September 14, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1848-P; RIN 0938-AV82
FHIR-Based Digital Quality Measurement in the Quality Payment Program and Other CMS Quality Programs
Submitted electronically via regulations.gov

Dear Administrator Oz:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the "Fast Healthcare Interoperability Resources® (FHIR®)-Based Digital Quality Measurement in the Quality Payment Program and Other CMS Quality Programs - Request for Information" (RFI) in the "Medicare and Medicaid Programs; CY 2027 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program" proposed rule published in the July 16, 2026, edition of the *Federal Register*.

WEDI was formed in 1991 by then Department of Health and Human Services (HHS) Secretary Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. Named in the Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the Secretary of HHS, WEDI is the leading multi-stakeholder authority on the use of health information technology (IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI is recognized and trusted as a formal advisor to the Secretary. Our diverse membership includes health plans, providers, standards development organizations, vendors, federal and state government agencies, and patient advocacy organizations.

These comments were developed with the participation of WEDI's Value-Based Care Work Group (VBC WG). The VBC WG focuses on the business processes, data exchange, workflow, and administrative challenges that affect the transition from fee-for-service to value-based care. WEDI did not address the clinical merits of individual quality measures. Our comments focus on

implementation, standards, data governance, reporting burden, scoring fairness, and the ability of quality data to support value-based care operations.

WEDI strongly supports the Center for Medicare & Medicaid Services' (CMS') goal of moving toward standardized, interoperable, and more timely digital quality measurement. FHIR-based digital quality measures (dQMs) can reduce manual abstraction, improve reuse of data already generated in care delivery, support more timely quality improvement, and reduce the number of one-off reporting interfaces. These benefits, however, will not result from a format change alone. FHIR-based reporting requires coordinated changes to source data, measure logic, terminology, vendor products, aggregation, patient matching, attribution, governance, testing, submission, scoring, audit, and feedback workflows.

CMS proposes a two-year transition period in Calendar Year (CY)/Fiscal Year (FY) 2028 and 2029, with existing reporting options remaining available while selected FHIR-based dQM options are introduced, followed by mandatory FHIR-based reporting for transitioned measures beginning in CY/FY 2030. WEDI supports a phased transition and concurrent reporting. We urge, however, that CMS treat 2030 as the earliest conditional date rather than an automatic mandate. Mandatory adoption should occur measure by measure only after objective readiness criteria are met and after at least two complete end-to-end performance, submission, validation, and scoring cycles.

Summary of Considerations for CMS

1. Adopt a readiness-gated, measure-specific transition and define operational readiness as more than the publication of a FHIR specification.
2. Provide at least two complete end-to-end learning cycles before legacy reporting is retired; this will likely require a transition through CY/FY 2030 and mandatory reporting no earlier than CY/FY 2031 for the initial measures unless CMS demonstrates readiness sooner.
3. Make the first production year for each FHIR-based measure with no-downside and use dual reporting for reconciliation, validation, and benchmark development.
4. Maintain separate benchmarks by collection type until CMS demonstrates FHIR-based and legacy methods produce comparable results.
5. Define data completeness in multiple dimensions and distinguish data that are missing, unavailable, outside the reporting entity's control, or not applicable.
6. Publish a stable implementation package, compatibility matrix, test cases, and change-management process at least 18 months before the applicable performance period.
7. Create a national end-to-end testing and conformance environment that includes electronic health records (EHRs), registries, Qualified Clinical Data Registries (QCDRs), health information exchanges (HIEs), Accountable Care Organization (ACO) aggregators, payers, vendors, and CMS submission endpoints.
8. Fund shared services and technical assistance for solo, small, rural, underserved, specialty, dental, post-acute, behavioral health, and other resource-constrained settings.
9. Preserve the role of qualified intermediaries and clarify where measure calculation, aggregation, submission, and audit responsibilities may be performed.

10. Align the Quality Payment Program (QPP), Shared Savings Program, CMS Innovation Center models, hospital quality programs, certified health IT requirements, and private-sector measurement programs to support a “report once, use many” approach.
11. Require clear governance for provenance, patient matching, attribution, deduplication, source precedence, data correction, audit, privacy, and security.
12. Ensure the dQM infrastructure returns timely and actionable performance information to clinicians, ACOs, payers, and care teams rather than serving only as an annual compliance channel.

RFI Response

1. Transition Approach and Design

Readiness-gated and measure-specific

WEDI supports CMS' proposal to begin with a limited set of measures and expand over time. CMS should not, however, define a measure as ready merely because a FHIR-based specification has been published. A measure should be considered operationally available only when the full end-to-end workflow can be implemented, tested, supported, and audited across representative reporting environments.

CMS should publish a readiness rubric that must be satisfied before a legacy reporting option is retired. At a minimum, the rubric should require:

- A final, stable, versioned measure specification and value sets, with complete human-readable and machine-readable materials.
- A published compatibility matrix identifying the required FHIR version, US Core or US Quality Core/Quality Improvement Core (QI-Core) version, Data Exchange for Quality Management (DEQM) profile, Clinical Quality Language (CQL) and terminology versions, value sets, security requirements, population-scale exchange approach, and CMS submission format.
- Production-grade conformance tools, synthetic test data, expected results, edge cases, error messages, and resubmission procedures.
- Successful end-to-end testing across multiple EHR products, intermediaries, reporting entities, practice types, and organizational structures, including multi-EHR ACOs and small or rural practices.
- Evidence that source data needed for the measure is consistently available and semantically usable, not merely technically retrievable.
- Demonstrated comparability between FHIR-based and existing reporting results, with an explanation of expected differences.
- A burden and cost assessment showing that implementation does not depend on new manual clinician documentation or unreasonable vendor fees.
- Operational CMS intake, validation, correction, helpdesk, and audit processes.

- Input is received from stakeholders, separate from readiness determination, through official notice and comment rulemaking prior to mandatory use so that readiness is informed by operational realities of measure users.

Need for two complete learning cycles

Although CMS describes CY/FY 2028 and 2029 as a two-year transition, this proposed schedule provides only one complete learning cycle before mandatory adoption. The industry will not have complete 2029 submission, validation, scoring, and reconciliation results before systems must already be operating for the 2030 performance period. WEDI supports CMS requiring at least two complete performance and submission cycles before retiring a legacy method. For the initial measures, this likely means continuing concurrent reporting through CY/FY 2030 and beginning mandatory FHIR-based reporting no earlier than CY/FY 2031, unless CMS can demonstrate that all readiness criteria have been met and that stakeholders have had adequate notice. Additional consideration should be given to the resource burden and impacts created by other industry regulations, standards revisions, and system enhancements when phasing in measures. These same principles should apply to every measure that transitions later. Each measure should receive its own minimum concurrent reporting and validation period; measures should not receive a shorter glide path simply because they are introduced after the initial cohort.

Establish a staged transition model

WEDI suggests CMS consider the following staged approach:

- **Pre-transition preparation:** CMS publishes the complete implementation package, operates the testing environment, conducts representative pilots, and provides technical assistance.
- **First FHIR production year:** FHIR-based reporting is voluntary with no downside. Reporting entities may submit the FHIR-based result as a secondary validation submission while declaring a primary scoring method. CMS returns detailed reconciliation and data-quality reports.
- **Second FHIR production year:** FHIR-based reporting expands, but CMS maintains legacy options and scoring guardrails. CMS evaluates cross-method comparability, error rates, data completeness, burden, small-practice access, and vendor availability.
- **Readiness determination:** CMS publishes a measure-specific go/no-go decision through notice-and-comment rulemaking with sufficient lead time before mandatory use.
- **Mandatory year:** FHIR-based reporting becomes the required method only for measures that satisfy the readiness rubric. Measures that do not meet the rubric retain existing reporting options until they are ready.

Stability of specifications

CMS should publish the complete, final implementation package at least 18 months before the start of the performance period. Draft and pre-release implementation guide versions can

support pilots, but CMS should not require production reporting based on draft versions. CMS should avoid substantive changes within 12 months of a performance period and should limit in-year changes to clearly identified technical corrections. Every release should include a change log, backward-compatibility assessment, and transition guidance.

2. Scoring, Benchmarking, Data Submission, and Completeness

Reporting method and quality score

FHIR-based and legacy collection types may produce different performance rates because of differences in source coverage, data availability, denominator logic, timing, coding, or interpretation, even when the underlying care is the same. CMS should not place reporting entities into direct competition across collection types until it demonstrates that the methods are statistically and operationally comparable.

During the transition, CMS should consider:

- Maintaining separate benchmarks by collection type or using flat benchmarks or reporting-only credit where reliable historical benchmarks are not yet available.
- Making the first scoring year for each FHIR-based measure no-downside and providing credit for a complete, conformant submission without allowing technical transition effects to reduce payment.
- Requiring reporting entities that submit through more than one method to designate a primary scoring method before results are known; the secondary method should be used for validation and reconciliation, not post hoc score selection.
- Publishing cross-method variance analyses and explaining whether differences arise from data availability, specification logic, coding, aggregation, or actual clinical performance.
- Providing a correction and resubmission window when CMS validation identifies a technical, mapping, or data-quality issue.
- Avoiding penalizing a reporting entity for failures attributable to an EHR vendor, intermediary, external data source/service (e.g., transcription, system errors, discrepancies), or CMS endpoint when the entity has made reasonable and documented efforts to comply.

Data completeness definition

A single completeness percentage will not adequately describe FHIR-based reporting. CMS should consider distinguishing at least four dimensions:

- **Source coverage:** The proportion of relevant source systems, organizations, and data types connected to the reporting workflow.
- **Population coverage:** The proportion of eligible or attributed patients and encounters represented.
- **Data-element completeness:** The presence, validity, units, terminology, and temporal accuracy of the data needed for a specific measure. The Office of the National Coordinator

for Health Information Technology's (ONC) new platform, Cartos, could be useful and relevant here as a resource in support of dQM data completeness.

- **Submission completeness:** The proportion of expected measure reports or supporting artifacts successfully received and validated by CMS.

CMS should also consider establishing standardized missing-data and exception reason codes so that unavailable data, unsupported source systems, patient matching failures, data not applicable to the patient, and true documentation gaps are not treated as equivalent. CMS is encouraged to collect completeness information during the early transition years before setting punitive thresholds. Any threshold should be based on observed national capability and should account for the entity type, measure, source systems, and dependencies outside the reporting entity's control.

Detailed and timely submission feedback

Reporting entities need more than a pass/fail acknowledgement. CMS should consider returning machine-readable and human-readable validation results that identify missing resources, invalid terminology, denominator discrepancies, patient-matching failures, duplicate records, calculation errors, and submission status. Feedback should be available early enough to support correction before a payment consequence is final. CMS should also publish standard error codes and expected remediation steps so vendors and intermediaries can automate corrections.

3. Readiness Across Practices, Organizations, and Supporting Health IT Entities

FHIR API availability

While some organizations currently can exchange some data through a FHIR application programming interface (API), many cannot yet perform population-scale quality reporting. A production dQM workflow may require bulk extraction, access to data from multiple EHRs and non-EHR sources, patient identity resolution, attribution, terminology normalization, CQL execution, measure calculation, exception management, audit, and submission. CMS should assess each of these capabilities separately and should not infer readiness from the presence of a certified FHIR endpoint alone.

Define permitted implementation architecture

While this RFI identifies the role providers, intermediaries, and payers will play, we also recommend the agency fully define where data aggregation and measure calculation are expected to occur. Clarification is needed regarding whether a measure may be calculated by an EHR, a provider organization, a QCDR or qualified registry, an HIE or health information network (HIN), an ACO data aggregator, another trusted intermediary, or CMS itself. CMS should also consider supporting multiple conformant architectures rather than requiring every practice to build the same technical stack. Optimally, the requirements should clearly distinguish source-data exchange, aggregation, calculation, submission, and audit responsibilities.

CMS should also consider defining when population-scale exchange methods, including bulk FHIR approaches where appropriate, are expected. It is important to remember that one-patient-at-a-time API workflows may not be practical for large groups, ACOs, registries, and payer-provider quality programs. The implementation package should also explain how bulk extraction, DEQM reporting, summary MeasureReport submission, and any patient-level audit data work together.

Intermediaries as part of the solution

QCDRs, qualified registries, HIEs, HINs, clearinghouses, ACO enablement organizations, and other trusted intermediaries can provide shared capabilities that smaller organizations cannot build independently. CMS should preserve their ability to aggregate, normalize, calculate, validate, and submit dQM data when authorized. At the same time, CMS should require standards-conformant interfaces, transparent error reporting, data portability, and clear accountability so that organizations are not locked into proprietary reporting pathways.

Needed resource-constrained support

Technical assistance alone will not solve readiness if organizations cannot afford interfaces, vendor upgrades, data aggregation, testing, and staff. CMS should consider establishing a funded assistance model, potentially drawing on the successful Regional Extension Center concept, to provide shared engineering, contracting support, implementation playbooks, security guidance, conformance testing, and vendor escalation. Funding by CMS should also be explored to support a learning collaborative community that can scale in reach to effectively disseminate education materials, best practices, and other critical resources. Additionally, CMS should consider establishing grants, shared service arrangements, group-level reporting options, and extended flexibilities for entities whose readiness depends on vendors or external data sources.

We recommend flexibilities be targeted and transparent rather than permanent exemptions from modernization. Practices should be able to demonstrate reasonable progress, document a vendor or data-source limitation, use an approved shared service, and transition when the dependency is resolved. CMS should monitor whether the policy causes ACOs, medical groups, or networks to exclude small or specialty practices and should intervene before technical readiness becomes a barrier to value-based care participation.

4. Technical Standards, Versioning, and End-to-End Testing

Normative implementation package

CMS identifies the U.S. Core Data for Interoperability (USCDI)+ Quality Version 1 (V1), the US Quality Core Implementation Guide, DEQM, Measure Authoring Development Integrated Environment (MADiE), and FHIR dQM specifications as foundational components. Implementers need a single CMS-maintained package that states exactly which versions and profiles are required and how they fit together. We urge that the package includes:

- The required FHIR base version and compatible US Core, US Quality Core or QI-Core, and DEQM versions.
- The measure logic, CQL version, value sets, code systems, units of measure, and temporal conventions.
- The permitted source data and aggregation patterns, including bulk exchange, where applicable.
- Authentication, authorization, minimum-necessary, audit, and security requirements.
- Measure Report and submission requirements, correction workflows, acknowledgements, and error codes.
- A version compatibility matrix, change log, implementation examples, and migration guidance.
- A source of truth hierarchy for data validation and correction processes.

Testing the full workflow

MADiE and measure test cases are important, but successful authoring and unit testing do not prove that production data can be retrieved, normalized, aggregated, submitted, and scored. CMS should consider creating or sponsoring a national end-to-end testing environment with synthetic patients, representative source data, multiple EHR and intermediary implementations, CMS-like receiving endpoints, validation responses, and scoring reconciliation. Ideally, testing would include common and difficult scenarios, including multiple EHRs, incomplete external data, duplicate records, changing attribution, corrected data, late-arriving results, specialty workflows, and rural connectivity constraints.

CMS should also consider publishing conformance results and readiness metrics by product and implementation role, while avoiding a model that creates a single-vendor dependency or restricts competition. Coordination with ONC should take place to ensure that certified health IT requirements and testing tools support the data export, population-scale access, and other capabilities needed for the CMS quality reporting timeline.

5. Data Governance, Trust, Privacy, and Auditability

FHIR standardizes data representation and exchange, but it does not by itself resolve which source is authoritative, whether two records represent the same event, which organization is accountable for correcting an error, or whether data are fit for measurement. CMS should consider establishing a common governance framework that addresses:

- Patient matching and identity resolution across organizations and intermediaries.
- Attribution and accountable-population files, including timing, retroactive changes, and version control.
- Provenance and data lineage, including the original source, intermediary transformations, calculation engine, and submission history.
- Deduplication and source-precedence resolution rules when claims, EHR, laboratory, pharmacy, registry, and patient-generated data conflict.

- Data correction and dispute processes, including who may correct source data, derived data, or measure results.
- Audit logs and reproducibility so that an entity can recreate the measure result using the applicable specification and data version.
- Privacy, security, minimum-necessary exchange, role-based access, sensitive-data segmentation, and permitted uses by intermediaries.

Publishing an accountability matrix that identifies the responsibilities of the source organization, EHR vendor, intermediary, reporting entity, measure steward, and CMS would be helpful to the industry. We urge that enforcement focus on reasonable, documented efforts and should not penalize an entity for a defect it cannot directly correct. Clear governance will reduce disputes, duplicative validation, and manual reconciliation.

6. Value-Based Care and Shared Savings Program Considerations

Access to value-based care

The proposed rule documents that some Shared Savings Program ACOs have restricted or paused adding practices because of uncertainty around digital reporting standards; some practices have reportedly closed because of financial challenges associated with digital quality measurement; and some ACOs have begun removing practices that cannot meet digital reporting requirements. These are not incidental implementation concerns. They are evidence that quality reporting policy can alter market participation, practice stability, patient access, and the reach of value-based care.

It would be beneficial to monitor and publicly report whether the transition changes ACO participation, practice composition, specialist participation, rural participation, or patient access. We urge CMS not to sunset existing collection types or reporting incentives at the beginning of the transition period. We recommend those supports remain available through the full transition and should be retired only when the FHIR-based method is proven, accessible, and fairly scored. WEDI also recommends investigating and refining methods for combining new data with previously collected archived data to provide continuity, consistency in reporting, and avoid misinterpretation of new data.

ACO measure environment stability during the technology transition

ACOs must aggregate data across multiple participant tax identification numbers (TINs), specialties, facilities, EHRs, and community partners. CMS should avoid simultaneous expansion of the Alternative Payment Model Performance Pathway Plus measure set, major specification changes, new completeness thresholds, and new reporting architecture. Except for urgent patient-safety or statutory needs, CMS should maintain a stable measure set through the initial FHIR transition so organizations can direct resources to implementation and validation.

dQM infrastructure for prospective value-based care operations

The value of a digital quality infrastructure is not limited to an annual submission. We urge CMS to design the workflow so clinicians, ACOs, payers, and care teams can receive timely information about denominator status, missing data, care gaps, and performance trends during the measurement year. Timely feedback can support prevention, chronic disease management, specialist engagement, and corrective action before reconciliation. Further, the program should define how dQM data and results can be reused for care improvement while protecting against duplicative or conflicting payer-specific requirements.

7. Cross-Program Alignment and Administrative Simplification

Permitting CMS Innovation Center models to have separate requirements and timelines could undermine the administrative simplification benefits of the transition. Alternatively, CMS could establish one agency-wide dQM roadmap covering the QPP, Shared Savings Program, Innovation Center models, hospital and facility quality programs, and Promoting Interoperability. Program-specific variation should be limited to differences that are necessary and publicly justified.

CMS should also coordinate with ONC, Health Level 7, National Committee for Quality Assurance, measure stewards, private payers, and other appropriate stakeholders to ensure that organizations can reuse the same underlying data, terminology, interfaces, and governance for Medicare, Medicaid, commercial, accreditation, Healthcare Effectiveness Data and Information Set-related, and value-based payment needs where feasible. The policy objective should be “report once, use many,” not one FHIR pipeline per program or payer.

CMS should also consider evaluating administrative burden empirically. Implementation metrics should include one-time and ongoing costs, staff time, vendor fees, number of manual interventions, chart-retrieval activity, error rates, rejected submissions, data-correction cycles, and provider experience. We note that a process is not burden reducing merely because the final submission is electronic.

8. Implementation Governance, Transparency, and Partnership

CMS should consider establishing a formal, multi-stakeholder FHIR dQM Transition Collaborative. The collaborative should include clinicians, medical groups, ACOs, hospitals, health plans, EHR vendors, QCDRs, registries, HIEs and HINs, standards organizations, measure stewards, patient representatives, small and rural organizations, and other intermediaries. Its work should include public readiness criteria, testing priorities, implementation issue tracking, cross-program alignment, and annual readiness recommendations.

CMS should consider publishing an annual readiness dashboard that includes:

- The number of measures with final specifications and complete implementation packages.

- The number and diversity of organizations that have completed end-to-end testing.
- Successful submission and validation rates, error categories, and resubmission rates.
- Data completeness and latency by source type and organizational setting.
- Cross-method performance variance and benchmark stability.
- Implementation costs and burden by stakeholder type.
- Participation and access impacts for small, rural, underserved, specialty, and ACO practices.
- Vendor and intermediary availability, including areas of market concentration or access barriers.

9. Role of Vendors

Vendors play a critical role throughout the quality measurement process, including data abstraction, collection, analysis, and reporting, in decreasing reporting burdens. To support the ongoing role of vendors in the dQM ecosystem, CMS should consider:

- Permitting vendors to charge reasonable costs within the scope of their implementation on ongoing products and services, including source code, algorithms, models, calculation methods, mappings, trade secrets, or other confidential business information, necessary to meet CMS quality reporting requirements.
- Permitting vendors the option of not disclosing or transferring vendor-owned software, algorithms, clinical content, proprietary mappings, configurations, or other intellectual property within the dQM process.
- Distinguishing throughout the dQM framework the difference between transparency necessary to validate a measure and disclosure of proprietary commercial information.
- Limiting any CMS-funded technical assistance to vendor-neutral, standards-based products and services.
- Identifying or developing testing resources that do not require a single vendor or specific vendor proprietary products.
- Distinguishing quality-reporting feedback from clinical decision support, utilization management, care management, and medical-necessity determination beyond the vendor's contracted services.
- Not creating an "unrestricted right to copy" of vendor-owned content when allowing the reuse of data.
- Maintaining technology and content neutrality.

WEDI, through its VBC WG, is well positioned to support this work through: (i) Stakeholder education; (ii) Readiness surveys; (iii) Implementation roundtables; (iv) Public-private consultation; and (v) Development of operational guidance.

WEDI encourages CMS to use a structured, transparent process to obtain broad industry input before making the 2030 go/no-go decision.

Conclusion

WEDI supports CMS's commitment to modernizing quality measurement through FHIR-based dQMs. The opportunity is significant: data generated once during care could support quality improvement, value-based payment, care coordination, and regulatory reporting with less manual work and greater timeliness. That outcome will be achieved most effectively if CMS treats the transition as an end-to-end operational and governance transformation.

We believe implementing our above recommended action steps will help CMS modernize quality measurement without destabilizing clinician practices, excluding organizations from value-based care, or replacing one set of fragmented reporting burdens with another. WEDI brings together many work groups to advise on these issues and stands ready to further support the work outlined above.

WEDI appreciates the opportunity to provide these comments and welcomes continued collaboration with CMS on the transition to FHIR-based digital quality measurement. Please contact Robert Tennant, WEDI Executive Director, at rtennant@WEDI.org with any questions on this response.

Sincerely,
/s/
Merri-Lee Stine
Chair, WEDI

cc: WEDI Board of Directors