DrFirst, INC.

Formal Public Comment Submission

2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule

(CMS-0062)

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Executive Summary

DrFirst, Inc., respectfully submits these comments in response to the Centers for Medicare & Medicaid Services' 2026 Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062), published April 10, 2026[1], with a public comment period closing June 15, 2026.

DrFirst is a leading healthcare technology company with more than two decades of experience in electronic prescribing, medication management, and health IT interoperability. We provide clinical decision support, electronic prior authorization (ePA), specialty pharmacy workflow, real-time prescription benefit (RTPB) tools, and formulary and benefit (F&B) data exchange to hundreds of thousands of prescribers, payers, pharmacies, and health systems nationwide. DrFirst is an ONC-certified health IT developer and an active participant in the NCPDP and HL7 standards communities.

CMS-0062 represents one of the most consequential proposed rules for drug interoperability in the history of the Medicare and Medicaid programs. By mandating ePA for all drugs regardless of benefit type, and by proposing FHIR as a full HIPAA transaction standard for the first time, this rule signals a genuine sea change in administrative simplification. DrFirst strongly supports this direction.

Our comments address five core areas: (1) eliminating the portal exception to drive true electronic PA interoperability; (2) affirming and clarifying the dual-track architecture across FHIR Da Vinci and NCPDP standards; (3) recommending the Coverage Requirements Discovery (CRD) Information extension as the definitive mechanism to resolve the medical versus pharmacy benefit routing problem; (4) supporting ONC Health IT Certification for payer-facing APIs; and (5) endorsing the October 1, 2027, compliance deadline while offering targeted implementation guidance.

I. Background and DrFirst's Organizational Perspective

Prior authorization (PA) has remained one of the most persistent sources of administrative burden and care delay in the U.S. healthcare system. The American Medical Association's 2024 Prior Authorization Physician Survey found that 94% of physicians reported care delays tied to PA, and 78% reported that PA requirements had caused patients to abandon recommended treatments.[2] Despite the proliferation of ePA technology over the past decade, the majority of medical PAs are still processed through web portals, a manual, click-intensive experience that delivers none of the workflow integration, decision automation, or transparency benefits of true API-based exchange.

DrFirst occupies a unique position in this landscape. Through our Total Benefits platform, we are the only vendor providing a unified interface spanning both medical benefit drug PA (via FHIR Da Vinci CRD/DTR/PAS workflows) and pharmacy benefit drug PA (via NCPDP SCRIPT ePA transactions). We have direct, first-hand operational experience with the "same drug, different benefit type problem" that CMS has formally identified as a regulatory challenge. When a rheumatologist prescribes a biologic that may be administered in an infusion center (medical benefit) or dispensed for home self-administration (pharmacy benefit), the current system

provides no reliable, interoperable mechanism to determine which PA pathway applies before initiating the request. The consequences for patients—duplicate PA submissions, delays, and denials based on the wrong workflow—are real and measurable.

CMS-0062 builds directly on CMS-0057, which finalized API-based electronic PA requirements for non-drug services in 2024.[3] Replacing the X12N 278 standard that has governed administrative transactions since 1996 with FHIR-based exchange is not an incremental step, but a structural transformation that, in the future, should be applied to other X12N transactions, as well.

II. Eliminating the Direct Data Entry (Portal) Exception

II.A. CMS Should Narrow or Eliminate the HIPAA Portal Exception

CMS has solicited comment on whether to narrow or remove the Direct Data Entry (DDE) exception—the HIPAA provision that currently allows payers to satisfy electronic PA requirements through web portals rather than fully automated API-based exchange. DrFirst strongly recommends that CMS narrow this exception materially, with a defined sunset timeline, and articulate an affirmative policy that API-based exchange is the expected standard of care for electronic PA.

The continued availability of the portal exception has been the single most powerful brake on ePA adoption in the U.S. Payers that operate portal-based PA infrastructure have little financial incentive to invest in API development as long as portals satisfy legal compliance. The result is an ecosystem in which "electronic PA" has no consistent meaning. For some payers, it means true workflow-integrated FHIR API exchange with automated coverage determinations in seconds. For others, it means a web form that a staff member opens in a separate browser tab, manually re-enters patient data, and awaits a faxed decision 3-15 business days later.

CMS's own cited pilot data makes the case starkly: In the Regence–MultiCare FHIR pilot, PA decisions returned in roughly two minutes, down from a process that historically took days. Portal-based systems cannot replicate this outcome. The 71% approval rate with FHIR-based PA versus 46% via portal[4] further suggests that better data exchange produces better outcomes, not just faster ones.

Therefore, DrFirst recommends that CMS:

- Establish a defined sunset date—no later than October 1, 2028—for the DDE portal exception for all CMS-regulated payers subject to this rule. This provides an additional one-year runway from the proposed compliance date for this proposed rule. Should the October 1 date be extended, then we recommend tying the sunset date for the DDE portal exception to said date.
- Issue guidance clarifying that portal-based PA does not satisfy the API requirements for drugs under this proposed rule for payers.

III. The Dual-Track Architecture: FHIR Da Vinci and NCPDP

III.A. DrFirst Supports the Proposed Dual-Track Architecture

CMS-0062 proposes a dual-track PA architecture for drugs: FHIR Da Vinci (CRD, DTR, and PAS) for drugs covered under a medical benefit, and NCPDP SCRIPT 2023011 with complementary RTPB[5] and Formulary and Benefit (F&B) standards for drugs covered under a pharmacy benefit. DrFirst supports this dual-track architecture as a sound and necessary reflection of the clinical and operational realities of drug administration in the U.S.

The distinction between medical benefit and pharmacy benefit drugs reflects genuinely different care delivery models, prescribing workflows, dispensing channels, and clinical contexts. Oncology infusions, injectable biologics, and physician-administered drugs belong in a different data exchange framework than outpatient self-administered prescriptions. The FHIR Da Vinci standards were designed for the former; NCPDP SCRIPT was designed for the latter. Both standards development organizations have explicitly scoped their PA standards accordingly, and CMS is correct to draw the regulatory line where HL7 and NCPDP have already drawn the technical boundary.

DrFirst's recommendation is based on our real-world operational experience bridging these two tracks. Through our Total Benefits platform, we process both medical benefit drug PA requests (via Da Vinci workflows) and pharmacy benefit drug PA requests (via NCPDP SCRIPT ePA) within a single prescriber-facing interface. This experience gives us direct insight into the routing challenge CMS has identified: a prescriber initiating PA for a drug like adalimumab or lecanemab does not always know, at the point of ordering, whether the patient's coverage falls under the medical benefit or the pharmacy benefit (or both). The clinical decision must come first; the benefit determination must follow automatically, before the PA pathway is selected, to avoid duplicate requests, misrouted transactions, and administrative denials.

III.B. The Same Drug, Different Benefit Problem Requires a Regulatory Solution

In Medicare, the Part B versus Part D distinction is defined in statute and is largely predictable across plans. In Medicaid, CHIP, and QHP markets—all newly covered under CMS-0062—no equivalent statutory framework exists. The medical versus pharmacy benefit split is a plan design choice made independently by each payer, and it is not consistently disclosed to providers in a machine-readable format at the point of prescribing.

DrFirst's operational data confirms this is a material problem at scale. In our network, a meaningful percentage of specialty drug PA transactions are initially misrouted to the wrong benefit track, creating administrative rework, delay, and patient harm. Providers should not bear the burden of determining benefit type through manual research. DrFirst recommends that benefit type determination should become a computable, real-time transaction that resolves before the PA request is initiated.

IV. CRD Coverage Information Extension as the Authoritative Routing Mechanism

CMS solicits comment on how the CRD Coverage Information extension could indicate whether a drug is covered under a medical benefit, and whether RTPB could serve an equivalent function. DrFirst recommends that CMS designate the CRD Coverage Information extension as the primary, authoritative mechanism for communicating benefit type at the point of prescribing for medical benefit drugs, while ensuring that RTPB continues to function as the real-time discovery tool for pharmacy benefit drugs.

IV.A. CRD Coverage Information as the Medical Benefit Signal

The CRD IG's Coverage Information extension already supports the communication of whether a drug is covered, whether PA is required, and relevant billing codes and reason qualifiers. It is triggered directly from the EHR's clinical orders workflow, which is precisely the moment when benefit type determination is most needed. As the entity that controls benefit design, the health plan is the authoritative source of this information and is already expected to respond to CRD queries under CMS-0057.

What is currently missing is an explicit benefit-type field in the Coverage Information extension—a machine-readable signal indicating whether a specific drug for a specific patient is covered under the medical benefit or the pharmacy benefit. To remedy this data-field gap, DrFirst recommends that CMS, working with HL7 and the Da Vinci project, require payers to populate this field in CRD responses. A positive CRD coverage response for a medical benefit drug would serve as the definitive signal to remain in the FHIR/Da Vinci PA track. A pharmacy benefit response—or a null response—would direct the prescriber system to the NCPDP SCRIPT workflow.

This approach has several practical advantages. It does not require payers to build new RTPB responder infrastructure for medical benefit drugs (a significant technical and contractual lift). It leverages the CRD query that will already fire for covered drugs under this rule. And it keeps benefit determination within the FHIR ecosystem for medical benefit drugs, ensuring consistency with the broader Da Vinci framework.

IV.B. RTPB Should Continue to Serve Pharmacy Benefit Discovery

DrFirst strongly supports the proposed requirement that Medicaid and CHIP payers support RTPB and Formulary and Benefit standards.[6,7] Today, RTPB queries flow from EHRs through e-prescribing networks to PBMs, which respond with pharmacy benefit coverage, formulary status, and estimated patient cost-sharing. The expansion to Medicaid and CHIP payers will close a significant gap that currently results in "plan does not support" failures at the point of prescribing.

DrFirst also recommends that CMS clarify that existing NCPDP Coverage Restriction Codes (specifically Codes 816 and 817) can and should be used by PBMs responding to RTPB queries to indicate when a drug is not covered under the pharmacy benefit but may be covered under the medical benefit. This would allow existing RTPB infrastructure, which prescribers and EHRs

already use, to serve as a secondary routing signal without requiring entirely new technical infrastructure.

IV.C. Clearinghouse Readiness

CMS notes in the preamble that it is unclear how health care clearinghouses will adopt FHIR-based exchange, and solicits comment on the level of effort required. There are approximately 162 health care clearinghouses in the U.S. Their role in aggregating, translating, and routing electronic transactions between providers and payers makes them a critical dependency in any transition from X12N to FHIR.

DrFirst recommends that clearinghouses be held to the same timeline as payers and providers, given their pivotal role in the medication management process.

V. Support for ONC Health IT Certification for Payer-Facing APIs

CMS has included a significant Request for Information exploring whether the ONC Health IT Certification Program should be leveraged to ensure that API technology used by payers meets CMS technical requirements. DrFirst strongly supports this direction and urges CMS and ONC to move expeditiously toward a certification framework covering payer-facing PA APIs, in alignment with existing requirements for provider-facing technology.

The absence of payer-side certification has been a structural asymmetry in health IT governance since the Meaningful Use era. ONC's certification program has, since 2011, provided a rigorous framework for validating that EHR systems implement standards correctly and interoperably[8], creating a baseline of technical trust that enabled the broader interoperability ecosystem. No equivalent framework currently exists for payer technology. As CMS-0062 requires payers to implement complex FHIR IGs (CRD, DTR, PAS) with specific version requirements and real-time performance expectations, the absence of certification creates a compliance verification gap that will undermine the rule's objectives.

As an ONC-certified health IT developer, DrFirst has direct experience with the value certification provides—both in ensuring implementation quality and in establishing a common technical vocabulary that enables true interoperability across vendors. We believe the same framework, appropriately scoped for payer contexts, would yield significant benefits for the drug PA ecosystem.

Specifically, DrFirst recommends:

- CMS and ONC should establish a joint certification program for payer Prior Authorization APIs, covering the CRD, DTR, and PAS IGs at the versions required by this rule (CRD 2.2.1, DTR 2.2.0, PAS 2.2.1 – STU 2.2, per 45 CFR 170.215(j))[9,10,11].
- Certification should cover not only conformance to the standard but also real-world interoperability testing—specifically, validated exchange with certified EHR systems and certified health IT intermediaries.

- CMS should condition Medicare Advantage contract renewal, Medicaid managed care plan certification, and QHP federal exchange participation on demonstrated API certification for covered payers.
- NCPDP SCRIPT ePA compliance for pharmacy benefit drugs should be subject to analogous testing and conformance requirements under a complementary framework.

We acknowledge the legal complexity regarding ONC's authority under HITECH to certify payer technology historically outside the program's scope. However, CMS's programmatic authority—including control over Medicare Advantage contracts, federal Medicaid matching funds, and QHP certification—provides a distinct and robust enforcement mechanism. CMS should use that authority to make API conformance testing a condition of program participation.

VI. Endorsing the October 1, 2027, Compliance Deadline

CMS proposes an October 1, 2027, compliance date for mandatory electronic drug PA across all impacted payer types. DrFirst supports this timeline and urges CMS to hold firm against what will predictably be significant industry pressure to extend it.

The PA burden for specialty and complex drugs is a daily clinical crisis, not a theoretical policy problem. Oncologists are abandoning biologics that patients need because the PA process is too burdensome to complete in a timely fashion. Specialty pharmacy patients experience dangerous therapy gaps because benefit type uncertainty delays PA initiation by days or weeks. The 72-hour decision window for standard drug PA requests and the 24-hour window for expedited requests reflect the clinical urgency CMS has correctly identified. These are minimum standards of care, not aspirational goals.

DrFirst's assessment of the technical landscape is that October 2027 is achievable for payers that engage now. The Da Vinci CRD, DTR, and PAS implementation guides are mature, well-documented, and have been tested in real-world production environments. The NCPDP SCRIPT ePA standard is already required for Medicare Part D and is operationally deployed at scale across the e-prescribing network. The primary gap is payer willingness to invest in API development ahead of a regulatory deadline, not technical feasibility.

VII. The Centralized API Endpoint Directory

CMS proposes to require all impacted payers to report their FHIR API endpoints to CMS and publish this information in a centralized, publicly accessible directory. DrFirst enthusiastically supports this proposal. The absence of a centralized payer endpoint directory has been one of the most underappreciated sources of friction in health IT interoperability. Vendors building payer connections currently must discover API endpoints through manual outreach, commercial directories of varying completeness, and direct bilateral negotiations—a process that is expensive, slow, and systematically advantages large incumbents over innovative entrants.

A CMS-published endpoint directory will dramatically reduce connection discovery and maintenance costs across the industry, enable smaller vendors to build payer integrations that are currently cost-prohibitive, and create accountability infrastructure—a public record of which payers have implemented required APIs—that will assist CMS in monitoring compliance.

DrFirst recommends that CMS:

- Require payers to report endpoints no later than 90 days prior to each applicable compliance deadline.
- Include in the directory each payer's conformance status, supported IG versions, and test environment availability.
- Publish the directory via a machine-readable FHIR API, not merely a static file, to allow automated discovery and integration by vendors and developers.

VIII. Conclusion

CMS-0062 is a genuinely important proposed rule. It closes a gap that has frustrated clinicians, patients, and interoperability advocates for years. It proposes replacing a 30-year-old HIPAA transaction standard with modern FHIR infrastructure. And it takes the first meaningful regulatory steps toward holding payers accountable for the quality of their API implementations.

DrFirst urges CMS to finalize this rule with the following principles intact:

1. Portals are not sufficient.
2. APIs are the standard.
3. Dual-track architecture is clinically correct and should be affirmed.
4. Benefit type determination must be solved at the data exchange layer, not the provider interface layer.
5. Payer API certification is overdue and achievable through the existing CMS program authority.
6. The October 2027 deadline reflects clinical urgency that cannot be indefinitely deferred to accommodate payer implementation preferences.

DrFirst stands ready to work with CMS, ONC, HL7, NCPDP, and our partners across the healthcare ecosystem to support the successful implementation of this rule. We welcome the opportunity to provide additional data, technical assistance, or subject matter expertise as CMS moves toward finalization.

Respectfully submitted,

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Key Citations and References

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