

JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-0057-P
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via regulations.gov

Re: Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, and other entities (CMS-0057-P; RIN 0938-AU87)

Justice in Aging appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) noted above.¹ Justice in Aging uses the power of law to fight senior poverty by securing access to affordable health care, economic security, and the courts for older adults with limited resources. We have decades of experience with Medicaid and Medicare, with a focus on long-term services and supports (LTSS) and the particular needs of those dually eligible for Medicare and Medicaid coverage.

Our advocacy focuses on populations of older adults who have historically faced discrimination, including women, LGBTQI+ people, people of color, people who have limited English proficiency (LEP), and people with disabilities. Therefore, ensuring that programs and services fully and fairly serve these communities in an equitable manner is at the heart of our work.

We are pleased with the direction of this important rulemaking and believe it is a significant step to increasing transparency and reducing barriers to coordination of health care. We particularly appreciate that the agency is addressing prior authorization, an area where current practices have frustrated providers and, in many cases, caused serious harm to individuals needing care. Our comments focus on aspects of the NPRM that are particularly important to the direct interface between these programs and low income older adults, and we offer several recommendations to strengthen the rules, with particular attention to the goal of fair and equitable access to Medicare and Medicaid programs.

II(A)(2)(a): Enhancing the Patient Access API: Prior Authorization Information

We generally support the implementation of the proposed Patient Access Application Programming Interface (API) rules to improve patient access to information about their insurance coverage.

We note with concern that, throughout this NPRM, CMS has stated that the proposed rules will not apply to drugs covered by any of the payers that are the focus of this rule. We see no good reason to completely exclude drugs, and particularly to exclude Part B drugs, from the prior authorization rules proposed here. A recent study of four large Medicare Advantage (MA) insurers by the American Journal of Managed Care found that those insurers frequently use prior authorizations to control the use of

¹ Notice of Proposed Rulemaking (NPRM), 87 Fed. Reg. 76,238, *et seq.* (Dec. 13, 2022).

high-cost provider-administered drugs.² The study found that of the top 20 physician-administered drugs, 17 were subject to prior authorization and 10 were subject to step therapy by at least 1 insurer.³ Further, the study acknowledged that if prior authorizations and step therapy are used inappropriately, they can harm beneficiary access.⁴

We also believe that Part D drugs should be incorporated into this regulatory structure, although we recognize that it may take more time to harmonize the current Medicare Part D prior authorization regime with more universal standards. It is important that the uniformity and transparency for enrollees embodied in the interoperability proposal also apply to drug approvals in all types of plans, including Part D plans. The ability for providers and enrollees to track the progress of a prior authorization request is as important, and many times more important, for prescription drugs than for other covered services.

We urge CMS to move forward to incorporate prior authorizations of prescription drugs into its broader prior authorization design and oversight of impacted payers, regardless of the mode of administration.

II(A)(2)(d): Patient Access API Metrics

We urge CMS to require payers that administer multiple plans under a single contract to report data to CMS at the plan level. Collecting data at the parent organization level or contract level, as proposed in the NPRM,⁵ can obscure patterns and problems at the level of individual plans.

We support the proposal to require payers to report aggregated demographic information, such as sex, race, age, ethnicity, and geographical (e.g., zip code) data.⁶ We further recommend that CMS also require payers to report patient primary language and disability status. Payers already have or can easily gather such information from enrollees, either from claims data or from enrollment. We recommend including an option on future CMS and private enrollment applications for enrollees to report sexual orientation and gender identity (SOGI) so that this information can also be reported. We recommend that patient access API metrics and all data required under any part of this proposed rule be reported in a disaggregable form that can facilitate intersectional analysis, to distinguish patterns, e.g., among black women over 65, in order for CMS and researchers to fully identify disparities in patient access to health data.⁷

II(B)(1): Provider Access API: RFC re Medicare Fee for Service (FFS)

Justice in Aging strongly supports the proposed regulatory updates and, in response to its request for comment on the matter, also **strongly urges CMS to implement the Provider Access API proposals for Medicare fee for service (FFS).** Advocates in the field report that providers routinely struggle to get information about the applicable standards and status of prior authorizations submitted under Medicare FFS. Applying these proposed rules to Medicare FFS would significantly facilitate care for enrollees.

² Kelly E. Anderson, *et al.*, “Medicare Advantage Coverage Restrictions for the Costliest Physician-Administered Drugs,” *Am. J. of Managed Care*, 28:7 at e255 (July 2022), available at https://cdn.sanity.io/files/0vv8moc6/ajmc/d67e7ef94f480d7bdc7d76d372d1abff2c7e45df.pdf/AJMC_07_2022_An_derson_final.pdf.

³ *Id.*

⁴ *Id.*

⁵ NPRM, 87 Fed. Reg. at 76,249.

⁶ NPRM, 87 Fed. Reg. at 76,250.

⁷ *Id.*

II(B)(2): Proposed Requirements for Payers: Provider Access API for Individual Patient Information

Justice in Aging generally supports CMS's proposed new requirement for provider access APIs.⁸ We note with concern, however, that the proposed requirement does not currently apply to out-of-network providers. We urge CMS instead to require payers to share the data with all providers, regardless of whether the provider is under contract or enrolled with the payer.⁹ Such access would be critical in cases of out-of-town emergencies, or indeed any situation requiring out-of-network care. For example, if an enrollee were visiting her sister in another state, and had to go to an out-of-network emergency room there, it would significantly improve her treatment if the out-of-network attending health care provider could quickly and easily access her information via her payer's provider access API.

While CMS expressed concern about potential fraud (e.g., bad actors posing as out-of-network providers), existing procedures could be adapted to verify that the provider has a treatment relationship with the patient. For example, that patient could sign a release of information, or the provider could file a contemporaneous medical record showing the patient is under their treatment (e.g., an ER admission record).¹⁰ Payers could provide a standard section on their websites by which out-of-network providers could apply for access through the Provider API using such procedures. The challenges to implementing out-of-network access are minor compared to the benefit to patients.

II(B)(3)(b): Opt Out for Provider Access API

In light of the importance of shared health information for care coordination, we believe that an opt out provision for plans sharing records with providers is appropriate. We note, however, that as proposed, the opt out can be limited to an all-or-nothing choice: withholding information from all providers or allowing access to all. CMS has indicated that it encourages plans to offer more granular options such as denying access to a particular provider or particular types of providers.¹¹ Further, the agency also asked comment on giving patients more granular control over which data they would allow a plan to share, for instance, data from only particular timeframes.¹² We encourage CMS to pursue each of these options, both to empower individuals to take fuller charge of their care and also to encourage individuals to consent to sharing most of the health data needed to coordinate their care by allowing them to specify exactly which data they do not want to share and with whom.

These options are especially important for people who have health records that may reveal sensitive information or a history that they do not want to have to explain. For example, older adults may want to exclude health records from a period of addiction decades ago, or an episode of incarceration. An individual entering a skilled nursing facility may not want staff to know their sexual orientation until the individual feels comfortable sharing the information. Giving individuals the power to control when and how sensitive data is shared is an important element in person-centered care and in establishing trust. We ask CMS to develop systems to allow more nuanced choices.

⁸ NPRM, 87 Fed. Reg. at 76,255, 76,258.

⁹ NPRM, 87 Fed. Reg. at 76,256.

¹⁰ NPRM, 87 Fed. Reg. at 76,257.

¹¹ NPRM, 87 Fed. Reg. at 76,259.

¹² NPRM, 87 Fed. Reg. at 76,261.

(II)(B)(3)(c): Patient Resources Regarding the Provider Access API

Regarding the format and content of patient notices about the Provider Access API,¹³ we recommend that notices must be: **written at the sixth-grade reading level; focus group tested; written in accurate but positive language (so as not to unduly discourage participation); and translated into the required threshold languages for the coverage area.** This information should be provided at the time of enrollment and annually.

We also take this opportunity to renew with CMS our longstanding request for the agency to revisit its threshold requirements for translations by MA and Part D plans. Current 42 C.F.R. § 422.2267(a)(2) and its companion regulation for Part D, 42 C.F.R. § 423.2267(a)(2), require translation of certain marketing and communications materials “into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.” We recommend setting a more inclusive threshold that, in addition to using percentage of individuals in a PBP, also requires translation if a numerical threshold is reached. That threshold could be based either on the number of individuals speaking the non-English language in the PBP service area or the number enrolled in the plan.

(II)(B)(4)(a): Provider Access API: Extensions and Exemptions for Medicaid FFS

We note that, for this and several other requirements throughout this rule, CMS proposes to allow state Medicaid fee for service programs to request a one-time extension of up to 1 year to implement those requirements.¹⁴ Given the many problems Medicare and Medicaid enrollees have faced in accessing benefits and care because of state-level delays in implementation of effective data transfer systems with their Medicaid programs, we recommend that, for this and all other provisions, CMS impress on states the importance of bringing their FFS programs into compliance with these rules and remain firm that no further extensions beyond one year will be granted.

(II)(C)(1): Payer to Payer Data Exchange on FHIR¹⁵

We strongly support the proposed rules to require data exchange among payers.¹⁶ Low income individuals often have to change plans, or be enrolled in concurrent plans, such as a MA plan and Medicaid FFS or Managed Care. Lack of patient data-sharing between plans hampers care. This proposal will advance CMS’s equity goals, especially for low-income older adults. We note, for example, that a core element of Dual Eligible Special Needs Plans (D-SNPs) is coordination of Medicare and Medicaid benefits. Coordination between payers is essential for such care and benefit coordination.

(II)(C)(3)(b): Payer-to-Payer API Data Content Requirements

In response to its request for comment regarding possible future rulemaking, **we strongly urge CMS to propose a rule requiring new payers to honor prior authorizations from a previous payer¹⁷** for the remainder of the authorization period. Under such circumstances, the previous payer has already evaluated the patient’s condition and determined that the service is medically necessary according to standards established either by CMS or by otherwise generally recognized authorities. There is no *medical* reason why the mere change in insurance enrollment should require or permit a re-evaluation of the medical necessity of the treatment. If a patient continues to utilize the treatment after switching

¹³ See *id.*

¹⁴ NPRM, 87 Fed. Reg. at 76,261-62.

¹⁵ Fast Healthcare Interoperability Resources (FHIR).

¹⁶ NPRM, 87 Fed. Reg. at 76,268.

¹⁷ NPRM, 87 Fed. Reg. at 76,270.

payers, that necessarily implies that: (1) the provider continues to prescribe and/or administer the treatment; (2) the patient continues to want the treatment; and (3) both are relying on being able to utilize the treatment at least for the remainder of the current prior authorization period.

We note particularly that in the Medicare-Medicaid Financial Alignment Initiative, plans were required to incorporate continuity of care provisions allowing an enrollee, for a period of time, to retain a provider who is out of the network of the enrollee's new plan.¹⁸ Several states are incorporating this important enrollee protection in their D-SNP contracts as well as in Medicaid managed care plans.¹⁹ The protection would be of little value, however, if an enrollee would have to start from scratch to get a new authorization to continue a treatment plan started with that provider. The disruption in care would negate the benefit.

(II)(C)(3)(c): Identifying Previous and Concurrent Payers and Opt In

We generally support CMS's proposal for an **opt in** process for gathering patients' permission for payer to payer data exchange.²⁰ It should be feasible to secure patient permission during enrollment. CMS should, however, monitor this process closely to see if there are high opt out rates, particularly among certain populations. As noted above, disaggregable demographic information will be needed to determine whether there is an unusually high opt out rate among, e.g., African American older adults.

(II)(C)(3)(g): Patient Education Requirements

We agree that payers need only provide these materials annually to any patients who have *not* opted in and those with known concurrent payers.²¹ Having plans reach out on an annual basis to individuals who have opted out will be important to ensure that they are reminded of their choices and given a new chance to opt in.

(II)(C)(4)(b): Payer to Payer Data Exchange in Medicaid and CHIP: Permission and Exchange Considerations

We strongly support CMS's rule in this section that patients should *not* be required to use an online patient portal or other app to opt in.²² While many older adults are quite "tech savvy," we hear from our colleagues in the field that many also struggle with required online applications and in many cases just give up and forego care as a result. Low income older adults, including many who are dually eligible for Medicare and Medicaid, are among those with the lowest computer literacy and also frequently lack dependable internet access. Older adults should never be *required* to do anything online in order to access health care to the full extent. Having alternate access, particularly by telephone and with interpreter services available as needed, is essential.

¹⁸ See, e.g., RTI, *et al.*, Report on Early Implementation of the Demonstrations under the Financial Alignment Initiative, at 22 (Oct. 15, 2015), available at [Report on Early Implementation of Demonstrations under the Financial Alignment Initiative \(cms.gov\)](#).

¹⁹ See, e.g., Calif. Dep't Health Care Services (DHCS), "CalAIM Dual Eligible Special Needs Plans Policy Guide," at 15 (Jan 3, 2023), available at [DHCS Letterhead \(ca.gov\)](#); DHCS, "Continuity of Care for Medi-Cal Managed Care Members," available at [Continuity of Care](#).

²⁰ NPRM, 87 Fed. Reg. at 76,273.

²¹ NPRM, 87 Fed. Reg. at 76,276.

²² NPRM, 87 Fed. Reg. at 76,278.

(II)(D)(1): Improving Prior Authorization Processes

Justice in Aging generally supports CMS's proposals in this section to improve the prior authorization process.²³ We are glad to see that CMS is considering implementing its proposed prior authorization rules in Original Medicare, and encourage it to do so.

For all the reasons noted above in section (II)(A)(2)(a), however, **we repeat our request that CMS move forward to incorporate prior authorizations of prescription drugs into its broader prior authorization design and oversight of impacted payers, regardless of the modality of administration.**

While CMS asserts that it is excluding drugs from this rule "because the processes and standards for prior authorization applicable to drugs differ from other items and services,"²⁴ the same could be said about the processes and standards for prior authorization of, for example, durable medical equipment, e.g., a wheelchair, compared to surgery or cancer treatment.

What is most important for providers and patients is the specific reason for any denial of drug coverage: the standard applied, the source of the standard, and the specific facts of the case on which the denial was based. It is difficult to credit that, while implementing these streamlining technologies for a wide array of procedures, it would be overly burdensome or impossible for a payer to enter into the Patient and Provider Access APIs the reason why coverage for a particular drug was denied. Moreover, in the event coverage for a critical drug *is* denied, and the provider or patient appeals, the payer will have to provide this information any way in the course of the appeal. Failure to provide this information up front through an Access API merely complicates and delays appeal as well as potentially necessary treatment.

(II)(D)(3)(a): Prior Authorization Requirements, Documentation & Decision (PARDD) API

We generally approve of CMS's requirement that payers inform providers through the PARDD API of an approval, a denial (with "specific reason"), or a request for additional required information.²⁵ Our colleagues in the field report that providers and patients routinely complain of cryptic denials or payers' failure to communicate about the prior authorization. As we discuss below, the reason for any denial should be specific to the facts of the individual patient, not a generic, conclusory statement such as "no medical necessity."

(II)(D)(4)(a): Requirement for Payers to Provide Status and Reason for Denial

We applaud CMS's proposal to require payers to provide a specific reason for denied prior authorization decisions.²⁶ As noted above, providers and patients often struggle with cryptic or non-existent information about the reason for a denial. This requires time-consuming research, such as multiple calls to the payer, often only to find out that all the payer wanted was a piece of evidence from the treatment record that the provider could have readily submitted to the payer had the payer requested it clearly and unambiguously in the denial. All of which needlessly delays treatment.

We are concerned, however, that the proposed rule does not state more precisely what would constitute a sufficiently "specific reason" for the denial. Currently, many payers simply state "no medical necessity," but such a generic statement is just a circular restatement of the denial.

²³ NPRM, 87 Fed. Reg. at 76,285, *et seq.*

²⁴ NPRM, 87 Fed. Reg. at 76,285.

²⁵ NPRM, 87 Fed. Reg. at 76,289.

²⁶ NPRM, 87 Fed. Reg. at 76,292.

We therefore recommend that CMS amend the proposed rule to lay out the requirements more explicitly. We propose the following:

To be sufficiently specific, the reason for denial must articulate the specific standard for medical necessity that the payer applied to the request, the source of the standard, and why the particular facts of the patient’s case and the evidence submitted in the prior authorization failed to meet that standard.

Providing such information in an initial denial will expedite resolution of the request without necessarily requiring formal appeal—which in turn will expedite needed treatment.

(II)(D)(5)(b): Proposals to Address Timeframes for Decisions on Standard and Expedited Prior Authorization Requests

We urge CMS to adopt the alternate, faster timeframes it has proposed, i.e., five calendar days for standard requests and 48 hours for expedited.²⁷ The underlying premise of these rules is that the prior authorization process should not be allowed to unnecessarily delay treatment. Given that payers can request an extension of up to 14 days—if *necessary*—to consider a standard request, imposing a five-day deadline to respond would advance treatment faster while allowing payers some flexibility in special cases. Furthermore, in the case of an urgent need requiring expedited review, 48 hours should be sufficient.

We note with concern, however, that CMS does not propose any consequence for failure to meet these deadlines. Providers and patients faced with payer inaction will have no way to force a decision, leaving treatment in limbo. While we acknowledge CMS’s reasons for declining to impose a “deemed approval” in the case of a missed deadline, we do think it is reasonable and necessary to impose a “deemed denial.” **CMS should therefore amend this proposed rule to provide that: if a payer has failed to communicate a decision on a request for prior authorization within the required deadline, including any formally requested extension, then the prior authorization shall be deemed to have been denied and the request will automatically proceed to the next level of appeal.**

This approach has been helpful in the Medicare Part D prescription drug program. It does not burden the enrollee. Further, statistics on the number of automatic escalations because of plan inaction are easy to compile and are helpful in identifying plans with prior authorization procedures needing attention.

(II)(D)(6)(b): Medicaid FFS Prior Authorization Notice Requirements

While we generally support the Medicaid fee for service PA notice requirements, we note with concern that CMS has intentionally refrained from setting any deadline for Medicaid FFS programs to inform patients of the status of their prior authorization requests.²⁸ **Medicaid FFS enrollees should have the same protections as any individual enrolled with any of the other impacted payers, and Medicaid FFS programs should be subject to the same notice deadline (preferably five days).** We recognize that existing Medicaid “notice and fair hearing requirements will remain in full effect without change,”²⁹ but the simple fact is that the health care needs of enrollees in FFS Medicaid are just as urgent as those of enrollees in Medicaid managed care or in other plans covered by these rules. CMS should ensure that state FFS Medicaid programs are just as responsive to those needs as are Medicaid managed care plans.

²⁷ NPRM, 87 Fed. Reg. at 76,297.

²⁸ NPRM, 87 Fed. Reg. at 76,299.

²⁹ *Id.*

(II)(D)(6)(c): Medicaid Managed Care Prior Authorization Notice Requirements

While the 7-day deadline for notifying a provider of decisions on standard requests is helpful,³⁰ **we urge CMS to consider applying a 5-day deadline** for all the same reasons stated above in section (II)(D)(5)(b). Further, **we urge CMS to apply, as it has suggested as an alternate proposal, a 48-hour deadline for responding to expedited requests**, rather than the existing 72-hour deadline. When the systems proposed in this rulemaking are in place, plans and FFS programs should be able to be nimbler and more responsive to the care needs of patients.

(II)(D)(8): Public Reporting of Prior Authorization Metrics

We generally support the requirement that impacted payers publicly report certain aggregated metrics about prior authorization on their websites or via a publicly accessible hyperlink(s).³¹ We object, however, to requiring reporting only at the organizational level for MA, particularly when CMS is proposing that reporting must be at the plan level for Medicaid and CHIP managed care.³² **Reporting for MA should also be at the plan level.** What really matters for enrollees is the rate of approval or denial within their plan or a plan in which they are considering enrollment. Reporting on the organizational level for MA plans can obscure significant differences among plans, especially when some plans are skewed toward lower income enrollees. Both enrollees and regulators need to see a sharper picture.

We also recommend that CMS add the following to its list of required data³³ to be reported:

1. The total *absolute number* of prior authorization requests along with the absolute number of denials, extensions, and approvals, not only the *percentage* that were approved or denied, for each category of services;
2. The total *absolute number* and the *percentage* of appeals that arose from the denial of prior authorizations.

The data that CMS currently proposes to collect consist only of percentages. Absolute numbers are needed to know the amount of prior authorizations processed in order to compare the utilization of the prior authorization process across plans and payers.

Further, we note that requiring the data to be “aggregated for all items and services” will be misleading.³⁴ Prior authorizations for certain items or services may be granted routinely, while for others there may be frequent denials. The relevant issue for any patient evaluating their own or a different plan is the prior authorization record for the items and services they themselves use. It is the allowance/denial record by item or service that matters for patients. Members of the public should therefore have the ability to research approval and denial rates by item or service.

Finally, we recommend that prior authorization data include data regarding race, ethnicity, gender, age, primary language, disability status, SOGI, and geographical area, disaggregable and analyzable intersectionally, for all the reasons stated above in section (II)(A)(2)(d).

³⁰ NPRM, 87 Fed. Reg. at 76,300.

³¹ NPRM, 87 Fed. Reg. at 76,304.

³² *See id.*

³³ NPRM, 87 Fed. Reg. at 76,305.

³⁴ *Id.*

(II)(D)(9): “Gold-Carding” Programs for Prior Authorization

We appreciate the value of “Gold-Carding” programs for prior authorization, as well as CMS’s effort to ensure such programs benefit diverse populations, especially small and minority providers, and providers who disproportionately serve minority and underserved communities.³⁵ This proposal demonstrates yet another reason why CMS needs to require demographic data on prior authorizations that can be analyzed intersectionally. We urge CMS to identify providers who struggle with the prior authorization process in order to provide them with guidance so that that gold-carding and similar programs are equally available in minority and underserved communities.

(III)(C): Improving the Exchange of Information in Medicare Fee for Service

We applaud CMS’s interest in improving the exchange of information in Medicare FFS among prescribing providers, suppliers, and regional Medicare Administrative Contractors (MACs).³⁶ Our colleagues in the field regularly report or experience breakdowns in communication among these three types of actors, e.g., when a provider prescribes durable medical equipment for a patient, yet the supplier receives a rejection from the MAC because of insufficient documentation of medical necessity. The prescriber is unaware of the reason for the denial (or even that it occurred), while the supplier lacks the patient information to remedy the denial. It is critical that the MAC communicate both with the prescriber and the supplier of the item or service.

CMS can improve the exchange of medical documentation between and among providers, suppliers, and MACs first by educating providers about the Medicare Coverage Database (MCD) and how to use it.

Second, CMS should require the MAC to inform not only the supplier but also the prescriber of the specific reason for the denial, including the standard applied, the source of the standard, and the specific facts relied on. This could be accomplished with current technology or with the introduction of the Provider Access API to Original Medicare, as CMS has proposed.

Timeframe

We are concerned that many of the provisions in this proposed rule would not take effect until January 2026—even the non-technological prior authorization reforms. While we understand that some of the technological changes proposed in this rule could require up to three years to roll out, there are nevertheless many purely procedural changes that could be implemented in a shorter time, such as reducing the deadlines for prior authorization decisions, requiring specific reasons for denials of prior authorization, and reporting prior authorization metrics publicly. **We therefore urge CMS to shorten to twelve months the timeframe for implementing at least the procedural provisions of this rule.**

³⁵ NPRM, 87 Fed. Reg. at 76,307.

³⁶ NPRM, 87 Fed. Reg. at 76,324-25.

Conclusion

Thank you again for the opportunity to comment in support of these important changes to Medicare interoperability and prior authorization processes. If any questions arise concerning this submission, please contact Murray Scheel, Senior Staff Attorney, at mscheel@justiceinaging.org.

Sincerely,

A handwritten signature in cursive script that reads "Georgia Burke".

Georgia Burke
Director, Medicare Advocacy