Massachusetts Health Data Consortium

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June 15, 2026

To: Honorable Dr. Mehmet Oz, Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0062-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Oz:

On behalf of the Massachusetts Health Data Consortium (MHDC), we are pleased to provide public comments on the *Centers for Medicare and Medicaid Services (CMS) Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges* proposed rule [CMS-0062-P].

Introduction

As a non-profit, member-based organization focused on improving healthcare quality, transparency, and efficiency through better access to and exchange of health data, MHDC has served as a trusted, neutral convener that advances health information exchange, interoperability, and administrative simplification across Massachusetts and nationally for more than four decades. MHDC operates the New England Healthcare Exchange Network (NEHEN), providing secure data exchange and automation for thousands of health professionals and organizations, and continues to lead the way in transforming healthcare information infrastructure across New England.

MHDC strongly supports CMS's vision of modernizing the Drug Prior Authorization (PA) process, using proven standards and advancing Application Programming Interface (API)-enabled interoperability. As interoperability continues to evolve from document-centric exchange toward API-forward workflows, the central challenge is no longer technical feasibility, but operational ease and scalability of data exchange for PA. MHDC therefore believes the success of Drug PA will hinge on whether the final rule provides sufficient clarity and continuity to enable efficient, secure, and reliable PA decisions based on data integration, with clinical

guidance across the ecosystem to modernize PA authorization and reduce provider and patient burden while reducing the overall costs of care.

MHDC endorses requiring Medicare Advantage, Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plan issuers to support electronic prior authorization (ePA) for all drugs requiring PA. This will eliminate manual bottlenecks, reduce decision times, and improve care continuity for patients.

MHDC's recommendations in this letter draw on our long history of successfully engaging payers, providers, vendors, and exchanges in real-world exchange environments. Most importantly, all our comments are intended to support CMS's objectives by highlighting practical considerations to improve the operational reality of interoperability.

Key Recommendations

To ensure burden reduction across the ecosystem, MHDC recommends that CMS:

- Provide the industry with a minimum of 18 months from the final rule before compliance is required, in lieu of the proposed October 1, 2027, date, and establish provider directory infrastructure as a prerequisite to testing at scale.
- Define a minimum "interoperability floor" of certified capabilities that must persist through proposed removals and consolidations and discourage network-by-network or bilateral API arrangements that fragment exchange.
- Preserve National Council for Prescription Drug Programs (NCPDP®) Formulary & Benefit (F&B), Real-Time Prescription Benefit (RTPB), and SCRIPT as the standards for pharmacy benefit ePA, and adopt the HL7® Da Vinci Project CRD/DTR/PAS suite for medical benefit ePA, under a single routing rule that tells providers which path applies.
- Retire the legacy X12N 278 PA transaction in favor of HL7 FHIR®-based standards for medical PA, attachments, referrals, and eligibility, on an aligned timeline that avoids requiring payers to support two standards in parallel.
- Require coded, structured denial reasons drawn from a standard taxonomy (with optional free text), extending the existing Medicare Advantage requirement under 42 CFR §422.122(a) into the pharmacy benefit.
- Require payers to report machine-readable API endpoint metadata to a national, FHIR-enabled registry aligned with the National Directory of Healthcare Providers & Services (NDH) Endpoint Profile and establish a glide path away from portal-only PA so proprietary portals cannot substitute for standards-based exchange.
- Specify minimum security expectations, such as authentication, authorization, audit logging, and incident response, for API-based exchange and provide a transition plan that prevents a security gap between retired legacy certification criteria and mature API-forward requirements.

MHDC Comments and Recommendations

MHDC commends CMS's continued commitment to advancing ePA processes and understanding the need to close the gap for ePA of prescription drugs, including interoperability standards. This approach will improve patient safety and care, and reduce significant administrative burden by decreasing manual, paper-based processes, and shortening approval times. However, MHDC urges CMS to ensure that the industry, including payers, vendors, and health systems, is realistically prepared to implement these changes given implementation deadlines.

MHDC also commends the CMS Interoperability Framework initiative, which aims to standardize health data exchange, and now includes ePA, making it easier for providers, payers, and patients to share information securely. This creates an opportunity for coordinated upgrades so that when a prescriber sends an ePA request, the payer and pharmacy benefit manager (PBM) can respond instantly with accurate formulary and benefit data. We look forward to realizing the benefits of this work.

Timelines, Testing, and Payer Directories

Timelines and Prerequisites to Implement New Requirements. MHDC suggests that October 1, 2027, is a premature compliance date for many of the key proposals. PBMs and electronic health record (EHR) vendors and providers should be given time to update systems to support both medical and pharmacy benefit ePA workflows, including NCPDP SCRIPT and F&B Standards.

MHDC recommends the following actions for CMS to close these gaps for medical and pharmacy exchange:

- The January 1, 2027, enhancements from the 2024 CMS Interoperability and Prior Authorization final rule have not gone live yet, and Burden Reduction HL7® FHIR® APIs have not been subjected to feasibility testing at scale; hence, the compliance dates are too aggressive. MHDC recommends CMS provide the industry with a minimum of 18 months to comply with the final rule.
- Extend ONC's January 1, 2028, standards expiration requirement. EHR developers shared that aligning dates is positive. However, some vendors are currently implementing interoperability standards and requiring an upgrade to newer implementation guide (IG) versions by January 1, 2028, which may not be reasonable. In addition, health system compliance deadlines typically arrive before vendors are certified, creating both operational and compliance risks.
- Plans must be able to use prior standards versions until January 1, 2028.
- CMS should ensure the industry has the appropriate amount of time needed for testing required standards at scale. This will also ensure lessons learned can be applied, as there are multiple API IG versions at play. CMS must allow time for IG version alignment. Health plans have built earlier IG versions for two years; new requirements create a compliance conflict mid-build.

- We believe CMS should support mandatory interoperability testing before production go-live and provide educational resources and technical support for smaller or less-resourced organizations. We also support CMS in establishing performance monitoring and reporting requirements.
- Establishing a floor of the best mix of required standards to adhere to as a baseline will enable plans and system developers the opportunity to comply and advance the use of standards as they mature.
- It is also important for all actors to understand which versions of the standards are required by specific timelines to assist with compliance.
- Without an accurate national directory in place to support endpoint discovery, testing at scale will be nearly impossible. Payers will be challenged to identify the appropriate provider endpoints, and current approaches rely on manual, non-scalable processes. NEHEN's operations confirm this constraint daily: in the absence of a national directory, identifying the correct endpoints for a given provider today depends on mapping the information supplied in the exchange to pre-configured endpoints - a workable solution at regional scale, but one that cannot extend to a nationwide ePA mandate. A national, FHIR-enabled provider directory aligned with the National Directory of Healthcare Providers & Services (NDH) Endpoint Profile is the prerequisite that turns CMS's ePA APIs from a published specification into a usable network.
- Instead of October 1, 2027, MHDC recommends a deadline of 18 months or longer post-final rule for compliance. MHDC's recommendation is grounded in NEHEN's direct operating experience. As the operator of a multi-payer, multi-provider exchange that has moved production transactions across New England for more than two decades, NEHEN sees firsthand how long it takes to bring a new payer or provider into a production-ready state on a new standard. Even when the technical specification is settled, onboarding a single payer to a new FHIR IG can take up to 24 months end-to-end, which includes covering trading-partner agreements, implementation, endpoint provisioning, conformance testing, and production-volume validation. Reaching steady-state throughput across the network takes longer still. An October 1, 2027, compliance date will not allow that work to be done well; a minimum 18-month post-final-rule window will.

Interoperability

From MHDC's perspective, interoperability efforts are still in an early operational phase for many organizations, particularly for payer-provider exchange. Therefore, regulatory resets should strive to foster stability and promote progress during this transitional period.

Interoperability and API-Enabled Exchange. MHDC supports a "FHIR-first" approach and the prioritization of open, non-proprietary APIs as the foundation for future interoperability. MHDC also favors modernizing certification toward API-based exchange rather than document-centric approaches.

At the same time, MHDC cautions against removing too many core requirements without clear replacements, as it risks fragmentation. Historically, certification has provided a minimum

interoperability floor that reduces bespoke integrations and inconsistent vendor behaviors, so interoperability is not optional by design and does not depend on one-off commercial arrangements.

MHDC recommends:

- Defining a minimum "interoperability floor" that all certified products, including for the use of Drug ePA, must continue to support following proposed removals and consolidations.
- Clarifying with ONC how removed system certification criteria will be replaced by API-forward requirements over time.
- Offering transition guidance so organizations can confidently plan resource investments.
- Recognizing automation can streamline transactions, but clinical interpretation, advocacy, and care coordination remain essential functions.

These recommendations will provide for consistent baseline behavior that is especially valuable for several MHDC-facilitated use cases, such as: care coordination and referrals; patient access and consumer-facing workflows; payer-provider exchange for PA and quality reporting; public-interest reporting and other trusted exchange functions.

MHDC also urges CMS to discourage models that require network-by-network or connection-by-connection API arrangements. Interoperability at scale depends on predictable, reusable integration patterns over bespoke bilateral connections. NEHEN was built precisely to solve this problem at the regional level: with over 20 payers and over 260 provider organizations participating in the network, rather than each organization building, certifying, and maintaining bilateral integrations with every counterparty, NEHEN aggregates that exchange through a shared, governed infrastructure. The cost difference between an aggregated model and a fully bilateral one compounds with each new participant. Without an aggregated model, the operational burden of bilateral arrangements falls hardest on the smaller payers and provider organizations that CMS's rule is meant to bring into the standards-based ecosystem. The final rule should reinforce, not undercut, aggregated models that make standards-based exchange economically viable for participants of all sizes.

***NCPDP Standards*.** CMS proposes that all impacted health plans must support the NCPDP F&B Standard as part of the *CMS-0062-P*, with a required compliance date of October 1, 2027.

Today, ePA is now embedded in the NCPDP SCRIPT e-prescribing standard, enabling prescribers to send PA requests electronically and receive standardized responses, reducing reliance on paper/fax and cutting provider time. NCPDP standards have already been successfully incorporated by system developers into their products to accommodate various state regulatory requirements. Maintaining the NCPDP F&B standard for Drug ePAs under the pharmacy benefit remains the logical approach.

The threshold question for any drug PA workflow is whether the drug is covered under the plan's pharmacy benefit or the medical benefit. That routing determination dictates which standard applies, and NCPDP and FHIR must work together to answer it at the point of prescribing.

The standards align with routing as follows:

- **Pharmacy benefit drugs.** NCPDP Formulary & Benefit (F&B) and Real-Time Prescription Benefit (RTPB) standards identify coverage and PA requirements, while the NCPDP SCRIPT standard carries the ePA request and response between prescriber and health plan.
- **Medical benefit drugs and services.** The HL7 Da Vinci FHIR implementation guides, which include Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS), determine PA necessity, gather required documentation, and submit the request. Many health plans are already implementing these IGs to support ePA for medical benefit drugs today.

***Opportunities at the NCPDP–FHIR intersection*.** FHIR can complement NCPDP where the standards meet:

- CRD alongside Real-Time Pharmacy Benefit Checks (RTBC) to confirm benefit routing.
- FHIR-based extraction of clinical criteria (e.g., diagnosis from the EHR) to enrich RTBC.
- CDS Hooks and Clinical Quality Language (CQL) to drive question-sets and pre-population within SCRIPT.

MHDC recommends that CMS preserve NCPDP F&B, RTPB, and SCRIPT as the standards for pharmacy benefit ePA, and adopt the Da Vinci CRD/DTR/PAS suite as the FHIR-based standards for medical benefit ePA, consistent with CMS-0057-F. Aligning the two tracks under a single routing rule will give providers a predictable path to determine whether a PA is needed and how to submit it.

Communication across all stakeholders is critical to give providers, pharmacists, payers, and patients visibility into PA status throughout the process. MHDC recommends that CMS leverage existing NCPDP messaging and communications standards, such as the NCPDP Telecommunications Standard, to provide communication support between PBMs and Pharmacies regarding the status of PA. In addition, shared insight into PA via the SCRIPT Standard allows for real-time status updates (indicating Pending, Approved, or Denied) between the prescriber and the EHR as well as the payer and the PBM. Leveraging these existing NCPDP standards improves transparency across the care continuum, reduces administrative back-and-forth, and supports timely patient access to needed care. MHDC also recommends CMS provide guidance encouraging the use of pharmacy- or PBM-managed status updates to patients/members throughout the PA process.

MHDC believes workflow, process and education are also key to moving ePA forward across drug and medical benefits, which can assist in reducing provider and patient burden. Alignment across PA workflow processes is key to moving the industry forward.

Adopting FHIR Standards for Prior Authorization under HIPAA. Adopting FHIR-based APIs for PA under HIPAA using the HL7 Da Vinci Project Burden Reduction suite of implementation guides (IGs) will modernize technical architecture, improve interoperability, and enable integration with EHRs and pharmacy systems. We understand that the shift affects all HIPAA-covered entities (providers, plans, and clearinghouses), not just those regulated by CMS

programs. We, however, must ensure that industry has the appropriate amount of time to conform to and test the standards at scale. We believe moving to FHIR will support and improve:

- Real-time coverage checks
- Automated documentation retrieval
- Embedded clinical decision support
- Instant approvals for low-risk requests
- Pre-population of PA forms
- Reduction of provider burden
- Faster patient access to medications

MHDC recommends:

- Retiring legacy X12N 278 PA transaction standard and adoption of the HL7 FHIR standards for medical PA-related transactions, as CMS proposed.
- Using CRD for eligibility/coverage related to PAs, which can provide valuable information regarding when a PA is needed for items and services, including drugs, under the medical benefit.

Transparency

Denial Reasons. Clearer communication of denial reasons will reduce provider frustration and improve patient understanding. This is an important aspect of the PA process. By ensuring all information about the PA and its disposition is understood and shared, providers will be able to work with patients to provide appropriate care in a timely manner. We note that this mirrors the requirement already codified for Medicare Advantage (MA) organizations in 42 CFR §422.122(a), which states that a denial must include "a specific reason for the denial," regardless of communication method.

MHDC agrees with CMS that requiring the reason for a PA denial is necessary. Free-text denial reasons should not be allowed as they are insufficient to support appeals, hub support, analytics, or payer/provider quality improvement. Payers should provide a clear, specific, and actionable denial reason for every drug PA denial. Generic or vague language should not be allowed. This requirement aligns with existing MA/Medicaid PA rules and extends them into the pharmacy benefit.

MHDC recommends CMS require coding and structuring denial reasons, with optional text, and a standard denial taxonomy, such as:

- missing clinical documentation
- step therapy not met; specific step therapy required, including preferred alternatives and necessary trial durations.
- diagnosis mismatch
- quantity limit exceeded
- non-covered drug
- site-of-care restriction

- benefit exclusion
- medical necessity not established
- duplicate therapy
- payer needs additional information

API and Endpoint Reporting - Drugs. CMS proposes that health plans report API endpoints, capability statements, authentication details, and registration information to CMS, with updates within one week of changes. Reporting will be made publicly available on the health plan's website.

MHDC believes requiring API endpoint disclosure and usage reporting will help CMS monitor compliance and identify gaps in implementation. Reporting supports the overall transparency of API adoption and usage. It will also enable the opportunity to adjust and conduct industry education as necessary to ensure adoption. We note, however, that endpoint reporting is only useful if developers, EHRs, providers, and intermediaries can use it to measure success and manage improvement.

MHDC suggests reporting machine-readable national payer API endpoints to a national registry, preferably FHIR-enabled, and aligned with the NDH Endpoint Profile. CMS should require sufficient metadata to support real integration:

- Payer name and plan identifiers
- API use case
- Endpoint URL
- FHIR version
- Supported IG versions
- Auth method
- Registration process
- Sandbox/testing availability
- Production status
- Change history

Portal Exception. CMS asks whether it should revisit the direct data entry exception to move from portal-based transactions to fully electronic transactions using adopted standards.

While most portals use electronic transactions for pharmacy benefits, if portals remain the fallback forever, true ePA adoption will not advance. MHDC has firsthand experience in using a multi-payer portal as part of our NEHEN work, reaching providers and lessening the workflow abrasion.

MHDC recommends CMS preserve limited portal use for small/rural providers during transition, but establish a glide path away from portal-only PA. Payers should not be able to satisfy interoperability goals by maintaining proprietary portals and avoiding standards-based transactions.

Attachments

CMS is proposing the adoption of the HL7 FHIR standard and the HL7 Da Vinci Project Clinical Data Exchange IG (CDex) to exchange data in various formats. This would apply to all HIPAA-covered entities.

MHDC recommends that CDex should be used only when the Da Vinci Document Template and Rules (DTR) IG questionnaire cannot be used.

Referrals

CMS proposes replacing the X12 278 transaction with the FHIR standards and HL7 Da Vinci Project IGs.

MHDC recommends the industry move to FHIR as soon as possible. Asking health plans to support two standards is not feasible.

Eligibility

CMS proposes requiring the adoption of the FHIR standards, replacing the X12 270/271 for determining when a PA is required.

MHDC supports this, believing that the industry should use the best standard that lessens burden for providers. Providers must know whether a PA is required to provide the best care for their patients.

Alignment of Incentives

Payers, PBMs, and EHR vendors operate in a highly interconnected drug decision-making ecosystem. Misaligned workflows can cause delays, inconsistent formulary data, and increased phone/fax use. Nearly half of PA requests still rely on these outdated methods despite declining fax usage. Clinical and administrative burdens from PAs are significant: 95% of surveyed physicians say PAs delay care, 94% link them to burnout, and 26% report serious adverse events.[i]

Under CMS-0057-F, payers face a hard legal deadline of January 1, 2027, to have their APIs operational; EHR developers do not face a deadline to support the providers' side of those same workflows, and providers face no mandate at all, only a Merit-based Incentive Payment Program (MIPS) attestation incentive starting in 2027. Therefore, incentives are not aligned.

MHDC recommends:

- Aligning incentives to provide efficiency, so prescribers can choose only formulary-approved drugs upfront, reducing back-and-forth.
- Ensuring patient safety by aligning incentives for all parties (health plans, providers, and system developers) to synchronize clinical screening between prescribers and pharmacists to reduce medication errors.
- Continuing to support cost savings by working with payers, providers, and system developers to streamline workflows, which lowers administrative overhead and improves adherence, and aligning incentives with provider reimbursement.

Shortened Timeframes

MHDC believes the proposed seven-day standard and 72-hour urgent timelines are a major improvement over the current norm. We support these as a critical step toward real-time decision-making to ensure patients receive the care they require in a timely manner.

MHDC's Planned Drug PA Implementation Pilot

Subject to funding approval, MHDC will launch a Drug PA Implementation demonstration project in partnership with Point-of-Care Partners. Phase 1 of the demonstration project is designed to generate practical, transferable evidence on how existing pharmacy ePA standards perform in real-world use. When evidence is available, MHDC will share it with CMS as input for current and future rulemaking.

- ***Scope and standards baseline***. The project is scoped to Part D-covered drugs with relatively unambiguous PA criteria, and to organizations already using standards-based ePA tools. It relies entirely on existing national standards, such as NCPDP SCRIPT for ePA data exchange, NCPDP Real-Time Prescription Benefit (RTPB) for upstream coverage and benefit visibility, and HL7 FHIR where clinical context (such as diagnosis) must be extracted from the EHR to support a PA decision.
- ***Four testable hypotheses.*** The demonstration project is structured around four hypotheses that map directly to the operational problems CMS-0062-P is intended to address: (1) surfacing PA criteria and requirements upstream at the point of prescribing, including structured pre-population, has the greatest impact on reducing avoidable and incomplete PA starts; (2) implementation variation, rather than standards immaturity, is the primary fixable challenge in pharmacy ePA today, addressable through shared minimum data sets, common status semantics, and an agreed denial taxonomy; (3) shared PA status visibility across prescriber, pharmacy, and health plan reduces duplication and administrative burden; and (4) common metrics and governance enable continuous improvement and support scale decisions. Each hypothesis is paired with predeclared measures of success.
- ***Design discipline.*** The project is bounded in scope and time with a duration of approximately seven to eight months across six phases (charter and evidence frame; baseline and cohort selection; configuration guide and conformance checklist; pilot readiness; pilot execution; evaluation and scale decision). Three formal decision gates (cohort commitment, launch readiness, and scale decision) prevent the program from advancing without evidence. The project is designed to support two to three cohorts pairing providers with their existing health plan or PBM trading partners; baseline measurement and a community configuration guide are explicit deliverables produced before any execution begins.
- ***Deliverables relevant to this rulemaking***. The project will produce data-driven insights characterizing current-state, implementation guidance, a documented demonstration of how existing NCPDP and FHIR standards should be implemented to support real-world pharmacy ePA, standardized workflows through a shared taxonomy, and support scalable adoption of CMS-0062-P and CMS-0057.

MHDC welcomes CMS's engagement with the demonstration project and stands ready to brief CMS staff on pilot design, baseline findings, and final evaluation results as they become available.

RFI - Electronic Event Notifications for Value-Based Care and Care Coordination

MHDC strongly supports CMS's exploration of standardized electronic event notifications as a foundation for value-based care and care coordination. Notifications of admission, discharge, and transfer (ADT) events (and increasingly, of high-value clinical events such as ED visits, specialty consults, and procedure completions) are among the most operationally valuable forms of health-plan-provider and provider-provider exchange. MHDC's experience is that the value of these notifications scales directly with the breadth of participation and the consistency of the underlying data.

MHDC observes that today's event notification landscape is fragmented: some regions are well served by HIE-mediated notification networks, others rely on bilateral arrangements between health systems and accountable care organizations, and many providers and most health plans receive no actionable notifications at all. A federal floor would address this gap without displacing the regional infrastructure that already works.

MHDC recommends:

- Adopting HL7 FHIR Subscriptions and the Da Vinci Notifications IG as the standard transport for event notifications under HIPAA, with a defined minimum event set (at least ADT and ED encounter notifications) that all impacted health plans must support.
- Recognizing the role of intermediaries (HIEs, Qualified Health Information Networks, QHINs, under TEFCA, and aggregated networks such as NEHEN) as conforming delivery channels, so that health plans and providers can satisfy the requirement through existing regional infrastructure rather than bespoke point-to-point feeds.
- Aligning the notification data payload with USCDI so that downstream care coordination workflows can act on the notification without a secondary query for context.
- Providing explicit guidance on patient consent and notification suppression rules, so that HIV patient privacy protections and 42 CFR Part 2, state behavioral health privacy laws, and patient-directed opt-outs can be honored consistently across the network.

MHDC believes a federally anchored event notification floor, delivered through standards and existing aggregated networks, is the highest-leverage step CMS can take to operationalize value-based care commitments that already exist in payment models but lack consistent data infrastructure to support them.

RFI - Improving Implementation of Payer Application Programming Interface Technology

MHDC appreciates CMS's recognition that publishing API standards is necessary but not sufficient. The operational reality of payer API adoption is where interoperability succeeds or fails. As an operator of production payer-provider exchange, NEHEN sees the implementation gaps daily: API endpoints that are documented but not reachable, capability statements that diverge from actual behavior, authentication flows that work in sandboxes but break in

production, and IG versions that drift between trading partners. The gap between published specifications and usable network is the dominant barrier to meeting CMS-0057-F's January 1, 2027, milestones.

MHDC recommends that CMS pursue improvements along four lines:

- ***Certification and conformance testing.*** Health plans should be required to demonstrate FHIR API conformance against the relevant IG (CRD, DTR, PAS, Patient Access, Provider Access, Payer-to-Payer) through an independent test platform, not self-attestation. The Da Vinci Project's reference implementations and the HL7 Inferno test suite already provide the technical basis; CMS should designate a recognized testing path and require evidence of passage as a condition of compliance.
- ***A national, machine-readable endpoint registry.*** As detailed in this letter's API and Endpoint Reporting recommendation, CMS should require health plans to publish endpoint metadata to a national, FHIR-enabled registry aligned with the NDH Endpoint Profile, with mandatory fields covering endpoint URL, FHIR version, supported IG versions, authentication method, registration process, sandbox availability, production status, and change history. Without machine-readable discovery, providers and intermediaries cannot connect at scale.
- ***Real-world performance metrics.*** CMS should require health plans to report quarterly, machine-readable metrics on API performance, such as request volume, response time, error rate, and authentication-failure rate, broken out by API use case. Public reporting creates accountability and gives CMS evidence-based grounds to refine requirements over time.
- ***Support burden and intermediary recognition.*** Standards-based APIs reduce, but do not eliminate, the support burden of onboarding new trading partners. MHDC recommends that CMS explicitly recognize aggregated networks (HIEs, QHINs, regional exchanges such as NEHEN) as conforming intermediaries that can carry payer APIs on behalf of provider organizations, particularly smaller practices and rural providers who cannot reasonably integrate directly with every health plan they encounter. The final rule should not penalize, but should affirmatively support, models where API obligations are met through aggregated infrastructure.

MHDC believes these four improvements of testing, registry, metrics, and intermediary recognition are the difference between a payer API regime that exists on paper and one that operates at scale.

RFI - Step Therapy

MHDC recognizes step therapy as a legitimate utilization management tool when applied transparently and with appropriate clinical judgment, but its operational implementation today often creates avoidable burden for prescribers and delays for patients.

The core problem is informational: prescribers frequently cannot see at the point of prescribing what step therapy a health plan requires, what alternatives have already been tried (whether under the current plan or a prior one), or what the exception pathway looks like.

The result is trial-and-error prescribing, duplicate appeals, and patient frustration.

MHDC believes the standards-based ePA infrastructure CMS is advancing under this rule and CMS-0057-F is the right vehicle to address these gaps.

MHDC recommends:

- Requiring health plans to expose step therapy requirements through the same FHIR-based and NCPDP standards used for coverage and PA, so that step therapy requirements are visible to the prescriber at the point of prescribing rather than discovered through denial. CRD and RTBC are the natural carriers for this information.
- Requiring health plans to honor prior-trial documentation transmitted through standards-based ePA, so that a patient who has already failed step 1 under a previous plan or in a prior course of therapy is not required to repeat the step. This requires both a standard data element for prior-trial evidence and a regulatory expectation that health plans will accept it.
- Requiring a standards-based, electronic step therapy exception pathway with defined response timeframes parallel to the seven-day standard and 72-hour urgent PA timelines proposed elsewhere in this rule. Exceptions should not be a paper or portal process when the underlying PA workflow is electronic.
- Requiring coded, structured denial reasons for step therapy denials consistent with the denial taxonomy MHDC recommends in the Denial Reasons section above. By doing so, prescribers will understand what is required to satisfy the step or qualify for an exception.

MHDC believes these changes preserve health plans' ability to manage utilization while removing the information asymmetries that make step therapy a disproportionate source of provider burden and patient delay.

RFI - Laboratory Tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Items

MHDC supports extending standards-based PA to laboratory tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items. These categories share the same operational pain points as drug PA: phone and fax workflows, opaque criteria, inconsistent documentation requirements, and delays that translate directly into delayed diagnosis or delayed care. The standards CMS is advancing for drug and medical PA are largely applicable here without category-specific reinvention.

MHDC observes two implementation considerations specific to these categories:

- Lab and DMEPOS PA requirements are often documented in coverage policies and Local Coverage Determinations that are not currently expressed in machine-readable form; the value of CRD as a coverage-discovery mechanism depends on those policies being computable.

- DMEPOS involves a supplier's intermediary distinct from the prescribing provider, and the standards must accommodate the supplier's role in submitting documentation and receiving authorization.

MHDC recommends:

- Extending the HL7 Da Vinci CRD, DTR, and PAS implementation guides to laboratory and DMEPOS PA, under the same timeline as medical PA, so that health plans are not asked to maintain category-specific workflows.
- Requiring coverage policies and Local Coverage Determinations relevant to lab and DMEPOS PA to be published in machine-readable form (FHIR PlanDefinition / ActivityDefinition or equivalent) so that CRD can return actionable coverage information rather than a link to a PDF policy.
- Clarifying the role of DMEPOS suppliers in the standards-based workflow. Specifically, determining whether the supplier or the prescriber submits the PA, how documentation requests under DTR reach the supplier, and how authorization decisions are communicated back to both parties.
- Recognizing that lab PA in particular benefits from real-time decisioning. Many tests are ordered at the point of care, and a PA workflow that returns a decision in seconds rather than days preserves the clinical encounter. CMS should set explicit performance expectations for low-complexity lab PA decisions.

MHDC believes the same standards-based infrastructure CMS is building for drug PA should serve lab and DMEPOS without category-specific carve-outs. The targeted additions above can address what is genuinely different about these categories.

RFI – Increasing Healthcare Resiliency (Cybersecurity)

***Security of Health Information and Trust*.** MHDC supports embedding modern security into API-based exchanges. Removing or restructuring privacy and security certification criteria without clearly defined replacement baselines may weaken trust. Today, much data is exchanged on a point-to-point basis, which creates additional risk to the industry of data being compromised. NEHEN's experience operating a governed exchange across many payers and provider organizations illustrates the alternative: a shared infrastructure with uniform authentication, authorization, audit logging, and incident-response practices reduces the attack surface and the variability in security posture that point-to-point arrangements produce. As CMS retires legacy certification criteria and shifts toward API-forward exchange, the final rule should recognize aggregated, governed networks as a meaningful component of the security baseline, not just bilateral payer-to-provider connections secured one at a time.

MHDC therefore recommends:

- Specifying minimum security expectations for API-based exchange (e.g., for authentication, authorization, audit logging, incident response touchpoints).
- Providing a transition plan to avoid a security gap between removed legacy criteria and fully defined API-forward security requirements.

- Retaining targeted, audit-related capabilities until replacement requirements are more mature and testable.
- Setting clear vendor security expectations, as inconsistent vendor security expectations frequently lead to delays and require bespoke security reviews, special contract language, or additional security addenda during onboarding - adding cost and slowing implementation.
- Reducing low-value certification burden, while retaining guardrails for Decision Support Interventions (DSI) and security-related requirements.
- Outlining transparency and governance expectations for AI-enabled DSIs and cautions against eliminating transparency mechanisms without clear replacement approaches.

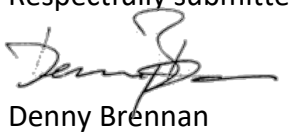
MHDC therefore stresses the need for:

- Clear governance expectations.
- Testing scenarios appropriate to the risk of intervention.
- Guardrails to prevent DSIs from interfering with EHI access needed for patient care.

Conclusion

MHDC is grateful for CMS's leadership in modernizing health IT policy and reducing low-value regulatory burden. We urge CMS, as well as ONC, to ensure that a standards-based approach, along with system certification, strengthens the operational reality of interoperability by preserving trust, preventing burden shifting, and discouraging pay-to-play access to health information. We believe giving all parties time to make required updates and testing will enable the U.S. to avoid interoperability gaps, reduce PA delays, and improve both clinical and administrative efficiency while creating a post-fax era.

Respectfully submitted,



Denny Brennan
Executive Director

[ii] ePA Explained: NCPDP SCRIPT & Surescripts Prior Authorization | IntuitionLabs