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June 11, 2026

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

Re: CMS-0062-P, Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs, 91 FR 19890 (April 14, 2026)

Dear Administrator Oz:

b.well Connected Health strongly supports the health data interoperability and transparency goals memorialized in CMS-0062-P. Its structural proposals — required FHIR implementation guides, a centralized endpoint directory, the first FHIR-enabled drug prior authorization, incorporation of small-group QHP issuers on FF-SHOPs, and the HIPAA update replacing X12N 278 with FHIR — are each, on their merits, the right next step in the Administration's interoperability agenda. The recommendations in this letter are offered to help CMS finalize the rule in a form that delivers the maximum, visible benefit to patients: cost transparency at the moment of prescribing, authorization decisions that travel with the patient when they change plans, and a defined pathway to establish real-world API performance from paper conformance.

For 11 million people, b.well holds a remarkably complete picture of their health: where they have been (24 million encounters), where they are going (2.9 million appointments), what their diagnoses or labs show (35 million conditions and 408 million observations), what their insurance has paid (75 million claims), and what they have been prescribed (42 million prescriptions). b.well operates the largest connected, live consumer health data network in the market, pledged as a CMS-Aligned

Network with live integration with TEFCA, and supports consumer-directed data exchange as part of the CARIN Alliance. Through these partnerships, we have shown that the Administration's goals of health data transparency can work to enable informed decision-making without further burdening patients and families.

The patient-impact case for getting this rule right is well-documented. The September 2025 Johns Hopkins systematic review in The American Journal of Medicine, synthesizing 25 U.S. studies, documents that prior authorization delays are associated with preventable hospitalization, disease exacerbation, prolonged hospital stays, and lower cancer survival. The American Medical Association's 2024 physician survey found that 82 percent of physicians say PA can lead to treatment abandonment and 29 percent reported PA contributed to a serious adverse event for a patient in their care. About one-third of patients who receive a PA approval never pick up the prescription, in many cases because the cost is not visible to them until the pharmacy counter. These are the outcomes the rule is positioned to improve and that should be counted in its impact analysis.

Each of the five recommendations below is offered in service of the Final Rule, with the goal of converting the rule's structural strength into outcomes patients can use. The appendix that follows responds to each Section III RFI through the patient-outcome lens of price transparency and portability.

1. Use the Section II.H proposal to extend the benefit to patients beyond the impacted-payer universe.

As the only provision in CMS-0062-P operating under HIPAA Administrative Simplification, Section II.H's replacing X12N 278 for dental, professional, and institutional prior authorization with FHIR (US Core, SMART App Launch, Da Vinci CRD/DTR/PAS, and Da Vinci CDex for attachments) reaches the entire covered-entity universe. This provision extends requirements for providing patients faster, less burdensome PA with better documentation to Medicare fee-for-service, commercial

payers, self-insured ERISA plans, every electronically-transacting provider, and every clearinghouse.

We respectfully recommend that the Final Rule (a) update the SMART App Launch citation from v2.0.0 to v2.2 with PKCE, which is the current security baseline in the FHIR community; (b) align the 24-month and 36-month HIPAA compliance windows with the October 1, 2027 API compliance dates in Section II.A so that payers can coordinate a single migration rather than maintaining parallel X12 and FHIR PA stacks; and (c) include in the Final Rule preamble reconciliation guidance for the adoption of Da Vinci CDex as the HIPAA attachment standard alongside the recently-finalized X12N 275 standard for claims attachments, so HIPAA covered entities have clear direction on how the two standards interact. We further ask CMS to set a timeline in the Final Rule to require covered entities under this provision to expose these data through the Patient Access API.

2. Finalize the National Directory IG at Section II.E.3 as the primary endpoint-discovery pathway, so a patient's chosen application can readily find the patient's plan.

Endpoint discovery is one of the most common sources of friction we observe between patient-facing applications and the payer FHIR APIs the rule already requires. Each payer publishes endpoints differently today, sometimes behind developer-portal click-throughs and bilateral agreements. From a patient's vantage, this means the application a patient has chosen may not be able to connect to a new plan readily when the patient changes coverage. The alternative proposal at Section II.E.3 — adopt the FAST National Directory of Healthcare Providers and Services Implementation Guide as the framework — is the structural fix.

We recommend the Final Rule finalize II.E.3 as the primary pathway, with bilateral § 422.119(h) endpoint reporting serving as the transition mechanism. The directory will best serve patients if it is freely available, FHIR-native, exposes OAuth and SMART metadata, supports FHIR Subscriptions for change notification, and carries a published uptime service-level objective.

3. In the Final Rule, extend the Real-Time Prescription Benefit Check to patients, including cash prices, with the same October 2027 compliance date.

The Real-Time Prescription Benefit standard CMS proposes at Section II.B.6 is a meaningful advance — and the patient-visible benefit can be even more meaningful if patients have the same real-time benefit visibility that the rule extends to prescribers. The CARIN Alliance published its Consumer Real-Time Pharmacy Benefit Check FHIR Implementation Guide in 2020, and the NCPDP Foundation awarded a grant in June 2025 specifically to harmonize the consumer IG with the provider-facing RTPB standard CMS is now proposing to mandate. The standards work is largely complete. Extending the benefit to patients in this rule would meaningfully reduce the pattern in which patients learn the cost of a medication only at the pharmacy counter, which contributes to the roughly one-third of approved prescriptions that are never picked up.

We respectfully ask that CMS's Final Rule require impacted payers to expose a consumer-facing RTPBC endpoint via the Patient Access API on the same October 1, 2027 timeline as the provider-facing RTPB standard. The response would include patient-specific out-of-pocket cost at both preferred and non-preferred pharmacies, formulary tier, prior authorization flag, lower-cost therapeutic alternatives, and availability of manufacturer coupons or patient assistance programs. Because patients sometimes pay less out of pocket using a cash or discount price than through their insurance benefit, a complete view of cost options helps patients make informed decisions at the point of prescribing. Accordingly, we recommend that the response include cash prices alongside the insurance-priced cost. The response timing should be consistent with the point-of-prescribing and point-of-selection workflows the Benefit Check is intended to serve, and specific timing metrics are best developed through the FHIR community process discussed in section 5.

The Formulary & Benefit data underlying RTPBC will best serve patients if it is machine-usable in addition to machine-readable. Experience with the Transparency in Coverage prescription drug

machine-readable file requirement suggests that final-rule clarity on usability expectations meaningfully improves the patient outcome. We recommend the Final Rule include (a) a daily refresh expectation for any formulary change affecting patient cost-share or PA status; (b) a constrained NCPDP coverage restriction value set with a published reference mapping; (c) population of therapeutic alternatives in RxNorm for PA-required or non-preferred-tier drug entries; and (d) access on consistent terms for any HIPAA-compliant application with patient authorization, on the same operational terms as payer portals. Critically, the Final Rule should require impacted payers to expose equivalent formulary data through the FHIR PDex US Drug Formulary IG.

We also ask that the other elements of the patient price-transparency package remain together in the Final Rule. Drug PA information flowing through the Patient Access API per Section II.F.1 lets the patient see authorization status, dosage approved, denial reason, and supporting documentation in the application they already use. The RTPB response from Section II.B.6, persisted and exposed through the Patient Access API for at least 12 months, gives the patient the same point-of-prescribing benefit information their provider saw. And the removal of drug formulary data from the Provider Access and Payer-to-Payer APIs in Section II.F.3 would best serve patients if conditioned on continued patient-side access through the Patient Access API and a free public Bulk Data endpoint for formulary data. Each of these is a critical need in the Final Rule, rather than a follow-on rulemaking.

4. Publish reference Da Vinci DTR Questionnaires for the top 20 medical-benefit drug PA categories — and name DTR as the medical-benefit parallel to RTPB.

From our operational vantage working with hundreds of payers, the October 1, 2027 compliance date for the medical-benefit drug PA pipeline is realistic — and it works best when payers and EHR vendors converge on the same documentation requirements rather than negotiating Da Vinci DTR Questionnaire shapes bilaterally for each high-volume drug category. CMS could meaningfully

accelerate that convergence by committing in the Final Rule, in coordination with HL7 and the Da Vinci Project, to publishing reference DTR Questionnaires for the top 20 medical-benefit drug PA categories by volume — including major oncology infusion regimens, biologics for autoimmune conditions, ophthalmology injectables, and other complex specialty therapies — within six months of the Final Rule.

The medical-benefit pathway also benefits from explicit recognition in the Final Rule preamble. Several major biologics exist in both Part B (IV-administered) and Part D (self-injectable) forms, including adalimumab, ustekinumab, and tocilizumab. A prescriber may not know at the point of prescribing which benefit pathway will apply. Because the RTPB standard CMS proposes routes to the pharmacy benefit, the Da Vinci DTR framework is the natural parallel for the medical-benefit PA workflow. Naming DTR in the Final Rule as a parallel requirement on the same October 1, 2027 compliance timeline would help ensure the transparency the rule is designed to produce extends to the drug categories that drive the largest authorization delays.

5. Signal a longer-term direction toward real-world API usability.

Conformance testing through public tools like HL7 Inferno establishes a useful baseline by validating that an API endpoint is present and well-formed, and meets specification under controlled conditions. That baseline matters and should continue. At the same time, conformance under artificial test conditions is not the same as demonstrating that an API works reliably in a production patient workflow. The community has not yet developed the test methods, metrics, and pass criteria to support CMS enforcement based on real-world API performance. Multiple public harnesses are available, their results are not directly comparable, and any compliance scheme built on the current toolset would risk cherry-picking and inconsistent pass thresholds.

The Final Rule has the opportunity to set the direction and the institutional commitment to get there as follows:

- Acknowledge in the preamble that real-world API usability — response completeness, predictable latency, scenario-based functional performance, and consistent third-party accessibility — is the goal.
- Commit CMS and ONC to supporting a multi-stakeholder process through HL7, the Da Vinci Project, the CARIN Alliance, and the broader FHIR community to develop robust test methods, metrics, and pass criteria for real-world API usability over the next two years.
- Encourage voluntary use of the existing public harnesses today, and voluntary publication of conformance results in machine-readable form, while signaling that mandatory use and enforcement will follow as community-developed test methods mature.
- Implement open third-party access on consistent terms in this final rule, including security-based rate limits, but strictly without conditioning API access on commercial agreements. This is the one performance-adjacent principle that does not require new test methods to implement, and we encourage CMS to include it in the Final Rule.

We continue to encourage CMS to hold the October 1, 2027 compliance date for the substantive provisions of the rule. The longer-term work on test methods and certification should not delay the structural advances CMS-0062-P proposes. We also respectfully encourage CMS to consider, alongside finalization of CMS-0062-P, a parallel focus on strengthening implementation of the existing Transparency in Coverage prescription drug machine-readable file requirement, so that the F&B and RTPB data this rule mandates is reinforced by the underlying drug-pricing transparency the prior rule established.

Conclusion

We strongly support the patient data control, price transparency, and portability that CMS-0062-P advances. The five recommendations above are intended to help CMS finalize the rule in a form that delivers the maximum patient-visible benefit by 2028.

We submit this letter in coordination with two other filings on this rule: the CARIN Alliance's submission, which addresses the consumer-directed exchange architecture and the CARIN Code of Conduct, and RxUtility's submission, which collects the patient-harm evidence from prior authorization and the experience of prior interoperability rules. We support those positions and write here to reinforce — not duplicate — that record, from the operational vantage of a production platform working across the very APIs CMS proposes to require.

We thank CMS for the opportunity to comment and we look forward to continuing the work of advancing data exchange and empowering consumers together.

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Appendix: RFI Responses

Section III: Patient Price Transparency and Portability

Section III contains five Requests for Information that may inform future rulemaking. The responses below interpret each through two patient outcomes the Administration is in a strong position to advance through the Final Rule for CMS-0062-P and the next rulemaking cycle: price transparency — the patient's ability to know cost, coverage, and authorization requirements before receiving care — and portability — the patient's ability to carry their data, their authorizations, and their treatment history with them as they move between providers, employers, plans, and life stages. Where a recommendation can be effected in the Final Rule for CMS-0062-P, we have noted it; the central consumer RTPBC, formulary functional performance, and DTR Questionnaire recommendations are offered as final-rule opportunities.

A. RFI III.A — Electronic Event Notifications for Value-Based Care and Care Coordination

Patient outcome at stake: portability of care coordination across providers, plans, ACOs, and the patient's own care team. Patients do not stay in one provider relationship for life. A patient managing a chronic condition often cycles among a primary care practitioner, a specialist, an ED visit, a hospitalization, a skilled-nursing stay, and a return to primary care within a single year. The 2020 rule's Conditions of Participation framework for hospital ADT notifications was the first federal step toward making sure the care team and the patient's own systems learn about those transitions in time to act. We respectfully offer the following recommendations to support the next step:

- Adopt the HL7 FHIR R4 Subscriptions Framework and the HL7 Da Vinci Unsolicited Notifications Implementation Guide, including its ADT use case, as the recommended near-term pathway and the required pathway following a notice-and-comment refresh. The HL7 v2.5.1 floor would remain valid for a 24-month transition period and then sunset. FHIR Subscriptions are the same infrastructure proposed for payer-API change notification under

Section II.E.3, so building one notification fabric across hospital-originated and payer-originated events is efficient.

- Expand the required recipient set beyond the patient's primary care practitioner to include (a) any ACO or value-based care entity to which the patient is attributed, with attribution communicated through the HL7 FHIR Da Vinci Member Attribution List IG; (b) any patient-mediated third-party application the patient has authorized through the Patient Access API; and (c) the patient's payer when that payer is conducting care management activities for the patient.
- Require notifications to carry structured content beyond the current three-element floor: encounter type and class, encounter time, discharge disposition, the encounter Location resource, the encounter's diagnoses (ICD-10 coded), and a DocumentReference pointer to the encounter's clinical summary.
- Consider adding a Medicare Promoting Interoperability Program measure for eligible hospitals and CAHs capturing the rate of timely notification delivery to authorized recipients, with the metric publicly reportable on Hospital Compare to support transparency.

B. RFI III.B — Increasing Health Care Resiliency

Patient outcome at stake: continuous availability of the patient's own data when payer, clearinghouse, or hospital systems are disrupted. Concentrated administrative infrastructure can affect patients at scale. When intermediary systems experience disruption, the patient's prescriptions can be delayed, their authorizations may take longer to process, and their applications may not be able to retrieve their own data. From a patient perspective, Section III.B is in important ways a portability-via-availability question, and we respectfully offer the following:

- Require modern transport security across all required payer APIs — TLS 1.3, with mutual TLS for B2B endpoints (Provider Access and Payer-to-Payer) and standard server TLS for patient-facing Patient Access endpoints.

- Adopt modern authentication — OAuth 2.1 with PKCE and SMART App Launch v2.2 across all FHIR APIs. The rule as drafted cites SMART App Launch v2.0.0, which predates PKCE adoption; updating to v2.2 in the Final Rule would strengthen the security baseline for the patient's data.
- Encourage Health-ISAC participation for impacted payers as a condition of CMS program participation, disclosure to CMS of any incident affecting API availability within 72 hours, and clarification that a prolonged unaddressed API outage is treated under the information-blocking exception framework.
- Pursue a hybrid routing architecture in which payers publish FHIR endpoints in the centralized National Directory so any authorized entity can reach them, clearinghouses remain a valid routing pathway with the same directory-publication discipline, and multi-clearinghouse redundancy disclosure helps the ecosystem identify single-clearinghouse dependencies before they become single-point failures.
- Make hospital ADT notification metrics publicly reportable at the hospital level on Hospital Compare. Clarify in survey-and-certification guidance that a hospital's failure to send notifications to a patient-authorized third-party application or to an attribution-listed value-based-care entity is a CoP non-compliance finding under 42 CFR 482.24(d). Treat hospital systems that consistently fail to send notifications as candidates for the existing information-blocking exception framework, recognizing that information blocking and CoP non-compliance are distinct but reinforcing levers.

C. RFI III.C — Improving Implementation of Payer API Technology

Patient outcome at stake: portability of the patient's app experience across plans. From the patient's perspective, the question Section III.C asks is whether the application a patient chooses today will continue to work the same way when the patient changes employers, ages into Medicare, or moves between Medicaid managed care plans. Today, payer FHIR implementations vary in ways that can affect app behavior when patients change plans. b.well's platform

demonstrates that we can accommodate that variation through payer-specific adaptations today, and consistent conformance with public verification would meaningfully reduce the work required to keep patient apps working as patients move.

Our recommendations here are deliberately staged to address what is and is not achievable in the near term from our experience. Today's public conformance tools (HL7 Inferno, Da Vinci Reference Implementations, CARIN Reference Implementation) test API conformance under controlled conditions, which is valuable but not the same as testing real-world usability. The community has not yet developed test methods, metrics, or pass criteria that would let CMS tie real-world API performance to enforcement consistently, and we do not think the final rule should attempt to build that on top of existing tools as they stand. Multiple harnesses produce non-comparable outputs; without a defined and community-validated notion of "pass," a mandate to use a designated harness today would risk cherry-picking and inconsistent thresholds.

- In the Final Rule: CMS and ONC should commit in the preamble to supporting development of robust test methods for real-world API usability through the HL7 / Da Vinci / CARIN community process. Existing public harnesses remain available for voluntary payer use, and payers are encouraged to publish results in, at minimum, machine-readable form. Open third-party access on consistent terms — security-based rate limits as appropriate, no commercial-agreement gatekeeping — can be implemented immediately in this final rule and is the one element of this recommendation that does not require new test methods. Where payers voluntarily use the existing harnesses, they should re-test on every IG version upgrade rather than relying on prior-version results, so published conformance reflects the current implementation.
- Medium-term, as community-developed methods mature: ONC should finalize voluntary certification criteria for payer API technology in 45 CFR 170.315, drawing on the community-developed test methods, mirroring the HTI-2 proposals withdrawn in December 2025 and updated for the named IG STU versions in the CMS-0062-P final rule. Open API testing is

critical where tied to real world, standardized “API usability” measures that set a floor and incentivize vendors to demonstrate that their usable APIs meet those measures.

- Within two years: CMS should encourage payers to use certified payer API technology as a condition of program participation, calibrated as "either certify your own implementation or use a certified technology supplier" so the discipline applies consistently across payer technology choices.
- CMS's program-participation authority offers a clear primary enforcement lever once the underlying test methods are mature and consistently applied. The ONC certification program then provides the technical mechanism CMS's program authority can call upon, without requiring an expansion of ONC's HITECH authority.

D. RFI III.D — Step Therapy

Patient outcome at stake: portability of the patient's treatment history across plan transitions. A patient on a chronic condition often spends months titrating to an effective therapy on a prior plan. When a patient changes employers, ages into Medicare, or moves between Medicaid managed care plans, the new plan, lacking access to the prior plan's step-therapy history, may require the patient to retry medications she has already tried. This is costly, adds administrative burden, and of course is harmful to the patient’s health. The Payer-to-Payer API is well-suited as a structural vehicle to address treatment history portability. We recommend that:

- The Payer-to-Payer API transmit structured step-therapy history in FHIR resource form. Minimum payload per drug or drug class: drug or class tried (RxNorm), dose, frequency, duration, outcome (failure, intolerance, adverse effect, partial response, contraindication) as a coded value from a CMS-curated value set, prescriber-of-record, dates, and supporting clinical documentation through DocumentReference. FHIR resource pattern: MedicationStatement (trial) + Communication or Condition (outcome) + Provenance (source attribution). HL7 and the Da Vinci Project could publish a reference IG within six months of the Final Rule.

- Receiving payers credit the prior payer's step-therapy determination unless the receiving payer can document a clinically appropriate reason for re-imposition. Acceptable clinical reasons could be enumerated: significant clinical change since the prior trial; new evidence-based therapy unavailable at time of prior trial; safety advisory issued since prior trial; documented prior trial inadequate for clinical reasons.
- A default five-year look-back period. Within five years, the default is credit; beyond five years, the receiving payer's clinical assessment of whether a fresh trial is appropriate has more weight.
- Step-therapy history and current step-therapy status are exposed in the Patient Access API in order to be most useful and timely to the patient.

E. RFI III.E — Laboratory Tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Patient outcome at stake: price transparency before the order is placed, and portability of authorization decisions after. The lab and DMEPOS RFI is, from the patient's perspective, two related questions. The first is price transparency before the order is placed: the patient and the ordering provider would benefit from knowing whether the test or item requires prior authorization and what the patient's cost exposure looks like, at the time the order is written. The second is portability of authorization decisions after: an authorization issued through the FHIR PA pipeline functions best when it is treated as the binding commitment it represents. We respectfully offer the following:

- Extend the FHIR Da Vinci CRD/DTR/PAS pipeline to laboratory tests and DMEPOS items. Payers could populate the PA API with the list of items requiring PA, at minimum machine-readable and queryable by LOINC (labs) and HCPCS (DMEPOS), so the patient and the ordering provider know whether PA is required at the time the order is written.

- Publish reference Da Vinci DTR Questionnaires for the high-volume lab and DMEPOS PA categories. For labs: hereditary cancer panels, pharmacogenomics, NIPT, MAAAs, companion diagnostics, and molecular and genetic testing categories. For DMEPOS: complex rehabilitation technology, ventilation, hospital beds, oxygen, CPAP/BiPAP, and prosthetics.
- Match lab and DMEPOS PA decision timeframes to the drug PA timeframes proposed in this rule — 72 hours for standard requests, 24 hours for expedited. Routinely track, assess, and enforce compliance with these timeframes.
- Provide clear treatment of post-payment recoupment for items that received electronic PA approval through the FHIR PA API. Patients benefit most when an electronic authorization represents a stable commitment rather than a provisional one subject to later reversal.
- The Final Rule preamble could clarify, consistent with what CMS already states in the III.E background, that MA plans' reliance on the Medicare Part B laboratory date-of-service policy to deny PA after specimen collection is not consistent with MA program rules. An accompanying QSO memo could support consistent implementation.
- Acceptance of the test requisition form (TRF) as valid medical-necessity documentation for in-scope laboratory tests would reduce documentation friction, through guidance to MACs and corresponding expectations in the QHP certification process.
- Disclosure of contracted laboratory benefit managers (LBMs) and publication of LBM medical policy alongside the payer's own medical policy in, at minimum, machine-readable form would help patients and providers understand the operative rules. Treating LBM-imposed PA rules as the payer's own for purposes of recoupment, appeal, and Patient Access API transparency would support consistent patient experience.
- DMEPOS suppliers could be granted standing to initiate the FHIR PAS PA request on behalf of the patient when the ordering provider has issued an order but has not submitted the PA — analogous to the laboratory's existing standing under MA rules.

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Section II: Additional Recommendations for the Record

The recommendations in this subsection address specific Section II provisions that are not centered in the five anchor recommendations in the cover letter, but that b.well believes should be on the docket for CMS's consideration as the agency finalizes the rule. Each is offered as a Final-Rule opportunity unless otherwise noted.

A. Section II.A — Interoperability Standards for APIs

- II.A.2 — Name the specific NCPDP SCRIPT, Formulary & Benefit, and Real-Time Prescription Benefit versions in the final rule, and explicitly sunset fax and phone PA channels for in-scope pharmacy-benefit drugs no later than six months after the compliance date. The point of requiring a standard is to retire the workflow it replaces.
- II.A.3 — On the unexpired-versions framework, cap concurrent live versions of any required standard at two; require a minimum 12-month overlap before sunset of an older version; require payers to publish active and supported version metadata on the FHIR CapabilityStatement and at a .well-known endpoint; require payers to notify CMS (and the published endpoint directory) at least 90 days before sunsetting a version.
- II.A.4 — Name specific STU versions of each required implementation guide in the final rule — CARIN Blue Button 2.2.0, Da Vinci PDex 2.1.0 and its sub-IGs, Da Vinci CRD 2.2.1, DTR 2.2.0, PAS 2.2.1, the current Bulk Data Access version, and the current CDex version — rather than referring to the IGs generally. Without named versions, "required" can mean different things at different payers.
- II.A.4.c — Where payers voluntarily use the existing public conformance harnesses, they should re-test on every IG version upgrade rather than relying on prior-version results, so published conformance reflects the current implementation.
- II.A.4.d — Clarify in the final rule preamble that voluntary early adoption of a newer version of a required standard does not foreclose continued support of the older required version during the transition period; payers should not be forced to retire an older version before its expiration date solely because they have voluntarily adopted the newer one.

- II.A.5 — On the RFI for additional recommended IGs, b.well recommends adding the following to the recommended set in 45 CFR 170.215 with a clear glide path toward required status in a future rule: SMART App Launch v2.2 (with PKCE), SMART Health Cards / Health Links, HL7 International Patient Summary (IPS), Da Vinci Health Record Exchange (HRex), Da Vinci Consent, FHIR Subscriptions framework (R4B/R5 backport), HL7 SDOH Clinical Care IG and Gravity Project value sets, and the CMS Interoperability Framework Individual Access IGs once published.
- II.A.6 — On the Provider Directory clarification, name PDex Plan-Net STU 1.1 (or its successor at finalization) as the required directory IG; mandate exposure of OAuth and SMART metadata at the standard .well-known/smart-configuration endpoint; require payers to populate the accessibility, language capability, and TTY/ASL extensions defined in Plan-Net, so directories serve members with disabilities and limited-English-proficiency members rather than only sighted English-speaking members.

B. Section II.B — Electronic Prior Authorization for Drugs

- II.B.4 — Require pharmacies to expose NCPDP SCRIPT-derived PA status through the Patient Access API, so the patient sees the same PA status the pharmacist sees at the dispensing window.
- II.B.5. — In addition to the NCPDP F&B requirement, require impacted payers to expose equivalent formulary data through the FHIR PDex US Drug Formulary IG. This avoids forcing consumer applications and AI assistants to translate between NCPDP and FHIR representations bidirectionally for the same underlying data, and lets developers serving patient-facing use cases work in the FHIR ecosystem in which they already operate.
- II.B.7 — On the state Medicaid/CHIP extension pathway and QHP exception pathway, cap state extensions at no more than two consecutive years; require quarterly public progress reporting from any state on extension; require state extension requests and CMS granting decisions to be posted on regulations.gov for transparency; decouple the extension sunset

from the Section II.H HIPAA compliance date so extensions do not become indefinite if II.H is not finalized.

C. Section II.C — Decision Timeframes and Public Reporting of Metrics

- II.C.2 — Bind the specific reason for denial requirement to a coded value set built on HL7 v3 ActReason and X12 Claim Adjustment Reason Codes (CMS-curated). Permit a supplementary free-text explanation, but require the coded value as the operative reason so that downstream automations (appeals, alternative-therapy lookup, AI-assisted triage) can act on it.
- II.C.3.b — Publish definitive SLA-clock-pause guidance for Da Vinci DTR follow-up question loops so payer, provider, and aggregator systems compute deadlines identically. Clarify that the clock runs in calendar (not business) hours and starts from the payer's receipt of a request containing sufficient documentation to make a decision.
- II.C.3.c — Use the final rule itself to enumerate the specific drug categories that fall outside "covered outpatient drugs" and lack existing PA timeframes, and assign each a default timeframe (72-hour standard, 24-hour expedited) consistent with the broader drug PA framework, rather than leaving alignment to payer interpretation.
- II.C.3.d — b.well strongly supports the 24-hour CHIP FFS prescription drug PA timeframe without qualification. Pediatric members face missed school days, missed parent work days, and avoidable emergency-department visits when CHIP drug PA is slow.
- II.C.6 and II.C.7 — Publish the additional non-drug PA metrics and the drug PA metrics in machine-readable schema (FHIR Measure / DEQM); require payers to expose the metrics via a public Bulk Data endpoint alongside the publicly-posted aggregation, so researchers, advocates, and app developers can consume the data programmatically.

D. Section II.D — Small Group Market QHP Issuers on FF-SHOPs

- II.D — Explicitly permit small-group QHP issuers on FF-SHOPs to use the same FHIR infrastructure in which they already operate for their individual-market QHP business —

many issuers operate in both markets and the data shape is identical. Align the FF-SHOP compliance date with the FF-Exchange compliance date to avoid market confusion. Communicate clearly that the rule does not require new vendor relationships or new endpoint infrastructure where the issuer already has the same vendor and endpoint serving its individual-market business.

E. Section II.E — Reporting Payer API Endpoints

- II.E.2 — Define a minimum API documentation set in the final rule: the FHIR CapabilityStatement URL, the supported SearchParameters, the list of conformance test results, the sandbox URL, and technical contact information. A common documentation floor materially reduces the cycle time between when a payer goes live and when third-party developers can ship integrations.
- II.E.1 and II.E.5 — Require each impacted payer to attest to the accuracy of its endpoint metadata on a routine cadence, with a public audit log of changes available alongside the directory, and require the directory to publish a machine-readable change log so app developers can detect endpoint updates programmatically rather than discovering them only when an authentication call fails.

F. Section II.F — Updates to Patient Access, Provider Directory, Provider Access, and Payer-to-Payer APIs

- II.F.1 — Specify the FHIR resource graph in the final rule for drug PA data in the Patient, Provider Access, and Payer-to-Payer APIs: Claim and ClaimResponse for the PA decision; DocumentReference for unstructured documentation; Communication for denial reasons. Without specifying the resource graph, app developers will need to negotiate the data shape with each payer individually, which is the fragmentation the rule otherwise eliminates.
- II.F.2 — In addition to the proposed usage volume metrics, add quality indicators that distinguish APIs that work from APIs that exist: p95 (and p99) API latency, error rate by HTTP

status family, OAuth authorization success rate, and count of unique active third-party app clients that have connected. Publish payer-level metrics in FHIR Measure.

- II.F.4 — On the denial or discontinuation of access to the Provider Directory API, restrict legitimate denial grounds to demonstrated security or abuse incidents; require any payer denying access to post a public reason; require an appeals pathway; and prohibit denial based on commercial relationship or absence of a payer-vendor agreement. Public-facing directory data should not be gatekept behind bilateral commercial arrangements.

G. Section II.G — Open Payments Civil Monetary Penalties

- II.G.1.b — On the proposed definition of "failure to report," b.well supports the definition and the resulting CMP authority as a transparency-protective measure.

G. Section II.H — HIPAA Standards Related to Prior Authorization

- II.H.11 — Reference DTR Questionnaires for drug PA categories should include language-access requirements explicitly: questions intended to be presented to a patient (consent confirmations, patient-reported clinical information) should be authored in a way that supports translation into the languages CMS already requires for member-facing materials, with the FHIR Questionnaire resource carrying language-tagged display strings rather than English-only labels. Including this expectation in the reference Questionnaires sets the convention for the entire FHIR PA ecosystem.

G. Section II.J — ONC Adoption of Updated Health IT Standards

- II.J — Name specific IG STU versions in the final rule rather than referring to them generally (the same versions enumerated above for Section II.A); commit to no shorter than 18 months between rule finalization and the January 1, 2028 expiration of the current versions of the standards at 45 CFR 170.215(j)(1)–(3), (k)(1), (m), and (n), so payers, providers, and aggregators have realistic migration runway; publish, alongside the final rule, a public crosswalk of breaking changes between the expiring and adopted versions of each

standard, so every implementer does not rediscover the same migration issues independently; and ensure that documents incorporated by reference at § 170.299 are available at free public URLs, since standards intended to enable broad interoperability should not sit behind paywalls.

Closing note

We believe the above recommendations belong in the Final Rule for CMS-0062-P alongside those that are appropriate for the next rulemaking cycle, either to materially extend the patient-visible benefit of the rule's structural advances or support interoperability and standards integrations improving the timeliness and data quality on which the health system relies.

We look forward to working with CMS on our shared objectives to serve patients and families through our collaborations on data exchange and the future implementation of the Final Rule.

Please do not hesitate to contact us if you have any questions.

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