



January 4, 2021

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: RIN 0938-AT99 Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (the "PA Proposed Rule" or "Proposed Rule")

Dear Administrator Verma:

The Regulatory Relief Coalition (RRC) is pleased to have the opportunity to comment on the prior authorization (PA) Proposed Rule. The RRC is a group of national physician specialty organizations advocating for regulatory burden reduction in programs administered by the Centers for Medicare and Medicaid Administration (CMS) so that physicians can spend more time treating patients. Most recently, we have focused on common-sense reform of Medicare Advantage Organizations' (MAOs') use of PA. Our aim is to ensure that PA is not a barrier to timely access to care for the patients we serve.

The PA Proposed Rule would place new requirements on certain "Impacted Payers," including state Medicaid and Childrens Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFE) to improve the electronic exchange of health care data through standards-based Application Programming Interfaces (API), and to streamline processes related to PA. The RRC believes that the PA Proposed Rule is a step forward in reigning in the mounting burden of PA processes. We are particularly gratified that the PA Proposed Rule reflects some of the principles of included in H.R. 3107, the *Improving Seniors' Timely Access to Care Act of 2019*. This important legislation establishes a blueprint for the reform of MA Plan PA processes, and at the close of the 116th Congress, had garnered the bipartisan support of 280 members of the House of Representatives. We applaud CMS for adopting the principles outlined in H.R. 3107 and look forward to working with the Agency to further refine and expand federal oversight over health plans' PA practices.

While the PA Proposed Rule is extremely complex and technical, the comment deadline is short, providing less than a month for the RRC and other interested parties to offer comments. For that reason, while the PA Proposed Rule includes substantial discussion and comment solicitation on technical issues and information technology (IT) standards, the RRC's comments set forth below focus on broad conceptual issues and policy directions rather than technical details. We have also attempted

to narrow our focus to comment on several key issues that are most likely to impact patients' access to care and providers' administrative burdens — generally found in the section of the Proposed Rule entitled “Documentation and Prior Authorization Burden Reduction.” Our feedback is described in detail below.

I. Scope of the PA Proposed Rule

A. Impacted Payers

We strongly urge CMS to expand the scope of PA Proposed Rule's requirements to apply to Medicare Advantage (MA) plans and any additional health plans subject to CMS' jurisdiction. We do not believe that there is any public policy rationale for only requiring a subset of health plans to implement the critical PA improvements described in the Proposed Rule while not demanding the same of MA plans, which are more directly under CMS' jurisdiction. These reforms hold the promise to make medically necessary services available to patients on a timelier basis and significantly increase the amount of time physicians can devote to patient care by substantially reducing the time spent pursuing PA. From a policy perspective, there simply is no reason to make these benefits available to patients enrolled in certain QHPs, Medicaid, and CHIP, but at the same time deny them to MA enrollees.

Moreover, as a practical matter, we do not believe that the systemic reform that CMS seeks to trigger through the PA Proposed Rule will materialize if MA plans are not included. It is our understanding that the fundamental strategic vision underlying the PA Proposed Rule is to impose PA requirements on a sufficiently large subset of an issuer's health plan offerings to incentivize the issuer to use the same IT systems and functionalities for its other health plan product lines, including any MA plans that the issuer may offer. The Proposed Rule is predicated on the assumption that once a sufficient number of health plans adopt the IT systems and PA practices described in the Proposed Rule, providers will invest in the technologies necessary to take advantage of automated PA to improve their own efficiency. In this manner, CMS seeks to use government authority over the Impacted Payers to leverage broader systemic change.

However, for this approach to work, the number of health plans impacted by the new PA requirements needs to reach a “tipping point” threshold that is sufficient to incentivize issuers to adopt comparable reforms for their commercial and other health plan product lines. On its face, the inclusion of all Medicaid FFS and Medicaid managed care plans, along with CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-Facilitated Exchanges (FFE)s¹ might appear sufficient to trigger the broader industry changes that CMS seeks.² However, state Medicaid programs, which are charged with implementing the ambitious reforms outlined in the PA Proposed Rules, are financially strapped and simply do not have the funds necessary to adopt CMS guidelines— even if they qualify for

¹ Based on 2018 data, QHPs in 34 states including the District of Columbia) are operated on FFEs and therefore would be subject to the new requirements. Vanessa C. Forsberg (Analyst in Health Care Financing) June 20, 2018 <https://fas.org/sgp/crs/misc/R44065.pdf>. Congressional Research Service. Overview of Health Insurance Exchanges. Vanessa C. Forsberg (Analyst in Health Care Financing) June 20, 2018.

² We understand that many Medicaid plan require PA for a broad range of services, and that a number of large health insurance companies have a significant stake in the Medicaid managed care market. <https://www.medicare.org/articles/does-medicare-require-prior-authorization-for-referrals>; <https://www.medicare.gov/Medicare/downloads/medicaid-mc-enrollment-report.pdf>; <https://www.medicare.org/articles/does-medicare-require-prior-authorization-for-referrals>; <https://www.medicare.gov/Medicare/downloads/medicaid-mc-enrollment-report.pdf>.

a limited federal funding match. States expect Medicaid enrollment and spending each to jump by more than 8 percent in fiscal year 2021 — chiefly due to a slumping economy amid the COVID-19 pandemic and federal conditions to maintain coverage to access enhanced federal matching funds. This follows total Medicaid spending growth of 6.3 percent for fiscal year 2020 — during which enrollment remained flat. In light of the extraordinary strain that the COVID-19 pandemic has placed on state budgets, we do not believe that it is realistic to assume that state Medicaid plans — whether operated on a FFS basis or through Managed Care Organizations — will have the financial resources to institute the IT and other systems changes mandated by the PA Proposed Rule.

In light of the pressing competing priorities faced by Medicaid programs and other Impacted Payers, we believe that it is highly unlikely that they will spend the resources necessary to implement the PA Proposed Rule, and the Proposed Rule does not appear to include any enforcement authority. Unless MA plans are included in the requirements, we do not believe that the PA Proposed Rule will trigger the type of systemic reform intended by CMS.

- **Recommendation:** *The RRC strongly urges CMS to include MA plans within the scope of the PA Proposed Rule.*
- **Recommendation:** *The RRC strongly urges CMS to include QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF-SHOPs) state-based Exchanges on the Federal Platform (SBE-FPs) and QHP issuers in SBE-FPs within the scope of the PA Proposed Rule.*

B. Prescription Drugs/Covered Outpatient Drugs

The PA Proposed Rule does not include prescription drugs and/or covered outpatient drugs in any of the proposals, although CMS seeks feedback on including them in the future. We recognize that automated systems for obtaining PA for prescription drugs are considerably further advanced and more commonly used than those for other items and services. For this reason, we understand that certain provisions of the PA Proposed Rule may not be needed for prescription drugs/covered outpatient drugs. However, we see no reason to delay other requirements that are equally required for prescription drugs/outpatient covered drugs as for the items and services that do fall within the scope of the PA Proposed Rule (e.g., transparency requirements; public reporting requirements; and Documentation Requirement Lookup Service (DRLS) API requirements).

- **Recommendation:** *The RRC urges CMS to and include prescription drugs/covered outpatient drugs along with other items and services within the scope of the PA Rule. We also urge CMS to work with the National Council for Prescription Drug Programs on standards that ensure that PAs for prescription drugs/covered outpatient drugs result in more expeditious PA determinations.*

C. Limiting Unnecessary PA

Fundamentally, the PA Proposed Rule focuses on easing the administrative burden of PA by laying the foundation for electronic submission and processing of PA requests. However, even if the PA process were seamless and fully automated, it should not be ubiquitous. We believe that the PA Proposed Rule would be greatly improved if it included requirements intended to reign in the spread of PA requirements to more and more items and services and to ensure that PA requirements are imposed only when there is a reason to believe that such items or services involved are overutilized.

- **Recommendation:** *The RRC urges CMS to widen the scope of the PA Proposed Rule to require health plans to restrict PA to those services for which there is evidence of overutilization and to review PA lists at least annually to remove PA restrictions on items and services that are routinely approved.*

II. Comments on Patient Access API, Provider Access API and Payer- to- Payer API

While our comments focus primarily on those sections of the Proposed Rule that directly address the need to reduce the administrative burdens associated with PA, several provisions relating to the Patient Access API, Provider Access API and the Payer-to-Payer API also address PA. Our recommendations concerning these sections of the Proposed Rule are set forth below:

- **Recommendation:** *The RRC strongly supports the proposed expansion of requirements for the Patient Access API and the requirement that Impacted Payers make available a Provider Access API.*
- **Recommendation:** *The RRC supports the inclusion of PA information in the Patient and Provider Access APIs and urges CMS to require Impacted Payers to include in the Patient Access and Provider Access APIs information on past prior authorization requests. This data is especially helpful in tracking the history of PA determinations to ensure consistency and facilitate continuity when a patient switches payers.*
- **Recommendation:** *The RRC recommends that the Patient Access API, the Provider Access API and the Payer to- Payer API include information on the status of prescription drug/covered outpatient drug PA requests. This data is especially helpful in tracking the history of PA determinations to ensure consistency and facilitate continuity when a patient switches payers.*
- **Recommendation:** *While the RRC recognizes that payers' lists of services subject to PA differ, we believe that a PA approval by a patient's payer should "carry over" when that patient switches to another payer and the successor payer also requires PA for the service. In cases involving chronic care, the predecessor payer's approval should carry over for at least 90 days. Such a requirement is necessary to ensure that patient care is not disrupted.*

III. Documentation and PA Burden Reduction through APIs

A. DRLS API

Under the PA Proposed Rule, beginning on January 1, 2023, each Impacted Payer would be required to implement and maintain a Fast Healthcare Interoperability Requirement (FHIR)-based DRLS API, populated with its list of covered items and services, not including prescription drugs and/or covered outpatient drugs) for which PA is required, along with the Impacted Payer's documentation requirements for obtaining approval for that item or service.

- **Recommendation:** *The RRC strongly supports the requirement that Impacted Payers implement a DRLS API meeting the specifications set forth in the Proposed Rule.*

While easy access to the information required to be included in the DRLS API proposal would most certainly ease some of the administrative burden associated with PA requirements, it is unclear whether the DRLS API can be implemented by Impacted Payers in the timeframe anticipated in the Proposed Rule. Moreover, even if the DRLS API is made available to providers on a timely basis, it is unclear

whether physicians will have cost-effective access to the technology necessary to interface with payer systems.

In the PA Proposed Rule, CMS requests comments on a potential short-term solution that would require Impacted Payers to post, on a public-facing website, their list of items and services for which PA is required and populate the website with their associated documentation rules as in interim step while they implement the DRLS API.

- **Recommendation:** *The RRC strongly supports including in the PA Final Rule a requirement that Impacted Payers post the PA information required to be included in the DRLS API on a public-facing website, pending implementation of the DRLS API.*

B. Prior Authorization Support (PAS) API

The Proposed Rule would require that Impacted Payers implement a PAS API to facilitate Health Insurance Portability and Accountability Act (HIPAA)-compliant PA requests and responses, including any forms or medical record documentation required by the payer for items or services for which the provider is seeking authorization. The Proposed Rule would require that the PAS API conform with the HL7 FHIR Da Vinci PAS Implementation Guideline beginning on January 1, 2023.

We are concerned that the PA Proposed Rule is extremely confusing with respect to the transaction standard that the new PAS API is required to meet. While the preamble requires that the PAS API comply with the HL7 FHIR standard, the proposed new regulation specifically requires compliance with HIPAA transaction standards, which currently require that the use of the ASC X12 278 (the 278 Standard)³ for all PA electronic transactions⁴ (effective on and after January 1, 2012.)⁵ In part because CMS has failed to finalize a standard for submitting supporting medical documentation (the “275 Attachment Standard”), both provider and health plan adoption of the 278 Standard has been extremely poor. Nonetheless, it remains the legally required transaction standard for PA requests and health plan responses under HIPAA. While we understand that a good case can be made that the HL7 FHIR standard is superior to the 278 Standard and should supersede it, if the PA process is to move toward automation, it is critical to remove all ambiguity about the technical standards to be used.

- **Recommendation:** *The RRC strongly recommends that CMS finalize the 275 Attachment Standard to facilitate the broad adoption of the 278 Standard and require Impacted Payers to support the 278 Standard, as HIPAA currently requires. The Proposed Rule should be modified to clearly require Impacted Plans to make available the PAS API functionalities available to providers who utilize the 278 Standard for the submission of PA requests. If the Final Rule requires the use of the HL7 FHIR standard for the PAS API, CMS should require Impacted Payers to support both the 278 Standard and the HL7FHIR standard during a reasonable transition period designed to enable practices to acquire and implement the necessary technology..*

³ Formally, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 - Health Care Services Review - Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review - Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1.

⁴ In HIPAA parlance, “referral certification and authorization” transactions.

⁵ 45 CFR §162.1302.

Regardless of whether the 278 Standard or the HL7 FHIR Standard is to be required, at present, the PA process is conducted primarily using facsimile and other non-automated submissions. As in the case of the DRLS API proposal, it is unclear whether and to what extent providers have — or are likely to have by 2023 — the technology necessary to take full advantage of the proposed PAS, especially since current Certified Electronic Health Record Technology (CEHRT) requirements do not require developers to include PA functionality as a condition of EHR certification. CMS expects that its proposals to require Impacted Payers to implement the DRLS and PAS APIs will incentivize providers to adopt, and health IT developers to develop, information systems and/or EHRs that can interface with PAS APIs. However, it is unclear whether or when the necessary technology is likely to become readily available to providers or whether, if available, it will carry a price tag that individual physician practices can afford. While CMS does (in passing) suggest that PA -related functionality might be included in certification criteria in the Office of the National Coordinator of Healthcare Technology (ONC) Health IT Certification Program in the future, the Proposed Rule does not include any proposal to this effect.

- **Recommendation:** *The RRC recommends that CMS work with ONC to modify the CEHRT requirements to include a requirement that, to be certified, electronic health record systems must include PA functionality.*

Since we believe that it is unlikely that the PAS API will be made broadly available by Impacted Payers by 2023 or that many individual physician practices will be in a position to take advantage of it even if it is available, we strongly urge CMS to consider an interim solution:

- **Recommendation:** *The RRC notes that the Proposed Rule’s PAS API requirement would require that Impacted Payers provide not only notification of the resolution of a PA request but also provide a specific reason for denial (if the request is denied). The RRC strongly supports this requirement and urges CMS to make the requirement applicable to PA requests and responses that are not processed using the PAS API. We also recommend that CMS require the use of a standardized set of denial codes (building on the X12 278 set of denial codes), rather than enabling Impacted Payers to adopt proprietary denial codes that will add to the burden for physicians’ practices.*
- **Recommendation:** *The RRC urges CMS to include in the final regulation a provision under which any PA request that includes all of the specific documentation required in the DRLS API is deemed to be approved if a determination is not made within the regulatory deadline. Such a provision will unequivocally incentivize Impacted Payers to put in place the PAS API as soon as practicable and will thereby advance CMS’ regulatory objectives.*

C. PA Decision Timeframes and Communications

CMS proposes changes that impact timeframes for PA determinations, shortening the period for certain Impacted Payers to make certain PA determinations. However, the revised requirements would still authorize a 14-day delay during the period from adoption of the new requirements through 2023 for an impacted payer to make a standard determination. We urge CMS to require Impacted Payers to provide real-time PA determinations except in the case of complex cases.

At the very least, we urge CMS to adopt the deadlines recently adopted by the Council for Affordable Quality Healthcare (CAQH) in the [CAQH Committee on Operating Rules for Information Exchange \(CORE\) Prior Authorization & Referrals \(278\) Infrastructure Rule vPA.2.0](#). (“Infrastructure Rule”). Section 4.5 of the Infrastructure Rule includes specific timeliness standards for health plan responses to providers. Under this section, a health plan or its agent is required to send an initial response within 20 seconds in scenarios when additional information/documentation is immediately known or within two

business days when additional information/documentation is not immediately known. Section 4.5 of the Infrastructure Rule further requires that a health plan or its agent must return the unsolicited 5010X217 278 Response containing an approval or denial within two business days following receipt of the complete prior authorization request. This timetable was supported by many payers when the issue was considered by the CAQH and we believe that these deadlines are more than sufficient for Impacted Payers to make PA determinations electronically.

- **Recommendation:** *The RRC urges that CMS require Impacted Payers to respond in real time for all but the most complex of PA requests, and that, at the very least, CMS require Impacted Payers to respond to PA requests in accordance with the deadlines set forth in Section 4.5 of the Infrastructure Rule.*

The Proposed Rule would not provide that a PA request is automatically approved if the Impacted Payer fails to meet the required time deadline. As noted in the Proposed Rule, if the deadline is missed, providers may need to contact the payer to determine the status of the request and whether additional information is needed.

- **Recommendation:** *The RRC strongly urges CMS to include in the final rule a provision that deems a PA request approved if the determination is not made in accordance with required time deadlines. Without this incentive to make timely decisions, failure to meet required time deadlines has no immediate impact on the payer, places the burden of follow-up on the provider for the payer's failure to comply with the applicable time deadline, and, most importantly, results in unwarranted delay in the delivery of patient care. At the very least, we request that a PA request be automatically approved if the deadline is missed and the Impacted Payer has also failed to implement a PAS API meeting the requirements in the Proposed Rule. This change would provide a strong incentive for an Impacted Payer to implement a PAS API on a timely basis.*

Under the Medicaid managed care rules, we further understand that a payer's failure to decide within the required timeframe is considered a denial and the Medicaid beneficiary is not entitled to a fair hearing if a PA request is denied.

- **Recommendation:** *For the reasons set forth above, the RRC urges CMS to modify the rules applicable to Medicaid managed care PA determinations such that a plan's failure to make a timely determination is deemed to constitute approval, rather than denial, of the PA request.*
- **Recommendation:** *The RRC also urges CMS to change its current policy, such that a Medicaid beneficiary may appeal the denial of a PA request.*

D. Public Reporting of PA Metrics

CMS proposes to require Impacted Payers to publicly report on specified PA metrics on their websites or via a publicly accessible hyperlink(s) at least annually. We understand that each metric would be reported separately for each item and service, not including prescription drugs and/or covered outpatient drugs, and the data would be required to be publicly reported for each metric. We note that the list of data elements required to be reported parallels the transparency requirements of H.R. 3107.

- **Recommendation:** *The RRC strongly supports the PA Proposed Rule's requirements for public reporting of PA metrics and urges CMS to include prescription drugs and/or covered outpatient drugs in this reporting requirement.*

- **Recommendation:** *In order to make publicly reported information easily accessible, the RRC requests that CMS collect these metrics and publish them in a standardized format on a public website.*

E. PA “Gold-Carding” Programs

The preamble to the PA Proposed Rule encourages payers to adopt gold-carding programs to relieve the PA burden for physicians whose PA requests are routinely approved. The Proposed Rule itself does not include any requirements or other incentives for Impacted Payers to implement such “gold carding” programs. CMS seeks comment for potential future rulemaking on the incorporation of gold-carding into star ratings for QHP issuers on the FFEs and on requiring gold-carding as part of an Impacted Payer’s PA policies.

- **Recommendation:** *The RRC urges CMS to incorporate a gold carding measure into the star ratings for QHP issuers on the FFEs. We also support including a requirement that Impacted Payers’ PA programs include a gold carding program that exempts from PA requirements providers whose PA requests are routinely approved.*

F. Making PA Approvals Binding

Finally, the PA Proposed Rule includes a discussion of whether Impacted Payers should be able to deny payment for an item or service that has been approved through a PA process. Ostensibly, PA processes are designed to ensure that an item or service is medically necessary before it is provided. The process imposes considerable time and cost burden on providers and results in delays in patient care — all to ensure that the payer agrees that the item or service will be covered. PA requests include sufficient patient identifiable information for the payer to determine whether the item or services for which approval is sought are medically necessary and whether the patient’s coverage is intact and whether any policy exclusion applies. Denials are binding on providers and patients and must be appealed for payment to be made. As such, we question why approvals are not equally binding on payers? Elementary fairness demands that a physician who provides a service in reliance on a PA approval should be entitled to rely on that determination. If not, what use is the entire time-consuming, costly PA process — for the provider, the payer or the patient?

We also believe that when a surgeon or other proceduralist obtains PA for a particular service and/or Current Procedural Technology (CPT) code but finds during the course of a procedure that a different or additional service and/or CPT code related to the initial procedure better describes what the patient required and is medically necessary, the payer’s PA should be considered binding for the surgical procedures that were performed.

- **Recommendation:** *The RRC strongly urges CMS to include in the PA Final Rule a provision that would preclude an Impacted Payer from denying payment for an item or service that has been approved through the Impacted Payer’s PA process. We also request that if a surgeon bills codes that better reflect the procedure(s) ultimately performed but are different from the ones for which prior authorization was obtained — but is still in the same code family or otherwise found to be medically necessary while the patient was on the operating table — the procedure(s) performed should be deemed to be approved.*

The RRC appreciates the opportunity to comment on this important Proposed Rule, and we strongly support the direction that it reflects. Members of the RRC coalition are: American Academy of Neurology, American Academy of Ophthalmology, American Association of Neurological Surgeons, American Association of Orthopaedic Surgeons, American College of Cardiology, American College of Rheumatology, American College of Surgeons, American Gastroenterological Association, Association for Clinical Oncology, Congress of Neurological Surgeons, National Association of Spine Specialists, and the Society for Cardiovascular Angiography and Interventions.

We look forward to working with CMS to ensure that PA processes do not delay or deny patients the care they need and to further reduce the administrative burdens that PA imposes on physician practices. If you have any questions about these comments, please contact Diane Millman, the RRC's regulatory counsel (Diane.Millman@PowersLaw.com).

Sincerely,

The Regulatory Relief Coalition