

A briefing on federal regulatory developments affecting diagnostic imaging interoperability, artificial intelligence, and digital quality measurement.

Primary Policy Signal of the Month: **ONC Diagnostic Imaging Interoperability and Data Access Policy Signals**

Recent policy discussions within the Office of the National Coordinator for Health IT (ONC), now operating under the Assistant Secretary for Technology Policy (ASTP), continue to emphasize expanded interoperability requirements across clinical data domains, including diagnostic imaging. Several initiatives involving USCDI expansion, FHIR-based access frameworks, and health information exchange policies are increasingly relevant to imaging workflows.

Although imaging is not always the primary focus of these initiatives, expanding expectations around structured clinical data exchange, standardized APIs, and data access frameworks are likely to influence how imaging metadata, reports, and potentially imaging objects themselves are exchanged across systems. As digital quality measurement and AI-enabled clinical decision support expand, regulatory attention may increasingly shift toward ensuring that imaging data can participate in broader health information ecosystems.

These developments represent a significant policy signal for imaging interoperability and may warrant continued engagement by the imaging informatics community to ensure that imaging workflows, imaging metadata, and radiology reporting structures are appropriately represented in national interoperability frameworks.

KEY REGULATORY DEVELOPMENTS

CMS OPPTS and Digital Quality Measurement Policy Activity

Recent policy activity related to hospital outpatient payment systems and digital quality measurement programs continues to reinforce the federal transition toward digital quality measurement infrastructure. As CMS advances

digital quality measurement frameworks, hospitals and health systems may experience increasing expectations around standardized clinical data capture and reporting.

Although these initiatives are not imaging-specific, imaging departments frequently participate in hospital quality measurement workflows, particularly when imaging is part of diagnostic pathways or treatment monitoring.

As digital quality measurement frameworks expand, the ability to reliably extract imaging-related clinical data from reporting systems and structured reports may become increasingly important.

These developments suggest continued convergence between imaging informatics, health IT infrastructure, and quality measurement programs.

HHS Artificial Intelligence Policy and Governance Initiatives

Several federal agencies continue to explore policy frameworks related to artificial intelligence governance in healthcare. These discussions include transparency expectations, performance monitoring considerations, and oversight structures for AI-enabled clinical tools.

Imaging represents one of the most mature and widely adopted domains for clinical AI deployment. As federal AI governance policies evolve, imaging AI systems—including triage tools, detection algorithms, and workflow orchestration systems—may increasingly fall within broader federal oversight frameworks.

Radiology stakeholders may therefore benefit from continued engagement in policy discussions related to AI validation, performance monitoring, and integration into clinical workflows.

IHE OPPORTUNITY SIGNALS

Imaging Interoperability in National Health Data Exchange

Federal interoperability policy increasingly focuses on structured clinical data exchange using standardized APIs and data models.

Imaging data has historically been exchanged using specialized imaging standards and workflows that differ from many other clinical data types.

As interoperability initiatives evolve, there may be opportunities to ensure that imaging workflows, imaging metadata, and imaging-related clinical reporting structures remain aligned with broader national interoperability frameworks. Profiles that support imaging workflow coordination, image availability, and reporting interoperability may play an important role in maintaining efficient cross-system imaging access.

IHE Leadership Discussion Consideration

Expanding federal interoperability frameworks may create opportunities for imaging-specific workflow standards to contribute to broader health data exchange architectures.

AI Integration within Imaging Workflows

Federal AI governance discussions frequently focus on algorithm transparency and validation. However, many operational challenges associated with AI deployment arise from workflow integration rather than algorithm performance alone.

Multi-vendor environments that include imaging modalities, PACS systems, reporting systems, and AI applications may benefit from clearly defined workflow integration standards. Structured approaches to validating AI workflow integration could reduce implementation complexity and improve reliability in clinical environments.

IHE Leadership Discussion Consideration

Federal attention to AI governance may create opportunities to highlight the importance of

standardized workflow integration for clinical AI deployment.

REGULATORY EARLY WARNING DASHBOARD

Artificial Intelligence Governance Expansion

Federal policy activity suggests continued development of AI oversight frameworks across healthcare sectors. Future initiatives may include expectations around monitoring of AI performance, transparency of training data characteristics, and operational oversight of AI-enabled clinical tools.

Given the widespread deployment of AI in imaging, radiology may serve as a reference domain for broader clinical AI governance approaches.

Likelihood: **Moderate**

Monitoring Recommendation:

Continue monitoring federal AI policy development and potential implications for imaging AI deployment.

Likelihood: **Moderate**

Monitoring Recommendation:

Monitor digital quality measurement initiatives and potential implications for imaging data capture and reporting structures.

SELECTED REGULATORY LINKS

ONC / ASTP Health IT Policy Activity

<https://www.healthit.gov>

CMS Digital Quality Measurement Initiative

<https://www.cms.gov/medicare/quality/digital-quality-measures>

HHS Artificial Intelligence Policy Initiatives

<https://www.hhs.gov/ai>

Federal Register – Health and Human Services

<https://www.federalregister.gov/agencies/health-and-human-services-department>

Digital Quality Measurement Infrastructure

Federal programs continue to transition toward digital quality measurement architectures. This transition may affect hospital reporting systems, clinical data capture workflows, and the use of structured clinical information.

As quality measurement increasingly relies on standardized clinical data models, the ability to incorporate imaging-related clinical information into these models may become increasingly relevant.