National Rural Health Association

March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: CMS–0057–P; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes

Submitted electronically via regulations.gov.

Dear Administrator Brooks-LaSure,

The National Rural Health Association (NRHA) is pleased to offer comments on CMS' Advancing Interoperability and Improving Prior Authorization Processes proposed rule. NRHA thanks CMS for its work towards achieving interoperability and increasing transparency and beneficiary engagement in prior authorization.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

II. Provisions of the Proposed Rule

NRHA broadly supports CMS' proposed provisions that would reduce burdens for providers and improve beneficiaries' experiences. Overall, application programming interfaces (APIs) will facilitate an efficient exchange of information between providers, payers, and beneficiaries. NRHA is also pleased to see the proposed changes to prior authorization, including the shorter timeframe for deciding upon prior authorization requests. NRHA particularly supports including Medicare Advantage (MA) organizations in the proposed rule in order to increase transparency and access to care for the 99% of beneficiaries that are in MA plans that require prior authorization for items and services.[1]

NRHA appreciates that CMS is also soliciting information on how beneficiaries with limited English proficiency, low literacy and low health literacy, and geographic and economic barriers face challenges accessing or using technology and apps. NRHA suggests rural-friendly revisions to certain requirements below.

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[1] Jeanie Fuglesten Biniek & Nolan Sroczynski, *Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021*, KAISER FAMILY FOUNDATION, Feb. 2, 2023, https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/.

A. Patient Access API

NRHA supports finalizing as proposed the changes to the Patient Access API. Specifically, NRHA supports the proposal to require payers to make information on prior authorization requests and decisions available in the API and that any updates on requests must be made available on the API within 1 business day. Additionally, NRHA believes that the proposal to include a specific reason for a denial will decrease the number of arbitrary denials. Allowing beneficiaries to easily access their health information gives them more autonomy over their care.

NRHA agrees with CMS that making this information available to beneficiaries in the Patient Access API will increase transparency and better equip them to engage with payers and their providers. However, NRHA is concerned about rural beneficiaries accessing the information provided by payers in the API via health apps. Unfortunately, the move towards more efficient and convenient information dissemination and communications leaves certain groups behind. Rural beneficiaries with limited English proficiency, with disabilities, with low literacy (including health and technology literacy), and other social risk factors may face difficulties accessing their health information on a health app. CMS should consider other instantaneous means for communicating the information that would become available within one day through the Patient Access API, such as phone calls to alert beneficiaries that the payer has decided upon their prior authorization request.

B. Provider Access API

2. Proposed Requirements for Payers: Provider Access API for Individual Patient Information
NRHA supports the proposed Provider Access API as it will enable providers to understand beneficiaries' medical history and make more informed decisions more easily.

3. Additional Proposed Requirements for the Provider Access API
NRHA supports CMS' opt-out model rather than the discussed opt-in model. We agree that for rural beneficiaries with lower technology and health literacy, an opt-in process may be too burdensome and would likely leave many beneficiaries out of the API. An opt-out option is more appropriate as we envision that a minority of beneficiaries will not want to participate in the Provider Access API.

NRHA urges CMS to require that all payers offer a mail, fax, or telephone option for the patient opt-out process. In some cases, non-electronic means are the easiest for rural beneficiaries to access and use. To ensure that the opt-out process is accessible, rural beneficiaries must have the option to opt-out without using an app or website. NRHA also urges CMS to include an option for beneficiaries to choose to opt-out of some data sharing but not all. Offering the ability to opt-out of certain data elements will likely encourage more beneficiaries to use the API rather than alienate some beneficiaries with an all or nothing approach.

Relatedly, NRHA urges CMS to require that all payers send beneficiaries their opt-out rights and instructions via mail in addition to making the information available online. The first notice of opt-out rights should be a standalone mailed document so that beneficiaries are easily alerted of their opt-out rights. CMS should require that payers send this information to current beneficiaries before the API is operational and to new beneficiaries upon enrollment after the API is operational in January 2026. Payers may then choose how and when to disseminate this information annually after beneficiaries have received it in paper form at least once, such as in annual enrollment information or member newsletters. Ensuring rural beneficiaries receive important information in the mail is critical, especially for beneficiaries that do not have reliable internet access or that do not regularly use the internet for health care.

C. Payer to Payer Data Exchange on FHIR

NRHA supports the proposed Payer to Payer API to facilitate beneficiary data exchanges upon coverage changes. NRHA applauds CMS' inclusion of prior authorization data in the Payer to Payer API because when beneficiaries switch coverage the information on prior authorizations is not always transferred to the new payer. When this information is not communicated to a new payer, providers and beneficiaries are likely forced to endure the process again by re-requesting prior authorization. This delays access to necessary care for beneficiaries and adds to rural providers' workloads. In some instances, delays due to prior authorization can lead to adverse health events, hospitalizations, or disability for the beneficiary.[2] NRHA expects that the Payer to Payer API will protect beneficiaries' access to previously approved medically necessary items and services.

In its recent contract year 2024 MA Policy and Technical Changes proposed rule, CMS proposed that all ongoing courses of treatment that were subject to prior authorization approval remain active for a 90-day period when a beneficiary switches to new MA coverage even if the provider is out-of-network in the new plan.[3] This proposal, in tandem with the Payer to Payer API, should streamline important exchanges of beneficiary information between payers for MA beneficiaries and remove some of the onus from rural providers to communicate beneficiary information.

D. Improving Prior Authorization Processes

3. Proposed Requirement for Payers: Implement an API for Prior Authorization Requirements, Documentation, and Decision (PARDD API)
NRHA supports the proposed PARDD API. We applaud efforts to automate parts of the prior authorization process for providers. Rural facilities often do not have a dedicated administrative employee that handles the prior authorization process. Instead, rural providers take on the additional burden on top of their other duties and already full workloads. NRHA members have noted that prior authorization can vary greatly between payers which makes the process even more difficult and burdensome. We are hopeful that this proposal is one step towards lightening the burden on rural providers and making prior authorization more standardized across payers.

We believe that the PARDD API would offer much needed transparency for rural providers around the prior authorization process. Including information on whether prior authorization is needed for items and services is one major improvement in transparency as each payer has different policies for items and services. Additionally, indicating the rules and requirements around prior authorization in the PARDD API will also decrease some burdens on rural providers.

However, just as NRHA is concerned about rural beneficiaries accessing their information through a health app for other APIs, we are also concerned about providers utilizing the PARDD API and other proposed APIs. Please see section II.E., *supra*, for more information.

4. Requirement for Payers To Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations

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[2] American Medical Association, 2021 AMA prior authorization physician survey (2022), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[3] Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 87 Fed. Reg. 79504 (Dec. 27, 2022) (revising 42 C.F.R. § 422.112).

CMS' proposal to make payers provide a timely and specific reason for a prior authorization denial is another important step towards better transparency and communication. In particular, NRHA supports the proposals in previous sections to include the specific reason for the denial in the Patient Access and Provider Access APIs.

Still, NRHA urges CMS to adopt stronger requirements for specific reason for an adverse determination. First, most impacted payers already must provide some information as to why the payer denied the request, however CMS does not provide more guidance on the level of specificity.[4] While this rule supplements the existing requirements, and mandates that payers include the specific reason for denial in the various proposed APIs, NRHA members have noted that more specificity is needed. A payer can use "lack of medical necessity" as a reason and that does not provide enough information to the provider and beneficiary to take further action, like appealing the decision or providing more supporting documentation. For example, only 11% of prior authorization denials by MA organizations are appealed.[5] The MA appeals process is underutilized even though most appeals are overturned in favor of the beneficiary.[6] Equipping providers and beneficiaries with more information will help to inform their decision-making process and ensure that action taken is in the best interest of the beneficiary.

NRHA suggests that CMS make payers provide more granular information on denials, for example, indicating what particular part of the beneficiary's supporting documentation led the payer to believe that the item or service was not medically necessary. Additionally, NRHA would like to see a broader definition of denial or adverse determination used. While a course of treatment may be approved, the payer may have denied the length of time requested by the provider. This should be included as a denial and the payer should explain why, for example, the timeframe for treatment was not approved for the full request.

5. Requirements for Prior Authorization Decision Timeframes and Communications
As discussed in this section of the preamble, providers cite prior authorization is a barrier to beneficiaries receiving care on time and note that this can lead to worse health outcomes. NRHA members have echoed these same concerns. Thus, NRHA supports shortening the timeframes for payers to make decisions on requests.

However, NRHA members have indicated that the proposed 7 calendar days for standard, non-urgent prior authorization requests is still too long. We appreciate that this proposal cuts the timeframe down in half from the current standard, but beneficiaries deserve quicker access to care. A shorter timeframe, like 5 calendar days, could be achieved, especially considering the proposed APIs that are meant to streamline and make prior authorization more efficient.

In addition, this proposed rule does not change the timeframe for expedited prior authorization requests, which in most cases is 72 hours. For a request that could lead to hospitalization or worse, NRHA believes that a shorter timeline is necessary. While NRHA believes that any prior authorization for urgent requests is too long, such requests should be decided within 24 to 48 hours of a payer receiving a request. Timely decisions on expedited prior authorization requests would ultimately achieve cost savings by avoiding costly hospitalizations or other care associated with delaying access to needed services.

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[4] 42 C.F.R. §§ 422.568(e), 483.404(b).
[5] Biniek & Sroczynski, *supra* note 1.
[6] *Id.*

CMS is not changing the exception that payers may extend the timeframe by up to 14 days. NRHA would like to flag the potential for payers to increase their use of extensions to decide on requests because of the shorter timeframe. NRHA suggests that payers report on their rate of extensions, broken down by whether it was payer or beneficiary driven in addition to the other metrics proposed at *II.D.8: Public Reporting of Prior Authorization Metrics.*

8. Public Reporting of Prior Authorization Metrics
NRHA appreciates the intent of requiring plans to report aggregated prior authorization metrics as it may help providers choose networks and help beneficiaries choose plans. However, for MA beneficiaries in particular, this data may not matter. Older, rural adults with lower literacy, including technology literacy, will likely not see the benefits of this information posted online even though they stand to gain the most from knowing and understanding this information. NRHA asks that CMS consider how the prior authorization metrics could be reported to beneficiaries in other formats, such as through opting in to annual mailed reports. Additionally, for those that search for the information on payer websites, the prior authorization metrics should be displayed in a logical and easy to find page on the website.

CMS should consider requiring more granular data to be reported, especially for MA organizations. Overall information on the amount of prior authorization requests approved and denied is helpful but does not paint the whole picture for beneficiaries. CMS should require payers to also include the approval and denial rates for the top requested items and services that require prior authorization. Payers should also report on the rate of extensions for prior authorization requests broken down by enrollee requests and payer-driven extensions.

Last, NRHA urges CMS to take action against payers that report a certain percentage of prior authorization denials. When a payer reports that over a given percentage, for example 85%, of all requests for a certain item or service are denied, this should trigger an immediate query into the payer and its practices. In conjunction with the recent contract year 2024 MA Policy and Technical Changes proposed rule,[7] this action could significantly improve prior authorization processes and discourage MA organizations from inappropriately denying medically necessary care.

E. Electronic Prior Authorization for the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program
F. Interoperability Standards for APIs

NRHA does not believe that including new MIPS and Medicare Promoting Interoperability Program measures will address concerns about low provider utilization of APIs, especially for small, rural providers. We also are concerned about the financial burden on providers associated with using APIs. Cost, limited access to capital, limited broadband, and employees' reluctance to buy in are challenges rural providers face in implementing or upgrading health IT.

Rural hospitals that use larger electronic health record (EHR) systems, like Epic or Cerner, likely have access to any regulatory updates as a part of their contract with the EHR company. However, smaller rural providers that use small EHR systems do not have this benefit. When a new regulatory requirement is implemented, like the new proposed MIPS and Promoting Interoperability measures, the small providers typically must pay the HER company to have the new feature built into their

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[7] 87 Fed. Reg. 79452.

system. The costs of the implementation, while significant, extend beyond integrating the new feature and includes indirect costs like time for training staff on the functionality. Rural hospitals cannot take on new regulatory requirements that involve technology upgrades without a tie to payment to increased reimbursement.

NRHA stresses that rural hospitals need technical assistance and financial support from CMS and HHS for implementing new features or technology to support API use. For our providers, it is not as simple as implementing a new API and reporting on a new measure, nor is measure reporting an adequate incentive for struggling rural providers. In fact, reporting is another burden on rural providers' plates. CMS should provide technical assistance or incentives outside of reporting programs for hospitals that do not have the capacity to keep up with new technology mandates.

III. Requests for Information

A. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

Social determinants of health (SDOH) affect an individual's health outcomes and health status and contribute to persistent health inequities observed between populations. They are often risk predictors for the development of chronic diseases. The University of Wisconsin Population Health Institute concludes that Social and Economic Factors drive 40% of health outcomes, with closely linked factors such as Physical Environment and Health Behaviors accounting for another 10% and 30%, respectively. Clinical Care accounts for the remaining 20%. Detrimental SDOHs are frequently observed in rural communities, including challenges with transportation, poverty, social isolation, and food deserts. These determinants put rural populations at higher risk for adverse health outcomes, as these communities are historically under-resourced, under-represented, poorer, and sicker. Rural providers often lack the time and resources necessary to care for patients experiencing negative SDOH.

The ICD-10-CM diagnosis codes adopted by the US in 2015 introduced "Z codes." Z codes are used as reason codes to capture "factors that influence health status and contact with health services." Collecting Z codes could strengthen quality improvement activities, identify factors that influence health outcomes, and more conclusively determine and characterize health disparities. Regular and consistent reporting of Z codes could enhance care coordination within hospitals and health systems. Specifically, Z codes can make discharge planning and transitional care more extensive. However, Z codes are voluntarily reported when, and if, they are supported in the patient's health record. There is no financial incentive to collect Z code-related information and there are technological challenges with the vast array of patient charting systems. As a result, fewer than 2% of healthcare facilities utilize Z codes, and it is hypothesized that this rate is even lower for rural facilities. Little to no literature exists quantifying or qualifying the use of Z codes by rural providers and facilities.

The barriers to identifying and reporting Z codes are especially pronounced in rural, underserved communities and healthcare settings. For rural providers, workflow and workforce capacity are already low due to shortages and heavy caseloads. Screening and recognition of some SDOH, on top of these existing workloads, may require engaging a social worker, care coordinator, or other individuals with specialized training. Also, rural providers are reluctant to screen for SDOH without the resources and processes in place to refer patients to another provider or the help that they need. The availability of other providers or resources for patients with SDOH is limited in rural communities, so even if patients are screened, providers do not have the ability to get them connected to the follow-up care that is required.

There are infrastructure barriers that limit the uptake of Z coding, including the lack of standardized electronic health record screening tools, lack of knowledge among providers, shortage of staff to acquire SDOH information, and very few trained coders. These barriers were identified by CMS in a Z code study evaluating utilization among Medicare beneficiaries. NRHA members have raised concerns that their existing infrastructure may not support Z code utilization and would likely require additional administrative resources to transition information between notes, charts, and coding of services.

NRHA recommends several policies and actions to encourage use of Z codes:

- Partner with the Federal Office of Rural Health Policy to develop a pilot proposal for rural facilities to implement and investigate barriers and opportunities for Z code implementation.
- Develop a rural pilot to test the use of Z codes to measure rural SDOH. The pilot should provide resources, including personnel and infrastructure funding and technical assistance, for a select group of diverse health providers, specifically including rural facilities and providers, to examine the burden and utility of Z code usage.
- Clarify guidance and provide standards for collecting SDOH information.
- Facilitate information sharing across beneficiary programs. CMS and HHS, with the Department of Agriculture, should facilitate information sharing to improve beneficiary enrollment in social support programs like Supplemental Nutrition Assistance Programs (SNAP) and other programs that address SDOH.
- Promote and support identifying SDOH resource needs of health providers by encouraging and incentivizing use of Z codes. This could be done through additional training, guidance on follow-up referrals, and financial incentives.
- Integrate community health workers (CHWs) into screening and collecting SDOH data. CHWs are trusted community members and therefore in a better position to collect potentially sensitive information. CMS and HHS should support CHWs through funding for programs that place CHWs in rural areas to address SDOH and allowing CHWs to bill for services incident to a physician under Medicare.

Thank you for the chance to offer comments on this proposed rule and for your consideration of our comments. We look forward to continuing our work together to ensure our mutual goal of improving quality and access to care for rural residents. If you would like additional information, please contact Alexa McKinley at amckinley@ruralhealth.us.

Sincerely,

Alan Morgan
Chief Executive Officer
National Rural Health Association