IHE Radiology Global Regulatory Monitoring Report

Volume 1 | Special Edition | July 15, 2026

PREPARED BY IHE RADIOLOGY PLANNING COMMITTEE

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Monitoring period	July 7, 2026 - July 15, 2026
Discovery window used	July 7, 2026 - July 15, 2026 (special edition; two supplied CMS proposed rules only)
Source policy	All included items were verified against official government sources and include working official links.

Prepared for strategic monitoring of diagnostic imaging, interoperability, clinical AI governance, and digital health infrastructure.

1. Executive Summary

This special edition reviews only the two official CMS documents supplied for analysis: the CY 2027 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center proposed rule (CMS-1850-P) and the CY 2027 Medicare Physician Fee Schedule proposed rule (CMS-1848-P). The review window was July 7 through July 15, 2026; the MPFS document is an official prepublication version scheduled for Federal Register publication on July 16. Discovery was conducted within both complete rules using the protocol v14 imaging, interoperability, artificial intelligence, software, quality-measure, and payment search terms, supplemented by table-of-contents review and targeted reading of relevant sections. Candidate items were verified against the supplied official CMS documents, screened for active status, scored for IHE Radiology relevance, and directly compared with the uploaded prior monitoring report before construction; no other countries, regions, or regulatory sources were searched for this special edition.

The strongest policy developments are unusually concentrated in areas central to radiology. The HOPPS proposal would apply PFS-equivalent payment to specified imaging-without-contrast APCs at excepted off-campus provider-based departments, establish an interim OPPS framework and a new status indicator for Software as a Medical Service, retain voluntary status for the hospital-level outpatient CT excessive-radiation-dose or inadequate-image-quality eCQM through the CY 2032 payment determination, and revise nuclear medicine APC and diagnostic radiopharmaceutical payment policies. The MPFS proposal adds a major RFI on duplicate imaging, result sharing, and interoperability; seeks

comment on a staged transition to FHIR-based digital quality measures; modifies the Diagnostic Radiology MIPS Value Pathway; proposes improvement activities for responsible AI use, diagnostic performance, and interoperable clinical decision support; and would revise the practice-expense methodology that affects imaging services.

Strategically, the two rules show CMS using payment policy, quality measurement, and program-integrity tools to push radiology toward more portable results, fewer avoidable repeat examinations, more explicit governance of algorithmic services, and more computable quality data. None of the proposals mandates an IHE profile, and several of the most important concepts remain requests for information rather than proposed requirements. Nevertheless, the rules create immediate opportunities for IHE Radiology to explain the technical difference between report exchange and complete imaging exchange, demonstrate standards-based pathways for image discovery and retrieval, connect imaging-native DICOM data to FHIR quality reporting, and provide testable implementation patterns for AI workflow, results, provenance, and monitoring. The most time-sensitive engagement windows are the August 31, 2026 HOPPS comment deadline and the September 14, 2026 MPFS comment deadline.

2. Policy Signal Dashboard

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
PFS-equivalent payment for imaging without contrast at excepted off-campus PBDs	CMS	Federal Register - Proposed Rule	July 7, 2026	August 31, 2026	5
Cross-setting payment framework for Software as a Medical Service (SaMS)	CMS	Federal Register - Proposed Rules	July 7 and July 16, 2026	August 31 and September 14, 2026	5
Hospital outpatient CT excessive-radiation-dose/image-quality eCQM remains voluntary through CY 2032	CMS	Federal Register - Proposed Rule / finalized measure-set continuation	July 7, 2026	August 31, 2026	5
Nuclear medicine APC restructuring and radiopharmaceutical payment thresholds	CMS	Federal Register - Proposed Rule	July 7, 2026	August 31, 2026	5
RFI on duplicate imaging, result sharing, and interoperability	CMS	Federal Register - Request for Information within Proposed Rule	July 16, 2026 (scheduled)	September 14, 2026	5
RFI on transition to FHIR-based digital quality measures	CMS	Federal Register - Request for Information within Proposed Rule	July 16, 2026 (scheduled)	September 14, 2026	4
Diagnostic Radiology MVP modifications, including CT dose measures	CMS	Federal Register - Proposed QPP policy	July 16, 2026 (scheduled)	September 14, 2026	5
MIPS improvement activities for responsible AI, diagnostic performance, and interoperable CDS	CMS	Federal Register - Proposed QPP policy	July 16, 2026 (scheduled)	September 14, 2026	4

Title	Agency	Policy Type	Publication Date	Comment Deadline	Relevance Score
PFS practice-expense methodology changes and radiology specialty impacts	CMS	Federal Register - Proposed payment policy	July 16, 2026 (scheduled)	September 14, 2026	3

3. North America Regulatory Scan

United States

PFS-Equivalent Payment for Imaging Without Contrast at Excepted Off-Campus Provider-Based Departments

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Rule; OPPS volume-control and site-specific payment policy

Publication Date: July 7, 2026

Official Source Link: Official HOPPS/ASC proposed rule | Comment docket

Comment Deadline: August 31, 2026

Summary: CMS proposes to pay a site-specific PFS-equivalent rate for HCPCS codes assigned to imaging-without-contrast APCs 5521 through 5524 and composite APCs 8004 (ultrasound), 8005 (CT/CTA without contrast), and 8007 (MRI/MRA without contrast) when furnished at excepted off-campus provider-based departments billing modifier PO. CMS reports that average OPPS rates for these departments are about 2.5 times PFS rates and that PFS payments across the affected APCs range from approximately 31 to 54 percent of OPPS payments. The proposal would be implemented non-budget-neutrally and is estimated to save $260 million in CY 2027, including $70 million in reduced beneficiary coinsurance, and $7.2 billion in net Part B spending from 2027 through 2036. Rural sole community hospitals would be exempt and would continue receiving full OPPS payment, including the existing 7.1-percent rural adjustment. (HOPPS proposed rule PDF pp. 430-447.)

Impact Assessment:

- **Imaging Operations:** Direct and potentially substantial. The proposal could change the financial viability and site-of-service strategy for noncontrast radiography, ultrasound, CT, and MRI furnished in affected off-campus departments; it may also redistribute imaging volume across hospital and freestanding settings.
- **AI Governance:** Indirect. Reduced technical margins may affect the resources available for purchasing, integrating, and monitoring AI and other software used in outpatient imaging, but the proposal does not establish AI requirements.
- **Interoperability:** Operationally important but not mandated. Greater movement of imaging among hospital, office, and freestanding settings increases the value of reliable cross-enterprise image and report discovery, retrieval, identity matching, and continuity of prior-exam access.

Relevance Score: 5

Cross-Setting Payment Framework for Software as a Medical Service (SaMS)

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Rules; OPPS and PFS algorithmic-service payment policy

Publication Date: July 7, 2026 (HOPPS) and July 16, 2026 scheduled publication (MPFS)

Official Source Link: Official HOPPS/ASC proposed rule | Official MPFS proposed rule

Comment Deadline: August 31, 2026 for HOPPS; September 14, 2026 for MPFS

Summary: CMS proposes replacing its prior Software as a Service terminology with Software as a Medical Service to describe software-based technologies that support clinical decision-making through algorithmic analysis, including clinical and diagnostic functions. Under the HOPPS proposal, CMS would designate 36 HCPCS codes as SaMS, move 21 separately paid services from clinical APCs to New Technology APCs while generally maintaining approximate CY 2026 payment continuity, and create status indicator O1 for separately paid SaMS; Table 61 includes numerous CT, MRI, cardiac, bone, retinal, and other imaging analyses. The MPFS companion proposal would move ten stand-alone algorithmic laboratory-data analyses from the Clinical Laboratory Fee Schedule to contractor pricing under the PFS and states that algorithmic analyses of imaging tests and prior laboratory data should be treated consistently within the broader SaMS framework. CMS describes the CY 2027 approach as interim and continues to seek a more comprehensive methodology that addresses limited cost transparency, proprietary algorithms, subscription or per-use arrangements, and program-integrity concerns. (HOPPS PDF pp. 448-462; MPFS PDF pp. 208-213.)

Impact Assessment:

- **Imaging Operations:** Direct. The proposal creates a more visible payment category for algorithmic imaging services and may influence coding, contracting, workflow placement, and whether a software output is separately paid, packaged, or not payable.
- **AI Governance:** Direct. CMS is distinguishing medically functional algorithmic services from general cloud software and is asking how payment should account for proprietary, scalable, and outcome-related value; payment recognition does not itself establish clinical validation, monitoring, or governance requirements.
- **Interoperability:** Material. SaMS depends on dependable access to source images and clinical context, structured return of results, provenance, and incorporation into the interpreting and downstream clinical workflow. These technical requirements are not specified by the payment proposal.

Relevance Score: 5

Hospital Outpatient CT Excessive-Radiation-Dose or Inadequate-Image-Quality eCQM Remains Voluntary Through CY 2032

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Rule; continuation of previously finalized Hospital Outpatient Quality Reporting measure set

Publication Date: July 7, 2026

Official Source Link: Official HOPPS/ASC proposed rule | Comment docket

Comment Deadline: August 31, 2026

Summary: CMS states that it is not proposing any other changes to the Hospital Outpatient Quality Reporting Program measure set beyond an unrelated colonoscopy measure proposal. Table 72 lists measure 3663e, Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level-Outpatient), as voluntary for the CY 2028, 2029, 2030, 2031, and 2032 payment determinations. The table expressly defines voluntary submission as optional and states that hospital outpatient departments that do not report the measure are not subject to a payment reduction for nonreporting. This does not preclude later rulemaking, but the current proposed rule does not establish mandatory Hospital OQR reporting or a payment consequence for this measure through CY 2032. (HOPPS PDF pp. 541-543.)

Impact Assessment:

- **Imaging Operations:** Direct. Hospitals considering implementation can treat the Hospital OQR measure as voluntary under the currently displayed measure set, while continuing to monitor future rulemaking and local quality priorities.
- **AI Governance:** Limited direct effect. The measure uses automated image-quality and dose-related data concepts, but the proposal does not create an AI governance policy.
- **Interoperability:** Potentially significant for voluntary adopters. Reliable acquisition of dose, patient-size, category, and image-quality data requires clear data provenance and a defensible path from imaging systems to the eCQM reporting environment.

Relevance Score: 5

Nuclear Medicine APC Restructuring and Radiopharmaceutical Payment Thresholds

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Rule; OPPS APC and radiopharmaceutical payment policy

Publication Date: July 7, 2026

Official Source Link: Official HOPPS/ASC proposed rule | Comment docket

Comment Deadline: August 31, 2026

Summary: CMS proposes to reorganize service assignments within the four-level Nuclear Medicine and Related Services APC series because separate payment for higher-cost diagnostic radiopharmaceuticals has reduced the distinction between Levels 3 and 4. The rule would assign cardiac PET services CPT 78431, 78432, and 78433 to APC 5594, Level 4 Nuclear Medicine and Related Services, and reassign other services based on updated claims data. For CY 2027, CMS proposes a $140 packaging threshold for drugs, biologicals, and therapeutic radiopharmaceuticals and a separate $665 per-day diagnostic radiopharmaceutical packaging threshold; diagnostic radiopharmaceuticals above that threshold would generally be separately paid at arithmetic mean unit cost when available. CMS otherwise proposes no

additional change to its established policies for separately payable therapeutic or diagnostic radiopharmaceuticals. (HOPPS PDF pp. 180-183 and 283-298.)

Impact Assessment:

- **Imaging Operations:** Direct. APC placement and radiopharmaceutical packaging determine hospital outpatient payment for nuclear medicine and PET services and may influence service-line economics, coding, and acquisition decisions.
- **AI Governance:** Indirect. The payment changes do not address algorithmic interpretation or AI governance, although some PET and nuclear medicine workflows may use separately coded SaMS tools.
- **Interoperability:** Indirect but relevant. Accurate association of radiopharmaceutical, procedure, acquisition, quantitative results, and reports remains important for billing, longitudinal comparison, and quality analysis; no new exchange standard is proposed.

Relevance Score: 5

Request for Information on Duplicate Imaging, Result Sharing, and Interoperability

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Request for Information within the CY 2027 MPFS Proposed Rule

Publication Date: July 16, 2026 (scheduled Federal Register publication; official prepublication document reviewed July 15)

Official Source Link: Official MPFS proposed rule | Comment docket

Comment Deadline: September 14, 2026

Summary: CMS states that imaging data and results are often siloed, contributing to incomplete or delayed care, duplicative testing, added cost, and unnecessary radiation exposure. The RFI asks about billing instructions, payment edits or reductions, recoupment, and frequency limits for duplicate tests while recognizing clinically justified repeat imaging in trauma, stroke, and evolving emergencies. CMS also asks whether participation in national interoperability networks, incentives, conformance testing, certification, implementation guidance, accountability, penalties, or other payment levers could improve image and result exchange. One specific question asks whether CMS should establish a minimum result-shareability standard, potentially using a structured FHIR R4 DiagnosticReport and a human-readable PDF/A sent to an ordering-provider endpoint as a condition of payment, with attention to rural and non-FHIR workflows. (MPFS PDF pp. 867-873.)

Impact Assessment:

- **Imaging Operations:** Direct and potentially high. Future payment consequences for repeat imaging could affect ordering, scheduling, medical-necessity documentation, access to priors, emergency exceptions, and responsibility when an outside examination cannot be located or used.
- **AI Governance:** Indirect. More complete access to prior images and reports can affect AI input quality, longitudinal comparisons, and the risk of acting on incomplete data, but the RFI does not propose AI rules.
- **Interoperability:** Direct and central. CMS is explicitly asking how to make images and results findable and usable across organizations and how standards, conformance testing, networks, authentication, authorization, and patient matching should support that goal. The RFI is not yet a proposed exchange mandate or payment condition.

Relevance Score: 5

Request for Information on Transition to FHIR-Based Digital Quality Measures

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Request for Information within the CY 2027 MPFS Proposed Rule

Publication Date: July 16, 2026 (scheduled Federal Register publication; official prepublication document reviewed July 15)

Official Source Link: Official MPFS proposed rule | Comment docket

Comment Deadline: September 14, 2026

Summary: CMS seeks comment on advancing from current clinical quality measure, eCQM, and QRDA reporting toward FHIR-based digital quality measures using resources that include USCDI+ Quality, the US Quality Core Implementation Guide, the Data Exchange for Quality Measures Implementation Guide, and the MADiE authoring environment. Subject to future rulemaking, CMS describes a possible two-year transition in CY/FY 2028 and 2029 during which FHIR-based options would coexist with current reporting methods. CMS then contemplates mandatory FHIR-based reporting for transitioned measures beginning in CY/FY 2030, including the CY 2030 performance period and 2032 MIPS payment year for the Quality Payment Program. CMS recognizes that timing and flexibility may need to vary by program and provider type, particularly for small, rural, or resource-constrained participants. (MPFS PDF pp. 908-914.)

Impact Assessment:

- **Imaging Operations:** Material for quality-reporting teams. Imaging measures that depend on modality, dose, image-quality, exam-category, and interpretation data may require new extraction, normalization, validation, and submission workflows.
- **AI Governance:** Indirect but growing. Computable measures may be used to evaluate AI-supported processes and outcomes, making traceability and reproducibility important even though the RFI does not itself regulate AI.
- **Interoperability:** Direct. The envisioned transition places FHIR at the reporting layer, but many imaging facts originate in DICOM objects, structured reports, dose reports, and device metadata; reliable mapping and preservation of provenance will be essential.

Relevance Score: 4

Diagnostic Radiology MIPS Value Pathway Modifications, Including CT Dose Measures

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Quality Payment Program policy

Publication Date: July 16, 2026 (scheduled Federal Register publication; official prepublication document reviewed July 15)

Official Source Link: Official MPFS proposed rule | Comment docket

Comment Deadline: September 14, 2026

Summary: For the CY 2027 performance period and 2029 MIPS payment year, CMS proposes core Diagnostic Radiology MVP measures Q145 on fluoroscopy dose indices, Q360 on potential high-dose CT and cardiac nuclear medicine studies, and Q405 on appropriate follow-up imaging for incidental abdominal lesions. CMS proposes adding ACRAD34, a QCDR measure assessing whether three specified CT exam types have dose-length product at or below size-specific diagnostic reference levels. The General Diagnostic Radiology grouping also continues to list Q494, Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Clinician Level), as an eCQM; the rule does not

identify Q494 as a newly added measure. CMS separately proposes four measures for a new Nuclear Medicine clinical grouping and removal of two improvement activities from the MVP. (MPFS PDF pp. 1542-1545.)

Impact Assessment:

- **Imaging Operations:** Direct. The proposed core and added measures increase the importance of reliable dose capture, protocol and exam identification, follow-up recommendation workflows, and QCDR/eCQM submission capabilities.
- **AI Governance:** Indirect. AI may assist dose optimization, incidental finding detection, or follow-up tracking, but performance accountability remains with the reporting clinician or organization.
- **Interoperability:** Material. Measure calculation depends on consistent movement of structured dose, exam, patient-size, recommendation, and follow-up data across imaging, reporting, registry, EHR, and quality-reporting systems.

Relevance Score: 5

MIPS Improvement Activities for Responsible AI, Diagnostic Performance, and Interoperable Clinical Decision Support

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed Quality Payment Program policy

Publication Date: July 16, 2026 (scheduled Federal Register publication; official prepublication document reviewed July 15)

Official Source Link: Official MPFS proposed rule | Comment docket

Comment Deadline: September 14, 2026

Summary: CMS proposes six new MIPS improvement activities, including Understand and Improve Diagnostic Performance and Clinician Use of AI to Improve Patient Care. The diagnostic-performance activity would use standardized processes to track diagnostic discrepancies, near misses, and data-accuracy problems and to conduct root-cause analysis and corrective action. The AI activity emphasizes responsible and transparent use, organizational policies for evaluation and monitoring, and use cases such as predictive analytics, clinical decision support, and risk stratification. CMS also proposes revising an existing clinical decision support activity to prioritize platform-agnostic, interoperable AI-enabled CDS with safeguards, monitoring, root-cause analysis, and risk mitigation. (MPFS PDF pp. 947-953 and Appendix B.)

Impact Assessment:

- **Imaging Operations:** Material. Radiology practices could use these activities to formalize discrepancy review, near-miss learning, AI implementation oversight, and corrective-action workflows.
- **AI Governance:** Direct. The proposed activities connect MIPS credit to governance practices such as evaluation, monitoring, transparency, safety review, and mitigation rather than mere adoption of an AI product.
- **Interoperability:** Direct for the revised CDS activity. CMS explicitly favors platform-agnostic, interoperable AI-enabled CDS, creating a policy signal for standardized integration and exchange of inputs, outputs, alerts, and audit information.

Relevance Score: 4

PFS Practice-Expense Methodology Changes and Radiology Specialty Impacts

Agency: Centers for Medicare & Medicaid Services (CMS), HHS

Policy Type: Federal Register - Proposed PFS payment methodology

Publication Date: July 16, 2026 (scheduled Federal Register publication; official prepublication document reviewed July 15)

Official Source Link: Official MPFS proposed rule | Comment docket

Comment Deadline: September 14, 2026

Summary: CMS proposes to allocate indirect practice expense using both work RVUs and clinical-labor RVUs for most services, rather than applying that approach only to services with separate professional, technical, and global components, which CMS describes as typically diagnostic and imaging services. CMS also proposes removing the indirect practice cost index steps over a two-year transition because the underlying specialty survey data are dated and can obscure code-level inputs, and it proposes a general annual practice-expense stabilization cap of plus or minus 5 percent subject to specified exceptions. CMS estimates aggregate combined RVU impacts of +3 percent for interventional radiology, +2 percent for nuclear medicine, +2 percent for radiology, +3 percent for radiation oncology and radiation therapy centers, and -1 percent for portable X-ray suppliers, with different nonfacility and facility effects. These specialty estimates exclude the separate effect of the conversion-factor updates and do not predict the payment change for any individual code or practice. (MPFS PDF pp. 15-29 and 1148-1151.)

Impact Assessment:

- **Imaging Operations:** Direct financial context. Aggregate increases do not eliminate code-level variation, site-of-service differences, conversion-factor effects, or the need to review the final addenda and local payer mix.
- **AI Governance:** Indirect. Practice economics affect the capacity to acquire and govern AI, but the PE methodology proposal does not set AI policy.
- **Interoperability:** Indirect. Payment pressure can influence investment in exchange and quality infrastructure; no interoperability requirement is attached to the PE methodology.

Relevance Score: 3

Canada

Special-edition scope note: Canada regulatory sources were not reviewed for this special edition, which was intentionally limited to the two supplied U.S. CMS proposed rules. No conclusion should be drawn from this report about whether qualifying developments occurred in Canada.

4. European Union Regulatory Scan

Special-edition scope note: the European Union regulatory sources were not reviewed for this special edition, which was intentionally limited to the two supplied U.S. CMS proposed rules. No conclusion should be drawn from this report about whether qualifying developments occurred in the European Union.

5. Japan Regulatory Scan

Special-edition scope note: Japan regulatory sources were not reviewed for this special edition, which was intentionally limited to the two supplied U.S. CMS proposed rules. No conclusion should be drawn from this report about whether qualifying developments occurred in Japan.

6. Australia Regulatory Scan

Special-edition scope note: Australia regulatory sources were not reviewed for this special edition, which was intentionally limited to the two supplied U.S. CMS proposed rules. No conclusion should be drawn from this report about whether qualifying developments occurred in Australia.

7. IHE Opportunity Scan

The opportunities below are interpretations of the two CMS rules from an IHE Radiology perspective. They are not statements that CMS has endorsed, required, or referenced any specific IHE profile.

Define a complete image-and-report exchange implementation pattern

The duplicate-imaging RFI creates an immediate opportunity to distinguish a shareable narrative result from a clinically reusable imaging study. IHE Radiology can describe a standards-based pattern that links reports to image manifests or imaging-study references; supports discovery, authorization, patient matching, and retrieval; and accommodates DICOM and DICOMweb access across enterprise and network boundaries. XDS-I.b and complementary IT Infrastructure mechanisms can be presented as proven building blocks rather than as a demand that CMS prescribe one architecture.

Respond to the proposed minimum shareability concept with imaging-specific detail

CMS specifically asks about FHIR R4 DiagnosticReport plus PDF/A. IHE Radiology can explain that this may improve report delivery but, by itself, does not guarantee access to diagnostic-quality images, series metadata, key objects, priors, or an appropriate viewer. A useful response would define the minimum information needed to locate and retrieve the related study, identify unavailable or incomplete priors, and document the exchange attempt before duplicate-test payment consequences are considered.

Connect SaMS payment to testable AI workflow and results integration

The new SaMS category increases the need for implementation guidance that is independent of a particular algorithm or commercial platform. IHE AI Workflow for Imaging, AI Results, and AI Results Assessment concepts can help specify how work is dispatched, how outputs are represented and linked to source data, how human review is recorded, and how provenance and version information are retained. Connectathon-tested transactions and procurement language could reduce the risk that payment recognition produces isolated point solutions.

Create a defensible imaging-to-FHIR quality data bridge

The FHIR dQM RFI and radiology dose measures expose a boundary between imaging-native source data and FHIR-based reporting. IHE Radiology can outline how DICOM metadata, Radiation Dose Structured Reports, procedure codes, patient-size information, and interpretation data are normalized, validated,

and mapped without losing source provenance. REM can remain a useful acquisition and aggregation foundation, while measure-specific implementation guidance should clearly separate data collection, categorization, calculation, and submission responsibilities.

Support responsible AI and diagnostic-performance governance

The proposed MIPS activities provide a concrete policy context for IHE guidance on monitoring AI-supported workflows, recording discrepancies and near misses, linking corrective actions to software versions, and exchanging structured results across systems. IHE can position interoperability as part of safety governance: an AI result that cannot be reliably associated with the patient, study, algorithm version, and interpreting workflow is difficult to monitor or audit.

Provide procurement language for cross-setting continuity

Site-neutral payment may shift where imaging is performed without reducing the clinical need for prior-image access. The purchaser guides can emphasize conformance evidence, cross-enterprise image availability, standards-based report and result ingestion, and clear vendor responsibility for exchange failures. This is especially relevant when hospital systems operate a mix of on-campus, off-campus, freestanding, and contracted imaging locations.

8. Regulatory Early Warning Dashboard

Signal	Current Status	IHE Radiology Significance	What to Monitor
Duplicate-imaging payment controls	RFI only; CMS asks about edits, reductions, recoupment, frequency limits, exceptions, and accountability.	Could evolve into direct payment consequences for repeat imaging.	Definitions of duplicate, clinical exceptions, responsibility when priors are unavailable or unusable, and due-process safeguards.
Minimum result-shareability standard	RFI only; CMS offers FHIR R4 DiagnosticReport plus PDF/A as an example for comment.	Could establish a payment-linked floor for diagnostic result exchange while leaving image access incomplete.	Whether the final concept includes study identifiers, image-access endpoints, DICOM/DICOMweb, conformance testing, and rural alternatives.
National interoperability network participation	RFI discussion; CMS notes possible incentives and future program levers but does not propose a participation requirement.	Could make network capability part of Medicare quality or participation policy.	Future Promoting Interoperability, Hospital IQR/OQR, QPP, or conditions-of-participation rulemaking.
FHIR-based quality reporting	RFI describes a possible 2028-2029 transition and mandatory reporting for transitioned measures beginning in 2030, subject to future rulemaking.	Would require dependable translation of imaging-native data into FHIR measure workflows.	Measure-by-measure timelines, implementation guides, testing expectations, source-data provenance, and small/rural flexibility.
Permanent SaMS payment methodology	CY 2027 proposal is explicitly interim; O1 and New Technology APC assignments are proposed first steps.	Long-term valuation may affect which imaging algorithms are commercially deployable and how they are billed.	Outcome-based valuation, subscription/per-click arrangements, transparency, multiple-procedure discounting, packaging, and program-integrity controls.

Signal	Current Status	IHE Radiology Significance	What to Monitor
Site-neutral payment expansion	Direct proposal for specified imaging-without-contrast APCs at excepted off-campus PBDs.	Could alter imaging site strategy and become a model for additional services or provider types.	Final exemptions, affected APCs, implementation mechanics, later expansion, and volume/access effects.
Divergent CT dose measure pathways	Hospital-level outpatient measure remains voluntary through CY 2032 in HOPPS; clinician-level Q494 remains in the Diagnostic Radiology MVP.	Organizations may face different implementation incentives by program, reporting level, and collection method.	Future Hospital OQR changes, MIPS specifications, data harmonization, and whether common source-data infrastructure can serve both measures.

9. Emerging Policy Signals (Pre-Regulatory)

- **Payment policy may become an interoperability enforcement mechanism.** The MPFS RFI goes beyond general encouragement of exchange and asks about nonpayment, reductions, recoupment, frequency limits, participation incentives, and minimum shareability. Because these are questions rather than proposals, the direction and scope remain unsettled, but the policy signal is stronger than a conventional interoperability statement.
- **CMS is separating report portability from the larger imaging problem, but the example may be incomplete.** The proposed FHIR DiagnosticReport plus PDF/A concept focuses on delivery of a result. The same RFI recognizes that imaging exchange also involves large image files, metadata, viewing, authentication, authorization, patient matching, and inconsistent conformance. This tension should be addressed before any result-sharing standard is tied to payment.
- **Algorithmic services are becoming a defined Medicare payment class.** The SaMS terminology, O1 status indicator, and cross-setting consistency discussion signal that CMS expects algorithmic diagnostic services to persist and expand. The unresolved questions concern valuation, transparency, packaging, licensing models, and program integrity rather than whether these services exist.
- **AI governance is moving into performance-improvement expectations.** The proposed MIPS activities frame responsible AI use around evaluation, monitoring, transparency, safety events, root-cause analysis, and mitigation. This is pre-regulatory in the sense that participation in a MIPS improvement activity is not a general AI condition of use, but it may normalize governance practices that later appear in other programs.
- **Imaging quality reporting is moving toward a FHIR submission layer while source data remain imaging-native.** The potential 2030 mandatory FHIR dQM direction, combined with CT dose measures in both Hospital OQR and MIPS contexts, points toward a need for stable mappings between DICOM-derived facts and FHIR quality artifacts. CMS has not proposed those imaging-specific mappings in these rules.

10. International Policy Developments IHE Radiology Should Monitor

International policy developments outside the United States were not reviewed for this special edition. This section is retained to preserve the protocol-defined report structure, but the absence of listed items must not be interpreted as a finding that no relevant developments occurred in Canada, the

European Union, Japan, Australia, or other jurisdictions. The next regular global monitoring cycle should resume the complete source review required by protocol v14.

Appendix A - Regulatory Sources Monitored

This special edition used a document-bounded discovery method at the user's direction. The two supplied CMS proposed rules were treated as the complete source universe; no external regulatory listing pages or non-U.S. sources were reviewed.

Official Source	Discovery Method	Date/Window	Key Sections Verified	Result
CMS-1850-P: CY 2027 OPPS/ASC Proposed Rule	Full-document text search, table-of-contents review, targeted section review, and page-level verification	July 7-15, 2026	Executive summary; imaging volume-control policy; SaMS; Nuclear Medicine APCs; radiopharmaceutical payment; Hospital OQR measure table	Four qualifying policy items retained; official source and August 31 deadline verified.
CMS-1848-P: CY 2027 MPFS Proposed Rule	Full-document text search, table-of-contents review, targeted section and Appendix B review, and page-level verification	July 15, 2026; scheduled publication July 16	PE methodology and impacts; SaMS; duplicate-imaging/interoperability RFI; FHIR dQM RFI; MIPS activities; Diagnostic Radiology MVP	Five qualifying policy items retained; official source and September 14 deadline verified.
Uploaded Volume 1, Issue 4 prior report	Direct title and policy-action comparison against all retained candidates	Comparison completed July 15, 2026	Policy Signal Dashboard and regional policy-item titles	No retained CMS-1850-P or CMS-1848-P item appeared in the uploaded prior report; no asterisks applied.

Official source links:

- CMS-1850-P HOPPS/ASC proposed rule
- CMS-1850-P comment docket
- CMS-1848-P MPFS proposed rule
- CMS-1848-P comment docket