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Re: Request for Information: Diagnostic Imaging Interoperability Standards and Certification, RIN 0955-AA11

The Long-Term and Post-Acute Care (LTPAC) Health Information Technology 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 Request for Information regarding diagnostic imaging interoperability standards and certification.

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), 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.

Executive Summary

The LTPAC Health IT Collaborative strongly supports ASTP/ONC's initiative to improve diagnostic imaging interoperability across the healthcare ecosystem. We recognize that diagnostic images are critical for supporting care decisions, monitoring treatment effectiveness, and enabling coordinated care transitions—functions that are essential in LTPAC settings where patients often present with complex, chronic conditions requiring longitudinal care coordination.

However, we wish to emphasize a critical distinction that differentiates LTPAC providers from hospitals and health systems: **diagnostic imaging services in LTPAC settings are predominantly ancillary services rather than integrated components of a broader health IT and electronic health record (EHR) platform.** This structural difference has implications for interoperability policy, standards adoption, and certification approaches.

Key recommendations include:

- Recognize that LTPAC providers primarily access diagnostic imaging and reports as external ancillary services (portable X-ray, mobile imaging, contracted radiology) rather than operating integrated imaging departments with PACS/VNA infrastructure
- Apply similar policy focus and interoperability emphasis to diagnostic imaging as is being developed for pharmacy and laboratory services, recognizing all three as critical ancillary services requiring seamless data exchange
- Prioritize bidirectional interoperability standards that enable LTPAC EHR systems to receive, display, and incorporate diagnostic imaging results from external providers without requiring LTPAC facilities to implement and maintain their own imaging infrastructure
- Develop certification criteria and standards that address the ancillary service model prevalent in LTPAC, not solely the integrated imaging department model typical of hospitals, health systems, and physician practices
- Ensure that interoperability solutions support the full spectrum of imaging modalities used in LTPAC settings, including portable X-ray, ultrasound, and other point-of-care imaging technologies
- Provide financial support and technical assistance to address the 15-year technology investment gap created by LTPAC exclusion from HITECH Act incentive programs
- Align diagnostic imaging interoperability requirements with existing LTPAC data exchange initiatives, including the PACIO Project FHIR implementation guides and USCDI expansion efforts
- Address bandwidth limitations in LTPAC settings, particularly in rural areas, recognizing that many facilities lack the network infrastructure to routinely receive large imaging files
- Establish standards for three-way communication similar to pharmacy e-prescribing workflows, addressing the triangulation between ordering physicians (with their own EHRs), LTPAC providers (with facility EHRs), and ancillary imaging service providers to ensure all parties receive necessary information for care coordination, prior authorization, referral management, and clinical decision-making

Without explicit attention to the ancillary service model that characterizes LTPAC imaging workflows, interoperability policies risk being designed exclusively for the hospital-centric integrated imaging model, leaving LTPAC providers and their vulnerable patient populations behind once again.

The LTPAC Context: Diagnostic Imaging as an Ancillary Service

How LTPAC Providers Use Diagnostic Imaging

Unlike acute care hospitals and large health systems that operate integrated radiology departments with dedicated PACS, VNA, and imaging IT infrastructure, LTPAC providers typically access diagnostic imaging through **external ancillary service relationships**:

- **Portable X-ray services:** Mobile radiology companies bring equipment to nursing facilities to perform bedside imaging for residents who cannot be safely transported
- **Mobile imaging services:** Contracted vendors provide ultrasound, echocardiography, and other imaging modalities on-site
- **Hospital-based imaging:** Residents transported to hospital emergency departments or outpatient radiology centers for CT, MRI, and other advanced imaging
- **Teleradiology interpretation:** Images captured by various providers are interpreted by radiologists who may not have direct access to the LTPAC EHR
- **Specialty imaging contractors:** Ophthalmology, vascular studies, bone density scans, and other specialized imaging provided by contracted service vendors

This ancillary service model creates unique interoperability challenges that differ fundamentally from the hospital imaging workflow:

- LTPAC providers **do not own or operate imaging equipment** (except in rare cases)
- LTPAC EHR systems must **receive and integrate imaging data from multiple external sources** with varying technical capabilities and interoperability maturity
- Imaging results often arrive via **fragmented channels due to working with multiple hospital and health systems**: fax, portal login, physical media (CDs), paper reports, or—in best cases—structured electronic exchange
- LTPAC clinical staff must **correlate imaging orders, studies, and results across multiple vendor systems** without unified workflow integration
- The burden of ensuring imaging data is incorporated into the longitudinal patient record falls disproportionately on **under-resourced LTPAC providers** rather than imaging specialists to ensure care coordination and transitions of care

The Three-Way Communication Challenge

A critical aspect of the LTPAC imaging workflow that differs from hospital-based imaging is the triangulation of information flow between three parties with separate EHR systems:

1. Ordering physician (attending physician, specialist, or nurse practitioner) with their own ambulatory EHR
2. LTPAC provider (skilled nursing facility, assisted living, home health agency) with facility-based EHR
3. Ancillary imaging service provider (portable X-ray company, hospital radiology department, mobile imaging vendor) with their own imaging and reporting systems

This three-way communication model is similar to the pharmacy e-prescribing workflow that has been addressed through NCPDP standards requiring information flow between prescribing physicians, dispensing pharmacies, and LTPAC facilities. The same approach is needed for diagnostic imaging to ensure:

- Ordering information reaches the imaging service provider with appropriate clinical context
- Scheduling and logistics information is shared with LTPAC coordinators who arrange transportation or facility access
- Results and reports are delivered to both the ordering physician and the LTPAC provider for care coordination
- Prior authorization documentation and requirements are accessible to all parties
- Referral and consultation workflows include all stakeholders in the care process

Without standardized three-way communication, critical information is lost, creating delays, duplicative testing, medication errors (when imaging informs medication decisions), care coordination failures, and patient safety risks.

The External Ancillary Services Analogy

The LTPAC sector's relationship with diagnostic imaging is similar to its relationship with external pharmacy, laboratory services, rehabilitation services (PT, OT, SLP)—which are also predominantly **external ancillary services** in LTPAC settings that require sharing of data across multiple parties. Most nursing facilities, assisted living communities, home health agencies, and hospice programs typically do not operate on-site pharmacies or clinical laboratories. Instead, they rely on:

- **Pharmacy services:** Long-term care pharmacies, retail pharmacies, and specialty pharmacies that dispense medications and provide consultant pharmacist services
- **Laboratory services:** Reference laboratories, hospital-based laboratories, and mobile phlebotomy services that perform clinical testing
- **Rehabilitation services:** Over half of LTPAC providers contract with external therapy service providers (physical therapy, occupational therapy, speech-language pathology) where data must be shared

Federal policy has successfully addressed interoperability for these ancillary services through a combination of standards adoption, certification requirements, and market-driven solutions:

- **Electronic prescribing (e-prescribing):** NCPDP SCRIPT standards enable bidirectional exchange of prescriptions, medication histories, and formulary information between EHR systems and pharmacy systems, with three-way communication requirements being phased in for LTPAC settings
- **Laboratory results:** HL7 v2.5.1 and HL7 FHIR standards enable transmission of laboratory orders and results between EHR systems and laboratory information systems
- **Certification criteria:** ONC Health IT Certification Program includes criteria for e-prescribing (§170.315(b)(3)) and clinical information reconciliation (§170.315(b)(2)), supporting pharmacy and lab data exchange

These standards and policies have created a foundation for data flows and **three-way communication between ancillary service providers, ordering physicians, and LTPAC EHR systems**. Prescriptions are transmitted electronically, medication histories are retrieved, laboratory results are delivered in structured formats, and clinical decision support can operate on this data.

Diagnostic imaging interoperability in LTPAC requires the same level of policy focus, adoption of mature standards, and three-way communication and flow of information.

Currently, imaging interoperability lags significantly behind pharmacy and laboratory:

- No widely adopted standards mandate bidirectional imaging exchange between ancillary imaging providers, ordering physicians, and LTPAC EHR systems
- LTPAC EHR vendors often lack robust support for receiving, storing, and displaying DICOM images or FHIR-based imaging references
- Imaging service vendors (portable X-ray, mobile ultrasound) have limited interoperability capabilities compared to pharmacy and laboratory vendors
- No certification criteria specifically address the ancillary imaging service workflow prevalent in LTPAC settings and three-way communication requirements

This disparity creates care coordination gaps, duplicative testing, delayed diagnoses, and administrative burden for LTPAC providers and their patients.

Response to RFI Questions

PM-1: Barriers Patients Experience with Electronic Access to Diagnostic Images

Given that many LTPAC residents have cognitive impairments or limited mobility, and frequently require responsible caregivers to act as their advocates, several significant barriers exist:

Reliance on Physical Media (CDs/DVDs): When LTPAC residents require imaging at hospitals or outpatient facilities, results are frequently provided on CDs or DVDs that must be physically transported back to the LTPAC setting. This creates multiple problems:

- **Caregiver burden:** Family caregivers or facility staff must manage physical media during care transitions
- **Media incompatibility:** LTPAC facilities often lack CD/DVD drives or compatible workstations to view images
- **Lost media:** Physical media is easily misplaced during transitions, particularly during emergency department visits or unplanned hospitalizations
- **Delayed access:** Days or weeks may pass before images are available to LTPAC clinical teams

Portal Fragmentation: Patients and caregivers must navigate multiple hospital portals, imaging center portals, and LTPAC facility portals—each with different login credentials, interfaces, and capabilities. For elderly patients with cognitive impairments and family caregivers managing complex care needs, this fragmentation is particularly burdensome.

Lack of Proxy Access: Many LTPAC residents require surrogate decision-makers (family members, legal guardians, healthcare proxies). However, patient-facing imaging access tools often lack robust proxy access mechanisms that would allow authorized caregivers to retrieve imaging on behalf of residents who cannot navigate technology independently.

Digital Literacy Barriers: The LTPAC population includes many individuals who lack experience with smartphones, computers, or patient portals. Even when electronic access is technically available, practical access remains limited due to digital literacy challenges.

Limited Longitudinal Access: When LTPAC residents move between care settings (hospital to skilled nursing facility, nursing facility to assisted living), prior imaging from previous providers is often inaccessible. Unlike pharmacy medication histories that can be electronically retrieved, there is no equivalent universal imaging history accessible to LTPAC providers.

Network Infrastructure Limitations: Many LTPAC facilities, particularly in rural areas, lack adequate broadband connectivity to support large image file transfers. This bandwidth constraint means that even when electronic imaging access is available, the practical ability to receive and view full-resolution images may be limited.

Successful Examples: The LTPAC sector has seen limited examples of successful electronic imaging access. Some regional health information exchanges (HIEs) have enabled imaging

exchange between hospitals and affiliated LTPAC providers, but these remain localized successes rather than scalable national models.

PM-2: Policies to Accelerate Electronic Diagnostic Image Access and Exchange

LTPAC-specific policy recommendations:

Extend Interoperability Requirements to Ancillary Imaging Service Providers: Just as e-prescribing standards apply to pharmacy vendors serving LTPAC, similar standards should apply to portable X-ray companies, mobile imaging services, and other ancillary imaging providers. ASTP/ONC should:

- Adopt standards requiring ancillary imaging service providers to transmit imaging results electronically to LTPAC EHR systems
- Establish certification criteria for imaging service vendor systems, ensuring they support standards-based exchange (DICOM, DICOMweb, FHIR ImagingStudy, IHE profiles)
- Phase out CMS reimbursement for ancillary imaging services that rely solely on physical media or fax-based result delivery

Align Diagnostic Imaging with USCDI and PACIO Standards: The United States Core Data for Interoperability (USCDI) includes Clinical Notes, Laboratory, and Medications but lacks comprehensive diagnostic imaging data elements[7]. ASTP/ONC should:

- Expand USCDI to include diagnostic imaging data elements (imaging study metadata, image references, radiology reports, structured findings)
- Leverage the PACIO Project's work on post-acute care data exchange to develop FHIR implementation guides specific to LTPAC imaging workflows
- Ensure that imaging data elements address functional imaging relevant to LTPAC populations (fall risk assessment via gait analysis, pressure injury imaging, aspiration risk via swallow studies)

Establish Bidirectional Exchange Requirements for LTPAC EHR Systems: Current certification criteria focus heavily on hospital and ambulatory EHR capabilities. ASTP/ONC should:

- Develop certification criteria specifically addressing LTPAC EHR systems' ability to receive, store, display, and integrate imaging data from external ancillary service providers
- Require support for FHIR ImagingStudy resource and DICOMweb APIs to enable standardized imaging access

- Ensure that LTPAC EHR vendors support imaging data reconciliation during care transitions (similar to medication reconciliation requirements)
- Address the need for LTPAC systems to participate in three-way communication workflows for imaging orders, scheduling, and results

Address the Referral and Prior Authorization Loop: Standards must address the complete workflow from physician order through imaging service delivery and result reporting, including:

- Electronic prior authorization processes that include all parties (ordering physician, LTPAC provider, imaging service, payer)
- Referral management workflows that coordinate scheduling, transportation, clinical documentation requirements
- Consent management across organizational boundaries
- Clinical context sharing to support appropriate imaging utilization and interpretation

This mirrors the approach taken in pharmacy e-prescribing where three-way communication ensures that prescriptions, medication administration records, and clinical updates flow appropriately between physicians, pharmacies, and LTPAC facilities.

Incentivize Imaging Interoperability Through Value-Based Payment Models: CMS should incorporate imaging interoperability into LTPAC quality reporting and value-based payment programs:

- Include electronic imaging exchange as a measure in the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program
- Reward LTPAC providers who successfully reduce duplicative imaging through effective information exchange
- Provide financial incentives for adoption of interoperable imaging workflows in Home Health Quality Reporting Program and Hospice Quality Reporting Program

Address Information Blocking in Imaging: The 21st Century Cures Act information blocking provisions should be clarified and enforced for imaging:

- Clarify that hospitals and imaging centers cannot refuse to provide imaging data to downstream LTPAC providers in their role as care coordinators
- Prohibit practices that limit LTPAC providers to low-resolution web viewers or PDF-encapsulated images when higher-quality source data exists
- Ensure that prior imaging studies are accessible to LTPAC providers for continuity of care

PM-2A: Policy, Financial, and Compliance Barriers

LTPAC-specific barriers include:

- **Contract limitations:** LTPAC providers often have limited negotiating power with ancillary imaging service vendors, who may not offer interoperable solutions or may charge premium fees for electronic exchange
- **Liability concerns:** LTPAC clinical staff may be uncertain about their liability when relying on imaging interpretations provided by external radiologists who lack access to the full patient context documented in the LTPAC EHR
- **State regulations:** Some state regulations governing nursing facilities may not explicitly address electronic imaging workflows, creating ambiguity about documentation and recordkeeping requirements
- **HIPAA complexity:** LTPAC providers express concerns about HIPAA compliance when imaging data flows through multiple entities (imaging service provider, teleradiology vendor, LTPAC facility), particularly when business associate agreements are unclear
- **Reimbursement inadequacy:** LTPAC providers receive no additional reimbursement for the care coordination work required to manage external imaging workflows, yet bear the administrative burden

PM-2B: Technical and Interoperability Concerns

- **Heterogeneous vendor ecosystems:** LTPAC providers may work with dozens of ancillary service vendors (multiple portable X-ray companies, various mobile imaging providers), each with different technical capabilities
- **Limited LTPAC EHR vendor support:** Many LTPAC EHR systems were not designed with imaging integration as a core capability, lacking DICOM viewers, FHIR ImagingStudy support, or robust image storage
- **Authorization and identity management:** Establishing trust relationships and authorization frameworks across multiple unaffiliated organizations (LTPAC provider, imaging service vendor, interpreting radiologist) remains technically complex
- **Provenance and data integrity:** LTPAC providers need assurance that imaging data received electronically is authentic, unaltered, and accurately attributed to the correct patient and study
- **Bandwidth constraints:** Many LTPAC facilities, especially in rural areas, lack sufficient network bandwidth to routinely receive large DICOM image files, making lightweight references to images stored elsewhere more practical than full image transmission

PM-3: Approaches to Transition from Physical Media to Electronic Exchange

Technical Approaches:

- **FHIR-based imaging references:** Adopt HL7 FHIR ImagingStudy and DocumentReference resources to enable lightweight imaging metadata exchange, with links to full DICOM studies stored in PACS or VNA systems accessible on-demand
- **DICOMweb APIs:** Mandate support for DICOMweb protocols (WADO-RS, QIDO-RS, STOW-RS) to enable RESTful access to imaging studies across organizational boundaries
- **IHE profiles for cross-enterprise exchange:** Leverage Integrating the Healthcare Enterprise (IHE) profiles such as XDS-I (Cross-Enterprise Document Sharing for Imaging) to enable imaging exchange through health information exchanges
- **Cloud-based imaging platforms:** Encourage adoption of cloud-based vendor-neutral archives (VNAs) that can serve as regional imaging repositories accessible to multiple LTPAC providers and ancillary service vendors
- **SMART on FHIR imaging apps:** Support development of SMART on FHIR applications that enable imaging access within LTPAC EHR workflows without requiring full PACS integration
- **Tiered approach to image resolution:** Establish standards that support both structured radiology reports with reference-quality images (for routine access) and on-demand access to full-resolution DICOM images (when clinically necessary), recognizing bandwidth limitations

Operational Approaches:

- **Health information exchange (HIE) participation:** Provide financial incentives and technical assistance to enable LTPAC providers to join regional HIEs that support imaging exchange capabilities
- **TEFCA participation:** Ensure that LTPAC providers can affordably participate in Qualified Health Information Networks (QHINs) under the Trusted Exchange Framework and Common Agreement (TEFCA), with specific support for imaging data exchange and recognition of bidirectional requirements
- **Vendor partnerships:** Encourage partnerships between LTPAC EHR vendors, physician EHR vendors, and imaging service vendors to develop pre-integrated interoperability solutions supporting three-way communication
- **Standard operating procedures:** Develop model workflows and standard operating procedures for electronic imaging exchange in LTPAC settings, addressing ordering, scheduling, result delivery, clinical review, and documentation across all three parties

Policy Approaches:

- **Reimbursement requirements:** CMS should condition reimbursement for ancillary imaging services on electronic result delivery to both the ordering provider's EHR system and the LTPAC provider's EHR system
- **Certification requirements:** Establish certification criteria for LTPAC EHR systems (to receive and display imaging), physician EHR systems (to order and receive results), and ancillary imaging service systems (to transmit imaging electronically to multiple recipients)
- **Financial support:** Provide grant funding and technical assistance to under-resourced LTPAC providers for upgrading infrastructure, training staff, and implementing interoperable imaging workflows—addressing the 15-year technology investment gap from HITECH exclusion
- **Model contracts:** Develop model contract language that LTPAC providers can use when negotiating with ancillary imaging service vendors to ensure electronic exchange capabilities and three-way communication requirements

PM-4: Full Resolution vs. Reference Images

LTPAC-specific considerations:

The appropriate level of image resolution depends on the clinical use case and care setting context. LTPAC providers need flexibility based on their unique workflow patterns and infrastructure constraints.

Full-Resolution DICOM Images Needed For:

- **Specialist consultation:** When LTPAC providers seek telehealth consultation with specialists (pulmonologists, cardiologists, orthopedists) who need to perform detailed image review
- **Longitudinal comparison:** Monitoring chronic conditions (heart failure, COPD, osteoarthritis) requires access to prior full-resolution images to assess progression
- **Transfer of care:** When residents transfer between LTPAC settings or back to acute care, receiving providers may need full diagnostic-quality images
- **Legal and regulatory compliance:** Full-resolution images may be necessary for quality assurance, medical-legal review, or regulatory audits
- **Physician review within facility:** When attending physicians, medical directors, or consulting specialists review patient records at the LTPAC facility using the facility EHR (rather than their own ambulatory EHR), they need access to diagnostic-quality imaging to inform treatment planning

Reference Images and Structured Reports Sufficient For:

- **Primary care review:** LTPAC medical directors and attending physicians often need only to view images alongside radiology reports to inform care decisions
- **Care coordination:** Nurses, therapists, and care coordinators benefit from visual reference but typically do not require diagnostic-quality resolution
- **Patient and family communication:** When discussing findings with residents and families, reference-quality images are usually adequate
- **Clinical decision support:** Automated analysis (e.g., AI-based fracture detection alerts) may operate on reference images or structured report data

Recommendation: ASTP/ONC should adopt a tiered approach that:

- Requires electronic availability of structured radiology reports and reference-quality images as a baseline for all LTPAC providers
- Ensures that full-resolution DICOM images are accessible on-demand when clinically necessary, without requiring LTPAC facilities to maintain local PACS infrastructure
- Supports FHIR ImagingStudy references that link to full-resolution images stored in authoritative repositories (hospital PACS, regional VNA, cloud-based imaging platform)
- Recognizes that LTPAC providers need flexibility based on clinical context, patient acuity, specialty consultation needs, and bandwidth constraints
- Prioritizes structured radiology reports as the primary essential element, with image access (reference or full-resolution) available based on clinical need

Importantly, the certification approach should not mandate that LTPAC EHR systems include full PACS functionality. Rather, standards should enable seamless access to images stored in external systems through web-based viewers, FHIR APIs, or other lightweight integration mechanisms that accommodate bandwidth limitations.

PM-5: Access to Quantitative Parameters Derived from Images

LTPAC-specific needs:

Quantitative imaging parameters are increasingly relevant in LTPAC settings for monitoring chronic conditions, assessing treatment response, and supporting clinical decision-making:

Relevant Quantitative Parameters:

- **Cardiac function:** Ejection fraction, chamber volumes, wall motion abnormalities (for heart failure management)
- **Pulmonary measures:** Lung volume, nodule size, pleural effusion quantification (for COPD, pneumonia, lung cancer monitoring)
- **Bone density:** T-scores and Z-scores from DEXA scans (for osteoporosis management and fracture risk assessment)
- **Vascular studies:** Stenosis percentage, plaque burden, flow velocities (for peripheral arterial disease and stroke risk)
- **Tumor measurements:** Lesion size, RECIST criteria (for oncology patients receiving palliative or maintenance care in LTPAC)
- **Functional imaging:** Gait analysis metrics, joint range-of-motion measurements (for rehabilitation therapy planning)

Current Challenges:

LTPAC clinicians report that quantitative imaging parameters are frequently **manually transcribed** from radiology reports into LTPAC EHR systems because no structured data exchange mechanism exists. This creates risks for:

- **Transcription errors:** Manual data entry introduces errors
- **Data loss:** Quantitative parameters may be overlooked if embedded in unstructured narrative reports
- **Inefficient workflows:** Clinical staff spend time on manual data entry rather than patient care
- **Impaired clinical decision support:** Automated alerts and risk stratification tools cannot operate on unstructured data
- **Incomplete three-way communication:** Quantitative parameters may be communicated to the ordering physician but not to the LTPAC provider, or vice versa

Recommendation:

ASTP/ONC should prioritize structured exchange of quantitative imaging parameters:

- Adopt **HL7 FHIR Observation resource** for representing quantitative imaging findings in computable format
- Include quantitative imaging data elements in **USCDI expansion** efforts
- Develop **LOINC codes** for commonly used quantitative imaging parameters relevant to chronic disease management in LTPAC populations
- Require that ancillary imaging service vendors and interpreting radiologists **provide structured quantitative data** alongside narrative reports to all recipients (ordering physician and LTPAC provider)

- Support **automated extraction** of quantitative parameters from radiology reports using natural language processing, with validation mechanisms to ensure accuracy

Quantitative imaging parameters should flow into both physician EHRs and LTPAC EHR systems with the same level of structure and computability as laboratory results, enabling trending over time, clinical decision support, and quality measurement.

Standards and Certified Health IT Functionality

SC-1: Current Technical Approaches for Imaging Access and Exchange

In LTPAC settings, imaging exchange methods are highly fragmented:

- **Physical media (CDs/DVDs)**: Still the most common method, despite limitations
- **Fax and mail**: Paper radiology reports faxed or mailed to LTPAC facilities
- **Health information exchange (HIE)**: Some LTPAC providers participate in regional HIEs that support imaging exchange through IHE XDS-I or proprietary interfaces
- **Vendor-specific portals**: Imaging service vendors may provide web portals where LTPAC staff must log in to view results (creating workflow disruption and requiring staff time to check multiple systems)
- **Direct messaging**: Limited adoption of Direct Protocol for transmitting imaging reports as attachments
- **Custom point-to-point interfaces**: Large health systems with affiliated LTPAC providers may have custom HL7 v2 or proprietary interfaces

Standards-based exchange remains the exception rather than the rule. DICOM, DICOMweb, FHIR, and IHE profiles are more commonly used **within hospital enterprises** than **across organizational boundaries** to LTPAC providers and ordering physicians in independent practices.

SC-2: Metadata Associated with Diagnostic Images

Imaging metadata in LTPAC workflows should include:

- **Patient demographics**: Name, date of birth, medical record number (with robust patient matching to prevent misidentification across multiple organizations)
- **Study metadata**: Study date, modality, body part examined, number of images/series
- **Clinical context**: Indication for imaging, relevant clinical history, ordering provider information

- **Interpretation:** Radiology report, critical findings, recommendations for follow-up
- **Quantitative findings:** Structured measurements and parameters (as discussed in PM-5)
- **Provenance:** Performing facility, interpreting radiologist, accreditation status
- **Prior studies:** References to prior imaging for comparison purposes
- **Recipient information:** Clear identification of all parties who should receive results (ordering physician and LTPAC provider)

AI-Generated Metadata: Artificial intelligence tools are increasingly used to:

- Auto-detect anatomical structures and label images
- Extract quantitative measurements (nodule size, bone density, ejection fraction)
- Generate structured findings (presence/absence of fracture, pleural effusion, etc.)
- Prioritize worklists based on critical findings

ASTP/ONC should ensure that AI-generated metadata is transparently labeled and that appropriate oversight mechanisms exist to validate accuracy, particularly given concerns about algorithmic bias affecting older adult populations (as detailed in the LTPAC Collaborative's prior comments on AI in clinical care).

SC-3: Technical Barriers Limiting Imaging Interoperability

LTPAC-specific barriers include:

- **Limited LTPAC EHR vendor support:** Many LTPAC EHR systems lack DICOM viewers, FHIR imaging resource support, or robust integration capabilities with external imaging systems
- **Ancillary vendor immaturity:** Portable X-ray and mobile imaging service vendors often have less sophisticated IT capabilities than hospital radiology departments, with limited standards adoption
- **Patient matching challenges:** Ensuring that imaging studies are accurately linked to the correct patient across organizational boundaries remains difficult, particularly for LTPAC residents who may have multiple medical record numbers across different provider systems
- **Network infrastructure limitations:** Some LTPAC facilities, particularly in rural areas, lack adequate broadband connectivity to support large image file transfers
- **Cost barriers:** Implementing imaging interoperability solutions (interfaces, middleware, DICOM viewers) represents significant expense for resource-constrained LTPAC providers who were excluded from HITECH funding

- **Proprietary formats:** Some imaging vendors use proprietary formats or require proprietary viewers, impeding standards-based exchange
- **Three-way routing complexity:** Existing standards and systems are often designed for two-party exchange (ordering provider to imaging service, imaging service to ordering provider) rather than the three-way distribution required in LTPAC workflows

Standards modifications needed:

- **FHIR ImagingStudy resource enhancements:** The FHIR ImagingStudy resource should be enhanced to better support **ancillary service workflows** and **three-way communication**, including clear representation of ordering provider, performing organization, interpreting radiologist, and care coordination entities (LTPAC providers) across organizational boundaries
- **PACIO imaging implementation guide:** The PACIO Project should develop an HL7 FHIR implementation guide specific to LTPAC imaging workflows, addressing portable X-ray, mobile imaging, three-way communication requirements, and care transition imaging exchange
- **DICOMweb adoption guidance:** Clear implementation guidance is needed for how ancillary imaging service vendors should support DICOMweb APIs to enable LTPAC EHR system access while accommodating bandwidth constraints

SC-4: Role of Certified Health IT and EHRs in Diagnostic Image Exchange

In LTPAC settings, EHR systems should play an active facilitation role in imaging exchange, but they are currently limited by:

- **Lack of certification requirements:** Current ONC certification criteria do not specifically address LTPAC EHR capabilities for receiving, displaying, and integrating imaging data from external ancillary service providers
- **Vendor prioritization:** LTPAC EHR vendors have limited business incentive to invest in imaging interoperability when certification does not require it and LTPAC providers have constrained budgets
- **Workflow fragmentation:** Without EHR integration, LTPAC clinical staff must access separate systems (imaging vendor portals, HIE portals) to view imaging, disrupting care workflows

LTPAC EHR systems should be certified to:

- **Receive imaging orders and results** via standards-based exchange (FHIR, HL7 v2, Direct)
- **Display radiology reports** within the EHR clinical workflow
- **Provide access to images** either through embedded DICOM viewers or seamless launch of external viewers (SMART on FHIR apps, DICOMweb viewers)
- **Support imaging data reconciliation** during care transitions, similar to medication reconciliation requirements
- **Enable image references in clinical documentation**, care plans, and communication with other providers
- **Participate in three-way communication workflows** for imaging orders, scheduling, and results distribution

Meanwhile, imaging systems (PACS, VNA, ancillary service vendor systems) should be certified or held to standards requiring:

- Electronic transmission of imaging results to multiple recipients (ordering physician and LTPAC provider) with appropriate routing
- Support for FHIR APIs, DICOMweb, and/or IHE profiles
- Structured metadata and quantitative parameter exchange
- Bandwidth-efficient delivery options (structured reports and reference images as baseline, full-resolution on demand)

Physician EHR systems should also support three-way workflows:

- Order transmission to imaging services with copy to LTPAC provider for care coordination
- Receipt of imaging results with ability to share with LTPAC provider
- Support for referral and prior authorization workflows that include LTPAC provider participation

The division of responsibility should mirror the pharmacy model: just as LTPAC EHR systems receive e-prescriptions and pharmacy systems transmit them (with three-way communication including physicians, pharmacies, and LTPAC facilities), LTPAC EHR systems should receive imaging results and imaging service systems should transmit them electronically to all relevant parties.

SC-5: Updating the Certification Program to Support Imaging

Yes, ASTP/ONC should update the Certification Program to explicitly address diagnostic imaging interoperability, with specific attention to the ancillary service model and three-way communication requirements prevalent in LTPAC settings.

Recommended certification criteria:

For LTPAC EHR Systems (Receiving Systems):

- **Imaging result receipt:** Ability to receive imaging study notifications, radiology reports, and image references via FHIR ImagingStudy, FHIR DocumentReference, HL7 v2 ORU messages, or Direct messaging
- **Display capabilities:** Ability to display radiology reports within EHR workflow and provide access to images through embedded viewers or launched applications
- **Data reconciliation:** Ability to reconcile imaging results received from external sources during care transitions and incorporate into longitudinal patient record
- **Patient access:** Ability to make imaging reports and image references available through patient portals and FHIR APIs (view, download, and transmit)
- **Clinical decision support integration:** Ability to use structured imaging findings and quantitative parameters in clinical decision support rules

For Physician EHR Systems (Ordering Systems):

- **Imaging order transmission:** Ability to transmit imaging orders electronically to imaging service providers with appropriate clinical context
- **Multi-recipient result routing:** Ability to receive imaging results and facilitate sharing with LTPAC providers involved in patient care
- **Referral and prior authorization workflows:** Support for electronic prior authorization and referral management including LTPAC provider participation

For Imaging Service Vendor Systems (Transmitting Systems):

- **Electronic result transmission:** Ability to transmit radiology reports and image references to multiple recipients (ordering provider and LTPAC provider) via standards-based exchange
- **FHIR API support:** Support for FHIR ImagingStudy resource and DICOMweb APIs to enable external system access to images
- **Structured data:** Ability to provide quantitative imaging parameters in structured format (FHIR Observation resources)
- **Metadata completeness:** Ability to provide complete study metadata, including provenance, clinical context, and prior study references
- **Bandwidth-sensitive delivery:** Support for tiered delivery (structured reports and reference images as baseline, full-resolution on-demand)

USCDI Expansion:

Diagnostic imaging data elements should be added to USCDI, including:

- Imaging study metadata (modality, body part, study date)
- Radiology reports (structured and narrative)
- Image references (links to DICOM studies)
- Quantitative imaging parameters (measurements, calculated values)
- Critical findings and follow-up recommendations

This would ensure that imaging data is treated with the same interoperability expectations as laboratory results, medications, and other core clinical data.

SC-6: Focus on Specific Use Cases

LTPAC-relevant imaging use cases that warrant specific attention:

- **Portable chest X-ray:** The most common imaging modality in LTPAC settings, used for pneumonia diagnosis, heart failure monitoring, and aspiration assessment
- **Bone density (DEXA) scans:** Critical for osteoporosis management and fracture risk assessment in elderly populations
- **Echocardiography:** Essential for heart failure management, valve disease monitoring, and cardiac function assessment
- **Vascular ultrasound:** Used for deep vein thrombosis diagnosis, peripheral arterial disease assessment, and stroke risk evaluation
- **Wound imaging:** Pressure injury assessment, healing progress monitoring (increasingly using smartphone-based imaging and AI analysis)
- **Functional imaging:** Gait analysis, swallow studies, and other functional assessments relevant to rehabilitation and therapy planning

While we do not recommend fragmented, specialty-specific approaches, **use case guidance** should address workflows common in LTPAC settings rather than assuming hospital-based radiology department workflows. Specifically, guidance should address:

- How portable imaging services integrate with LTPAC and physician EHR systems
- How three-way communication operates for common LTPAC imaging scenarios
- How bandwidth constraints affect workflow design
- How care coordination roles are supported through imaging data exchange

SC-7: Certification of Image Management Systems (PACS/VNA)

We support the concept of certifying image management systems to improve interoperability, with important caveats:

- **Certification should focus on interoperability capabilities** (support for FHIR APIs, DICOMweb, IHE profiles) rather than clinical functionality
- **Ancillary imaging service vendor systems** should be included in certification scope, not only hospital PACS/VNA systems
- **Certification should be voluntary** initially to avoid market disruption, with incentives for adoption through reimbursement policy
- **Standards should enable lightweight integration**, not require LTPAC providers to implement full PACS infrastructure

Recommended certification criteria for imaging systems:

- Support for FHIR ImagingStudy and DocumentReference resources via FHIR APIs
- Support for DICOMweb protocols (WADO-RS, QIDO-RS, STOW-RS)
- Ability to transmit radiology reports via multiple modalities (HL7 v2, FHIR, Direct) to multiple recipients
- Support for external viewer access through SMART on FHIR or web-based DICOM viewers
- Ability to provide structured quantitative parameters via FHIR Observation resources
- Support for patient access to images through patient-facing apps
- Support for three-way communication routing and distribution

SC-8: Standards Adoption Beyond Certification

Beyond certification, ASTP/ONC should adopt standards on behalf of HHS to improve interoperability and health IT alignment:

- **HL7 FHIR ImagingStudy and DocumentReference** resources as the standard for imaging metadata exchange
- **DICOMweb** as the standard for RESTful access to DICOM images
- **IHE profiles** (XDS-I, XCA-I) for cross-enterprise imaging exchange through HIEs
- **LOINC and SNOMED CT** codes for imaging procedures, findings, and recommendation

- **PACIO imaging implementation guide** (to be developed) for LTPAC-specific imaging workflows and three-way communication
- **Three-way communication standards** adapted from pharmacy e-prescribing models for imaging order and result routing

These standards should be incorporated into the HHS Health IT Alignment Program, guiding adoption across federal agencies (CMS, VA, IHS, DOD).

SC-9: Privacy and Security Concerns Specific to Diagnostic Images

LTPAC-specific privacy and security considerations:

- **Sensitive imaging:** Some imaging studies may reveal highly sensitive information (HIV-related complications, substance abuse injuries, psychiatric conditions) requiring enhanced privacy protections
- **Facial recognition risk:** Imaging of head/face creates potential for biometric identification and unauthorized re-identification of de-identified datasets
- **Large file sizes:** Transmitting and storing large imaging files creates network security and data breach risks, particularly when LTPAC facilities have limited cybersecurity resources
- **Third-party access:** LTPAC providers may lack expertise to properly configure access controls when imaging data flows through multiple parties (physician, LTPAC, imaging service, radiologist)
- **Multi-organizational consent:** When imaging data flows to multiple recipients (three-way communication), ensuring that patient consent covers all parties and uses becomes more complex

Recommendations:

- Ensure that privacy and security guidance addresses multi-party data flows characteristic of LTPAC workflows
- Provide model business associate agreements for LTPAC providers contracting with ancillary imaging services
- Develop segmentation standards that allow sensitive imaging to be appropriately restricted while maintaining workflow utility
- Include audit logging requirements in certification criteria to track who accesses imaging across organizational boundaries

- Provide technical assistance to under-resourced LTPAC providers on implementing appropriate privacy and security controls

Financial Support and Technical Assistance for LTPAC Providers

LTPAC providers face unique financial challenges in implementing imaging interoperability due to:

- **HITECH Act exclusion:** LTPAC providers were excluded from the HITECH Act Meaningful Use incentive programs, creating a 15-year technology investment gap compared to hospitals and physician practices
- **Limited operating margins:** Skilled nursing facilities, home health agencies, and hospice programs operate on thin margins, with limited capital for IT infrastructure investments
- **Resource constraints:** Small and rural LTPAC providers lack in-house IT expertise and rely heavily on vendor support
- **Bandwidth costs:** Upgrading network infrastructure to support imaging data exchange, particularly in rural areas, represents significant ongoing expense

Recommendations:

- **Grant programs:** Establish dedicated grant programs to support LTPAC providers in implementing imaging interoperability capabilities, including EHR upgrades, network infrastructure improvements, and interface development
- **Technical assistance:** Provide regional extension centers or similar technical assistance programs specifically focused on LTPAC imaging interoperability implementation
- **Model contracts and implementation guides:** Develop practical resources that LTPAC providers can use when negotiating with imaging service vendors and implementing workflows
- **Reimbursement support:** Consider CMS payment adjustments that recognize the care coordination work and infrastructure costs associated with electronic imaging data exchange
- **Vendor incentives:** Create financial incentives for LTPAC EHR vendors and imaging service vendors to develop pre-integrated, cost-effective interoperability solutions

Aligning to Broader Interoperability Initiatives

Diagnostic imaging interoperability for LTPAC should align with broader federal initiatives:

- **USCDI expansion:** Include diagnostic imaging data elements in future USCDI versions
- **PACIO Project:** Leverage PACIO FHIR implementation guides for post-acute care data exchange, developing imaging-specific profiles
- **TEFCA:** Ensure that imaging exchange is supported through TEFCA's Qualified Health Information Networks with appropriate consideration for three-way communication requirements
- **Prior authorization rules:** Align imaging prior authorization processes with CMS prior authorization interoperability rules
- **Information blocking:** Clarify that imaging data is subject to information blocking provisions and that LTPAC providers have rights to access imaging data for care coordination
- **AI in clinical care:** Coordinate with ongoing AI policy development to address AI-generated imaging findings and metadata
- **Pharmacy e-prescribing:** Learn from the successful three-way communication model established for pharmacy e-prescribing when designing imaging exchange workflows

Conclusion

The LTPAC Health IT Collaborative strongly supports ASTP/ONC's efforts to improve diagnostic imaging interoperability. However, we emphasize that imaging interoperability policies must explicitly address the ancillary service model and three-way communication requirements that characterize LTPAC workflows.

LTPAC providers do not operate integrated imaging departments. Instead, they coordinate care across multiple organizations—ordering physicians with independent EHR systems, ancillary imaging service providers with varying technical capabilities, and LTPAC facilities serving as care coordinators. Effective imaging interoperability requires that:

- **Standards support three-way communication** between physicians, imaging services, and LTPAC providers
- **Certification criteria address receiving systems** (LTPAC EHRs) as well as transmitting systems (imaging services and physician EHRs)
- **Policy incentives align** across pharmacy, laboratory, and imaging as comparable ancillary services
- **Financial support addresses** the 15-year technology investment gap from HITECH exclusion



- **Bandwidth realities are recognized**, with tiered approaches to image resolution and structured report priority
- **Workflow complexity is acknowledged**, including referral loops, prior authorization, and consent management across organizational boundaries

Without this explicit focus on LTPAC-specific needs, imaging interoperability policies risk perpetuating existing disparities, leaving the most vulnerable patient populations—older adults with complex chronic conditions requiring coordinated care—without the benefits of seamless imaging data exchange.

We appreciate the opportunity to provide these comments and stand ready to assist ASTP/ONC in developing imaging interoperability policies that serve all Americans across the full continuum of care.

Sincerely,

The LTPAC Health IT Collaborative

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