demonstrate HIPAA Security Rule compliance
- Extending the effective date to allow adequate time for LTPAC organizations to update procurement policies and vendor contracts, recognizing that small, rural, under-resourced, and Medicaid-reliant LTPAC providers often lack dedicated legal and IT security expertise to negotiate complex vendor agreements

2. Revisions to Transitions of Care and Clinical Information Reconciliation (§ 170.315(b)(1-2))

Our Concern: The proposed removal of the clinical information reconciliation and incorporation criterion (§ 170.315(b)(2)) effective January 1, 2027 (pp. 61018-61020) directly threatens patient safety in LTPAC settings. Care transitions—particularly from acute care hospitals to skilled nursing facilities, long-term care facilities, home health, and hospice—are high-risk events where medication errors, missing clinical information, and incomplete reconciliation can lead to adverse outcomes, readmissions, and mortality.

LTPAC providers were excluded from HITECH Act funding and current Promoting Interoperability programs, resulting in persistently low adoption of interoperability standards (including FHIR) despite sector-led standards development efforts. LTPAC providers rely heavily on the reconciliation capabilities embedded in certified health IT to ensure accurate

medication lists, allergy information, and problem lists when patients transition across settings. Unlike acute and ambulatory settings where patients may have continuity with a single provider or system, LTPAC patients frequently move across multiple unaffiliated organizations and care settings, making standardized reconciliation capabilities essential.

The revision to the transitions of care criterion (§ 170.315(b)(1)) may reduce requirements for structured data exchange, potentially reverting to unstructured document-based approaches that increase manual reconciliation burden and error risk.

Our Recommendation: We urge ASTP/ONC to retain the clinical information reconciliation and incorporation criterion and strengthen—rather than weaken—the transitions of care requirements to ensure that:

- Structured, computable data elements (medications, allergies, problems, procedures, immunizations) are transmitted and reconciled across care settings
- LTPAC-relevant data elements are included in standardized transition summaries and standardized medication profiles. The HL7 PACIO FHIR Workgroup is finalizing and preparing for release of the balloted HL7 Transition of Care Standard for Trial Use FHIR Implementation Guide including a USCDI-compliant transition of care dataset. Similarly, PACIO has developed standardized medication profile specifications to support medication reconciliation. Lack of funding for mandatory certification has resulted in these standards remaining in voluntary certification pathways with low adoption rates.
- ASTP/ONC provide assistance with awareness and adoption of the PACIO-developed transitions of care and medication reconciliation standards by all certified EHR vendors. Certified vendors serving acute and ambulatory settings must be required or incentivized to adopt LTPAC-relevant standards to enable bi-directional data exchange.

If removal of § 170.315(b)(2) proceeds despite our objections, we request that ASTP/ONC establish clear guidance on alternative mechanisms for ensuring medication reconciliation safety and cross-setting data integrity, including model contract language that providers can incorporate into vendor agreements to require reconciliation capabilities and LTPAC-relevant data element support.

3. Revisions to Patient Engagement Features (§ 170.315(e)(1) and (e)(3))

Our Concern: The proposed revisions to view, download, and transmit (VDT) capabilities and removal of patient health information capture (pp. 60990-60992, 61020) may reduce support for patient and family caregiver access and patient-generated health data—both critical for LTPAC populations.

In LTPAC settings, "patient engagement" often means family caregiver engagement for residents with cognitive impairments, dementia, or decisional incapacity. Family caregivers play essential roles in understanding care plans, coordinating across providers, monitoring health status changes, and contributing observations about functional decline, behavioral changes, and quality of life. The removal of patient health information capture certification requirements

may reduce vendor support for caregiver-contributed data (e.g., observations, symptoms, functional assessments, goals and preferences).

The revision to VDT that removes Web Content Accessibility Guidelines (WCAG) references may reduce accessibility for older adults and persons with disabilities—the core populations served by LTPAC providers.

LTPAC providers were excluded from HITECH Act funding and current Promoting Interoperability programs, limiting resources to independently develop patient and caregiver engagement technologies.

We recognize and support ASTP/ONC's strong emphasis on app-based patient engagement tools. However, in LTPAC settings, meaningful engagement must be designed for and through family caregivers and facility staff because many patients/residents cannot independently manage technology or use consumer apps or have cognitive impairments.

Our Recommendation: We urge ASTP/ONC to:

- Retain the patient health information capture criterion (§ 170.315(e)(3)) and expand it to explicitly include family caregiver-contributed data relevant to LTPAC care (functional status observations, behavioral changes, fall incidents, pain assessments, advance care planning preferences)
- Strengthen rather than weaken accessibility requirements in the VDT criterion to ensure that patient portals and access technologies meet the needs of older adults, persons with cognitive impairments, and persons with disabilities
- Clarify how the shift toward FHIR-based APIs will support family caregiver access, including proxy access mechanisms, delegation workflows, and caregiver-contributed data capture through third-party applications
- Provide implementation guidance and technical assistance to LTPAC health IT vendors on integrating caregiver engagement capabilities
- Provide guidance and pilots on how app-based engagement models can be adapted for LTPAC—such as caregiver portals, proxy access, and staff-mediated applications—and to clarify how FHIR-based API strategies will support caregiver engagement and facility-mediated access, not only individual consumer apps
- Ensure that price transparency rules take into consideration the types of patients and payment issues related to LTPAC settings and don't assume that rules that apply to hospitals and ambulatory care apply to all settings

If ASTP/ONC proceeds with removing view, download, and transmit capabilities and removal of patient health information capture despite our concerns, we request development of model contract language that LTPAC providers can use in vendor agreements to ensure patient and family caregiver access and patient-generated health data remains available and functional.

4. AI-Enabled Decision Support and Algorithm Transparency

Our Concern: The proposal to remove AI model card requirements from the decision support interventions criterion while simultaneously promoting "AI-enabled interoperability solutions" (pp. 61017-61018, 60974) creates a transparency and governance gap that is particularly concerning for LTPAC populations.

AI-enabled clinical decision support tools are increasingly deployed in LTPAC settings for fall risk prediction, pressure injury risk assessment, sepsis detection, functional decline prediction, and hospice eligibility determination. These algorithms directly influence clinical decision-making for vulnerable populations who may have limited ability to question or appeal algorithmic recommendations. Without transparency requirements, including both AI model cards and audit trails, LTPAC providers and patients cannot meaningfully evaluate the appropriateness, bias risks, or limitations of AI tools integrated into certified health IT.

The removal of model card requirements eliminates accountability mechanisms for algorithm developers and makes it difficult for LTPAC providers to fulfill their ethical and legal obligations to ensure that clinical decision support tools are evidence-based, validated for their patient populations, and free from harmful bias. From a patient safety and population health perspective, providers need transparency not only about how algorithms were developed (AI model cards) but also about the evidentiary basis for specific recommendations (audit trails). Without an audit trail, providers cannot determine whether an AI recommendation is based on a 25-year-old study that has since been disproven or on contemporary, high-quality evidence. If a provider faces legal or professional accountability questions about a clinical decision influenced by AI, stating "the AI told me, so I accepted its decision" is not a defensible response. LTPAC providers were excluded from HITECH Act funding and current Promoting Interoperability programs, limiting resources to independently validate AI tools or develop internal AI governance programs.

Our Recommendation: We urge ASTP/ONC to retain and strengthen algorithm transparency requirements for AI-enabled decision support integrated with certified health IT, including:

- Mandatory disclosure of algorithm purpose, intended use populations, validation data sources, performance metrics (sensitivity, specificity, positive/negative predictive value), known limitations, and potential bias risks through AI model cards that describe the tool's design, intended use, and validation
- Audit trail requirements that preserve documentation of the evidence sources and reasoning pathways underlying specific AI recommendations, enabling providers to understand whether recommendations are based on current, high-quality evidence or outdated studies
- Requirements that algorithms be validated on LTPAC-relevant populations (older adults, persons with multiple chronic conditions, persons with cognitive impairments) rather than only acute care or ambulatory populations
- Clear documentation of how algorithmic recommendations should be interpreted and integrated into clinical workflows

- Mechanisms for LTPAC providers to report algorithm performance issues, unexpected outcomes, or suspected bias to ASTP/ONC and FDA where applicable
- Requirement of all healthcare apps, including EHRs and third party apps, utilize the AI Transparency on FHIR (https://build.fhir.org/ig/HL7/aitransparency-ig/branches/main/index.html) to verify if and when "health data has been created, updated, or otherwise influenced by AI"
- Ongoing surveillance and post-market monitoring requirements for AI-enabled decision support tools

If ASTP/ONC proceeds with removing AI model card requirements and audit trail requirements from certification, we request establishment of an alternative oversight framework, potentially coordinated with FDA, CMS, and the Office for Civil Rights, to ensure AI safety and equity in LTPAC settings. Additionally, we urge development of model contract language that small, rural, and under-resourced LTPAC providers can use in vendor agreements to ensure patient safety and population health protection, including requirements for AI transparency, evidence-based validation, and provider liability protection.

5. Information Blocking Revisions and TEFCA

HTI-5 tightens information-blocking expectations and narrows key exceptions without providing scalable technical support for small, rural, and under-resourced LTPAC providers or the vendors who serve them. Policies designed around large, well-funded health systems are being applied as one-size-fits-all, while LTPAC providers and their vendors lack the funding and technical capacity to comply, yet still face enforcement and penalty risk.

Our Concern: The proposed removal of the TEFCA Manner Exception and revisions to the Manner Exception's "manner requested" condition (pp. 60974) create uncertainty for LTPAC providers who are evaluating participation in TEFCA-enabled health information exchange networks.

LTPAC providers often face significant technical, financial, and operational barriers to participating in health information exchange. Many LTPAC organizations are small, under-resourced, and located in rural or underserved areas where HIE infrastructure is limited. The removal of the TEFCA Manner Exception may eliminate flexibilities that could have facilitated LTPAC participation in nationwide exchange networks. Additionally, there are substantial cost barriers to entry for LTPAC providers seeking to participate in TEFCA Qualified Health Information Networks (QHINs).

The clarification that the Manner Exception does not apply to non-market-rate contracts, contracts of adhesion, or contracts with unconscionable terms is important for establishing clearer guardrails. However, we are concerned that LTPAC providers may lack the legal and technical expertise to evaluate whether specific contract terms meet these criteria, potentially exposing them to information blocking liability.

The HTI-5 proposal's updated definitions of "access" and "use," particularly provisions allowing certain modalities to be used "without limit," create significant risk when combined with third-party modification rights. Under "Third Party Seeking Modification," automated RPA processes or external entities may initiate record changes that appear native to the EHR, leaving LTPAC operators and clinicians accountable for records they did not author or authorize, while potentially overriding HIPAA-enabled EHR indicators documenting patient consent for information sharing. Continuous, high-volume automated access also creates serious system stability risks. Background RPA processes can lock clinical workstations at critical moments, rendering information such as allergy or adverse drug reaction data temporarily inaccessible at the bedside. The downstream consequences are severe including litigation exposure, reimbursement denials, enforcement actions, and patient safety events stemming from inaccurate or inaccessible clinical information.

Our primary concern relates to third-party access risks that could impact both LTPAC providers and their health IT vendors. The HTI-5 proposal tightens information-blocking expectations around how and when data must be made available (including automation and third-party access), narrows practical flexibility under "manner" and "infeasibility," and raises questions about how providers will manage security risk, cost, and oversight as access demands expand. For example, EHRs may be required to provide data to "all comers," including third parties seeking to accumulate and analyze PHI for purposes unrelated to patient care, such as trial attorneys conducting broad discoveries to identify potential litigation targets by examining health records of patients not related to specific cases. This risk is particularly acute for LTPAC providers, as their systems may serve as the "pipeline" for information flowing to third parties, even though vendors themselves may not be subject to the same HIPAA obligations as covered entities. While supporting patient access, we urge ONC to provide clearer guardrails particularly around reasonable timelines, operational feasibility, and protections against unintended consequences from unbounded third-party or automated access.

LTPAC providers were excluded from HITECH Act funding and current Promoting Interoperability programs, exacerbating resource constraints that limit participation in TEFCA and HIE networks.

Our Recommendation: We urge ASTP/ONC to:

- We recommend that information-blocking enforcement for LTPAC explicitly accounts for provider scale, historical exclusion from federal health IT funding, and dependencies on vendor capabilities, rather than assuming the same baseline as large, tech enabled health systems. HTI-5 should include a reasonable on-ramp and scalable expectations for LTPAC participation, with technical assistance and model contract tools as primary levers before penalties are applied.
- Provide clear guidance and examples on how LTPAC providers can evaluate whether contracts or participation agreements constitute "contracts of adhesion" or contain "unconscionable terms" in the context of TEFCA participation and HIE connectivity
- Clarify and constrain "without limit" automated access and third-party record modification rights. ASTP/ONC should explicitly establish that "Third Party Seeking Modification"

provisions do not permit RPA-driven agents to alter patient records without provider-supervised authorization, and that automated access modalities must incorporate reasonable technical constraints to prevent system performance degradation that could compromise clinical safety. This should include
  - Requiring automated agents to respect EHR-documented patient consent indicators and HIPAA-enabled access controls
  - Confirming that information blocking safe harbors do not compel LTPAC providers to permit third-party automated modifications that create unreasonable liability for records they did not author
  - Developing model contract language defining permissible scope of automated access, performance safeguards, and clear accountability for bot-generated documentation errors, reimbursement denials, or patient safety events
- Clarify how the removal of the TEFCA Manner Exception impacts LTPAC organizations that participate in TEFCA Qualified Health Information Networks (QHINs) or are considering participation, particularly with respect to cost barriers and operational requirements
- Ensure that information blocking enforcement recognizes the unique resource constraints, technical limitations, and market dynamics facing LTPAC providers, particularly small, rural, under-resourced, and Medicaid-reliant organizations
- Establish clearer guardrails around third-party access that protect LTPAC providers and their vendors from liability when third parties use access rights for purposes unrelated to patient care, including protections against broad discovery requests and unreasonable access demands
- Coordinate with CMS and state Medicaid agencies to align information blocking policies with LTPAC quality reporting, value-based payment, and interoperability incentive programs

6. Implementation Timelines and Transition Support

LTPAC providers and their vendors are already contending with the cumulative effects of being left out of prior federal HIT investments; imposing aggressive timelines and expanded obligations without commensurate support creates a double bind where the least resourced providers face new penalties for failing to do things they were never funded or scaled to do.

Our Concern: The staggered effective dates for various removals and revisions (pp. 61018-61021) create operational challenges for LTPAC providers and their health IT vendors.

LTPAC health IT vendors often serve smaller and rural markets, have fewer development resources, and operate on longer product development and release cycles compared to acute care and ambulatory EHR vendors. Rapid changes to certification requirements raise concerns about vendor capacity to support implementation across all care settings simultaneously, with LTPAC support potentially being delayed as vendors prioritize acute and ambulatory markets.

This may result in:

- Extended delays in updating LTPAC systems to comply with new requirements or remove deprecated functionality
- Increased costs passed through to LTPAC providers for system upgrades, interfaces, and technical support
- Functionality gaps where previously certified capabilities are removed before alternative solutions (e.g., FHIR-based APIs) are fully implemented and validated in LTPAC workflows
- Feasibility challenges in certain LTPAC settings, such as rural facilities lacking high-speed internet infrastructure necessary to support new interoperability requirements

LTPAC providers were excluded from HITECH Act funding and current Promoting Interoperability programs, limiting resources to absorb rapid implementation costs and technical changes.

Our Recommendation: We urge ASTP/ONC to:

- Extend implementation timelines for criteria removals that significantly impact LTPAC care coordination, patient safety, or family engagement (transitions of care reconciliation, patient engagement features, security capabilities) to no earlier than January 1, 2028
- Establish a hardship exception process for LTPAC providers facing feasibility challenges (e.g., lack of high-speed broadband access in rural areas) that prevent timely compliance with new requirements
- Provide comprehensive implementation guidance, technical assistance, and best practice resources specifically tailored to LTPAC settings, workflows, and vendor ecosystem
- Conduct targeted stakeholder engagement with LTPAC providers, health IT vendors serving LTPAC markets, and LTPAC quality and accreditation organizations to assess implementation readiness and identify barriers
- Monitor and publicly report on the impact of HTI-5 changes on LTPAC interoperability, care transitions, patient safety outcomes, and health equity metrics
- Establish mechanisms for LTPAC stakeholders to request technical assistance, report implementation challenges, and provide ongoing feedback on the real-world impact of certification program changes

We further recommend that ASTP/ONC design implementation supports—technical assistance, pilots, and model language resources—specifically to help small, rural, and Medicaid-reliant LTPAC providers and their niche vendors meet expectations without driving vendor consolidation or loss of specialist innovators that serve this sector.

7. Model Contract Language and Technical Assistance Resources

We view model contract language and standardized BAA provisions as core mitigation tools for LTPAC providers, particularly small and rural organizations with limited legal and IT resources. These tools are essential to compensating for the removal of certification-based protections in areas such as privacy and security (including audit trails and breach notification), AI transparency and liability (including model cards, audit trails, and evidence sources), third-party access guardrails under information blocking and TEFCA, and patient and caregiver engagement obligations when certification criteria are removed.

Because ASTP/ONC has already recognized small, rural and under-resourced providers as a priority, we request that LTPAC providers in small, rural and under-resourced communities be explicitly identified as key beneficiaries of any technical assistance and model-language initiatives emerging from HTI-5.

Throughout our comments, we have consistently identified the need for model contract language that LTPAC providers can use in vendor agreements to ensure essential capabilities remain available when certification requirements are removed. Given that different personnel at ASTP/ONC may review different sections of these comments, we consolidate here a comprehensive request for model language development across multiple domains:

Due to the fact that vendors are removing, modifying or not responding to model language, we urge ASTP/ONC to develop and publish required contract language, Business Associate Agreement (BAA) provisions, and procurement guidance that small, rural, under-resourced, and Medicaid-reliant LTPAC providers can use in vendor negotiations, covering:

1. ***Privacy and Security Requirements:*** Model BAA provisions and vendor agreement language addressing privacy and security capabilities (authentication, access control, audit trail preservation, encryption, integrity protection), breach notification obligations, data use restrictions, and vendor compliance with HIPAA Security Rule when certification criteria are removed
2. ***AI Transparency and Safety:*** Model language requiring vendors to provide AI model cards documenting algorithm purpose, intended use populations, validation data sources, performance metrics, limitations, and bias risks; audit trail requirements showing evidence sources underlying AI recommendations; validation on LTPAC populations; provider liability protections; and mechanisms for reporting algorithm performance issues
3. ***Transitions of Care and Clinical Reconciliation:*** Model language requiring structured data exchange, clinical information reconciliation capabilities, support for LTPAC-relevant data elements, and adoption of PACIO transitions of care and medication reconciliation standards
4. ***Patient and Caregiver Engagement***: Model language ensuring patient health information capture capabilities, family caregiver access (including proxy access and delegation workflows), and accessibility features for older adults and persons with disabilities

5. ***Third-Party Access Guardrails:*** Model language addressing appropriate limitations on third-party access to protect LTPAC providers from liability when third parties use information for purposes unrelated to patient care, including protections against broad discovery requests and unreasonable access demands

This consolidated model language should be developed in coordination with LTPAC provider associations, legal experts, and health IT vendors to ensure practical applicability while providing LTPAC providers with negotiation leverage and baseline protection of critical capabilities.

Cross-Cutting Concern: LTPAC-Specific Considerations in Health IT Policy

Over the last fifteen years, LTPAC providers have been excluded from nearly every major federal health IT investment initiative, including the HITECH Act incentive programs and subsequent Promoting Interoperability efforts. This pattern of exclusion is a cumulative, structural barrier, not a series of isolated oversights, and it means that each new policy wave (TEFCA, FHIR APIs, AI-enabled tools, and now HTI-5) arrives in a landscape where acute and ambulatory providers are at level seven or nine while LTPAC remains at level three.

Throughout our comments, a consistent theme emerges with respect to how health IT policies developed primarily for acute care and ambulatory settings often fail to account for the unique characteristics, workflows, populations, and resource constraints of LTPAC providers.

LTPAC settings differ from hospitals and physician practices in critical ways:

- ***Population characteristics:*** Older adults, people with multiple chronic conditions, cognitive impairments, functional limitations, end-of-life care needs, and longer lengths of stay
- ***Care model:*** Interdisciplinary team-based care involving physicians, nurses, therapists, social workers, dietitians, and direct care workers; heavy reliance on family caregivers; significant use of third-party vendors to provide major clinical support services (pharmacy, laboratory, therapy) requiring extensive interoperability
- ***Documentation and workflow:*** Focus on functional status, cognitive status, behavioral health, social needs, advance care planning, and quality of life, not just acute medical conditions
- ***Regulatory environment***: Subject to unique quality reporting, survey/inspection, and reimbursement requirements (MDS, OASIS, IRF-PAI, LCDS, Hospice Item Set, etc.)
- ***Health IT market:*** Smaller number of vendors, lower product investment, slower innovation cycles, higher relative cost burden
- ***Resource constraints:*** Lower margins, workforce shortages, small, rural, and under-resourced locations, limited IT staff and expertise

When certification criteria are removed without LTPAC-specific impact analysis, the result is often a reduction in vendor support for LTPAC-critical functionalities rather than the intended deregulatory benefit.

Our Recommendation: We urge ASTP/ONC to establish an LTPAC Health IT Advisory Group or formalize ongoing engagement mechanisms with LTPAC stakeholders to ensure that future health IT policies, certification requirements, standards adoption, and interoperability initiatives adequately consider LTPAC provider needs, workflows, and populations.

To be effective, this Advisory Group should function not only as a commenter on already-baked rules that were designed for hospitals and physician practices, but at the table co-designing future HTI rules (including HTI-6 and subsequent RFIs), implementation guides, and technical assistance resources. LTPAC organizations need to be included up front in policy design so that rules do not have to be re-engineered after the fact to accommodate this sector.

This group could provide input on:

- USCDI data element priorities for LTPAC settings
- FHIR implementation guide requirements for cross-setting care coordination
- Algorithm transparency and AI governance policies for vulnerable populations
- Interoperability requirements in CMS quality programs affecting LTPAC (SNF VBP, HH VBP, Hospice QRP, etc.)
- Technical assistance and implementation support needs for LTPAC providers and vendors

Conclusion

The LTPAC Health IT Collaborative appreciates HHS/ASTP/ONC's goals of reducing regulatory burden and promoting innovation through deregulation. We support efforts to eliminate duplicative requirements, streamline certification, and advance FHIR-based interoperability. However, we urge ASTP/ONC to carefully consider the unintended consequences of removing certification criteria that provide baseline assurance of critical capabilities for patient safety, care coordination, privacy protection, and family engagement, particularly for the vulnerable populations served in LTPAC settings.

The U.S. healthcare system is more than acute care hospitals and ambulatory physician practices. Patients with complex chronic conditions, functional limitations, and end-of-life care needs rely on a continuum of LTPAC services—skilled nursing facilities, home health agencies, hospice programs, assisted living communities, and long-term care facilities. Effective, safe, person-centered care for these populations depends on robust health IT capabilities that support cross-setting information exchange, medication safety, family caregiver engagement, and protection of privacy and dignity.

LTPAC providers are ready and willing to be radical innovators in support of ASTP/ONC's goals for a healthier, more transparent America, but current policy structures over-regulate and under-resource our settings while simultaneously adding new mandates and penalties. HTI-5-related health IT investments and policy flexibilities should be framed and deployed as tools to reduce fraud, improve accountability, and strengthen care for high-need older adults in LTPAC—not merely as additional avenues for oversight.

We urge ASTP/ONC to:
- Retain or phase more gradually the removal of privacy/security, transitions of care reconciliation, and patient engagement certification criteria
- Strengthen algorithm transparency through both AI model cards and audit trails for AI-enabled decision support affecting vulnerable populations
- Establish safeguards for automated and RPA-driven access to certified health IT
- Provide clear implementation guidance on information blocking requirements and TEFCA participation for LTPAC providers, including third-party access guardrails
- Develop model contract language across multiple domains to support LTPAC providers when certification protections are removed
- Extend timelines and provide targeted technical assistance to ensure successful transition for LTPAC organizations and vendors
- Establish ongoing LTPAC stakeholder engagement to inform future health IT policy development

The LTPAC sector stands ready to be an active and committed partner in advancing ASTP/ONC's vision for innovation, transparency, and a healthier America, including reducing the chronic disease burden and expanding meaningful patient and caregiver engagement across all care settings. These goals, however, cannot be fully realized if federal health IT policy continues to systematically bypass the high-need, high-cost populations that LTPAC providers serve every day. We are already on the front lines, delivering around-the-clock care to the older adults with multiple chronic conditions, cognitive impairment, and functional limitations whom these policies ultimately aim to benefit.

A national health IT strategy that leaves behind the sector caring for America's most medically complex and costliest population cannot achieve sustainable, equitable, or fiscally sound outcomes for any of us. Our goal is not to slow the pace of innovation, but to ensure that LTPAC is brought forward as a full and supported participant, so that the gap between our sector and the rest of the health system narrows rather than widens with every new policy wave.

We appreciate the opportunity to comment and stand ready to work collaboratively with ASTP/ONC, CMS, and other federal partners to advance interoperable, patient-centered health IT that serves all Americans across all care settings.

Sincerely,

The LTPAC Health IT Collaborative

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