266 West 37th Street, 3rd Floor
New York, NY 10018
212.869.3850/Fax: 212.869.3532

March 13, 2023

VIA ELECTRONIC SUBMISSION

Hon. Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: RIN 0938-AU87: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program [CMS-0057-P]

General Comments

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on the **Advancing Interoperability and Improving Prior Authorization Processes** proposed rule. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals.

Prior authorization is creating an ever-increasing burden on patients. We support many of the Centers for Medicare & Medicaid Services (CMS) provisions in this proposed rule that would reduce this burden by improving processes, timelines, access to information, and communication.

While we support increasing access to information, and we recognize the limits of CMS's authority to police privacy on computer software and phone apps, we urge the agency to do all it can, in concert with other agencies, Congress, and stakeholders, to protect patient privacy. Many of the details that

could be included in data transfers are sensitive and could be exploited by companies who could package and sell data for their own purposes. We appreciate the provisions in the rule that would increase patient awareness of these risks.

In addition, while we support increased transparency and publicly available information about insurer prior authorization rules and practices, we know that private monitoring or shopping or any other consumerist behavior cannot take the place of oversight. We urge CMS to create oversight plans and processes to ensure that any new requirements have teeth in them.

Appeals

Prior authorization is directly linked to another access barrier: the MA appeals process. Overly burdensome and difficult to navigate, the appeals system can further disconnect beneficiaries from needed care. A recent Kaiser Family Foundation (KFF) analysis showed only 11% of prior authorization denials were appealed in 2021. Of those, more than 80% were later overturned, either completely or in part.[1] A 2018 Health and Human Services Office of the Inspector General (OIG) investigation raised similar concerns, finding that while only 1% of prior authorization denials were appealed, 75% were overturned at the first level of review.[2] These reports, and our own experiences with helpline callers, clients, and other professionals, suggest improper denials are far too common and beneficiary appeals far too rare: in 2021 alone, erroneous denials accounted for nearly one-third of all calls to our helpline. Of those, 65% were about how to appeal a plan's decision.[3]

Coverage denials force beneficiaries to choose between seeking other care, paying out-of-pocket, or going without—or getting embroiled in a daunting appeals system. The low rate of appeals indicates the complexity of the process. We often hear from enrollees who don't know how to begin, as well as from those who can't; they simply don't have time to wait for treatment or to wade through what might be a thicket of denials across all of their care.

Importantly, even successful appeals come at a cost. The most significant risks are care delays and the resulting negative health outcomes. But appeals processes are also burdensome for beneficiary and provider alike, creating strain, expense, and extra work. Many beneficiaries abandon the process altogether, along with the care they need. And when plans systematically and inappropriately deny claims, it may have a chilling effect on providers' willingness to prescribe or provide a treatment or cause providers to spend additional time and resources "over proving" claims to avoid denials.

---

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

[2] U.S. Department of Health and Human Services Office of Inspector General, "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials," (September 25, 2018), https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp.

[3] Medicare Rights Center, "Medicare Trends and Recommendations: An Analysis of 2020-2021 Call Data from the Medicare Rights Center's National Helpline," (May 2022), https://www.medicarerights.org/pdf/2020-2021-helpline-trends-report.pdf.

Appeals are a necessary safety valve and important quality marker, but currently function as a very poor substitute for sound plan decisions or robust independent oversight. Both the denials that unnecessarily force people into a broken appeals system, and that system itself, must be addressed.

To reduce harmful and inaccurate denials—and the likelihood that an enrollee needs to file an appeal in the first place—we urge clearer rules, stronger enforcement, and more transparency. The newly finalized Risk Adjustment Data Validation (RADV) rule is a step in the right direction.[4] The OIG has also recommended tightening audit standards on MA plans, establishing firmer guidance about MA coverage criteria, and directing MA plans to review their processes and systems to better avoid payment errors.[5] We agree with these reforms and ask CMS to notify beneficiaries about plan violations, offering enrollment relief where needed.

MA plans that inappropriately deny care must not be permitted to benefit from it. Capitation provides a motive to deny or delay access to care, but penalties for bad actors can help reduce the force of this incentive. Or, if the decisions are simply mistakes, corrective actions from CMS can spur plans to take more care in their process design and decision-making.

To enhance data collection and reporting efforts, we ask CMS to monitor MA coverage and care decisions for high denial and overturn rates as well as for low appeal rates, and for patterns therein, like inappropriate denials for specific services or categories of care. Any trends that emerge should trigger a more comprehensive review to determine the underlying cause of the error and to obligate the plan to resolve it. Plans that regularly engage in such practices should lose the ability to enroll new members or, if the violations are severe, to contract with CMS, until corrections are made and publicly documented. Offending plans should remain subject to higher levels of review going forward and all captured data should be made publicly available. Finally, to best obtain the full range of data about pre- and post-service denials, we ask the agency to rescind the September 2020 guidance improperly limiting reported elements.[6]

Reforms are more urgent than ever as Medicare prepares for the Inflation Reduction Act's (IRA) landmark policy changes. Among its structural improvements, the IRA simplifies the Part D benefit and places a greater liability on plan sponsors in the catastrophic coverage phase. While we support this essential redesign, we are concerned it may incentivize more aggressive utilization management across the Medicare landscape—including within MA—putting more people at risk of experiencing a coverage denial and a dysfunctional appeals system.

---

[4] 88 Fed. Reg. 6643.

[5] U.S. Department of Health and Human Services Office of Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," (April 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[6] Centers for Medicare & Medicaid Services, "Revised Appeal and Grievance Data Form, Form CMS-R-0282," (September 24, 2020), https://www.hhs.gov/guidance/document/revised-appeal-and-grievance-data-form-form-cms-r-0282. (Removed the following data elements from the standardized Appeal and Grievance Data Form [Form CMS-R-0282] Expedited appeals; Disposition of expedited appeals, IRE (level 2) appeals, Disposition of IRE (level 2) appeals, Withdrawals).

II. Provisions of the Proposed Rule
A. Patient Access API
2. Enhancing the Patient Access API
a. Prior Authorization Information

Established in previous rulemaking,[7] the Patient Access Application Programming Interface (API) allows patients to access their own health information through apps that include information on patient claims, encounter data, and a subset of clinical data. CMS now proposes to require that information about prior authorizations be made available to patients through the Patient Access API. This would include the prior authorization status, the date the prior authorization was approved or denied, the date or circumstance under which the authorization ends, the items and services approved, and the quantity used to date under the authorization. The documentation required to be shared would include any materials that the provider sends to the payer to support a decision, structured or unstructured clinical data including laboratory results, scores or assessments, past medications or procedures, progress notes, or diagnostic reports. It would also include a specific reason for any denial. The requirement would include decisions that are pending, active, denied, expired, or in another status, for as long as the authorization is active and at least 1 year after the last status change. CMS notes that this requirement does not change any notice requirements that apply to prior authorization requests and decisions. We support these proposals. Increasing patient access to information around prior authorization will allow some patients to better track and understand the prior authorization processes they and their providers have initiated. This could, in turn, reduce the burden on both patients and providers. We also appreciate and appreciate the clarification regarding notice provisions. While information via a Patient Access API might prove valuable to many patients, it cannot take the place of formal notice.

We urge CMS, however, to apply each of the proposals in this rule to drugs covered by any of the payers. Part B drugs in particular are an important omission, but we also urge the inclusion of Part D drugs. Any rationale supporting a patient's ability to track prior authorization for services and treatments applies equally to access to drugs.

D. Improving Prior Authorization Processes
4. Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations
a. Reason for Denial of Prior Authorization & b. Existing Program-Specific Notice Requirements for Prior Authorization Denial Information

CMS proposes to require payers to provide a specific reason for denied prior authorization decisions, excluding prior authorization decisions for drugs, regardless of the method used to send the prior authorization request. We strongly support this proposal. We note, however, that while CMS flags the current requirement for Medicare Advantage (MA) plans to provide such information in its notices, our experience shows that plans often do no such thing and MA enrollees are left with no information about denial reasons except, perhaps, generic messages about a lack of medical necessity. And we are not

[7] 85 Fed. Reg. 25558.

alone in this experience. In 2015, 45% of Medicare Advantage plans sent denial letters with incomplete or incorrect information.[8]

As we highlighted in our introduction, vigorous oversight is desperately needed. The bare establishment of a rule does not ensure that patients or providers will have the protections and information they need. CMS must do more to make sure plan notices are correct, promptly delivered, available in languages other than English, and accessible to people with varying levels of health literacy. We also support invalidating and immediately escalating coverage denials that are not accompanied by proper notice.

5. Requirements for Prior Authorization Decision Timeframes and Communications
b. Proposals to Address Timeframes for Decisions on Standard and Expedited Prior Authorization Requests

CMS proposes to shorten the timeframe for MA organizations and applicable integrated plans, Medicaid fee-for-service (FFS) programs, and CHIP FFS programs from 14 to 7 days, or as expeditiously as the patient's condition requires, for standard requests. We support this reduction in the timeframe, at a minimum, but we urge CMS to go further and use a 5-day limit. Any delay can leave patients in limbo without the ability to either move forward with treatment or services or to change course into another option.

CMS proposes to leave in place the 72-hour deadline for expedited decisions made by MA organizations, applicable integrated plans, Medicaid managed care plans, and CHIP managed care entities. We urge CMS to shorten this to 48 hours.

CMS is not proposing to allow a missed deadline to trigger a deemed approval, saying it is not "practical" and that providers can contact payers to ascertain whether additional information is needed.[9] We believe this is an error as it shifts the burden back to the provider to enforce a regulatory requirement and chase after recalcitrant payers. We urge CMS to consider a missed deadline as a trigger to a deemed approval. Barring that, we urge CMS to consider a missed deadline as a trigger to a deemed denial with automatic escalation to the next stage in the appeals process.

8. Public Reporting of Prior Authorization Metrics

CMS proposes to require impacted payers to publicly report certain aggregated metrics about prior authorization by posting them directly on the payer's website or via a publicly accessible hyperlink(s) to better allow a patient or provider to understand an entity's performance on timeframes for approvals, on volumes of denials and appeals for prior authorization. The metrics would include

- A list of all items and services that require prior authorization.

[8] HHS Office of Inspector General, "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials" (September 2018), https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf.
[9] 87 Fed. Reg. 76238, 76297.

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan or issuer, for expedited prior authorizations, aggregated for all items and services.

We strongly support this requirement. It would be a step toward greater transparency for payer prior authorization policies and practices. We would additionally urge CMS to include information on prior authorization in Medicare's Plan Finder to ensure that individuals who are shopping for a plan can find it readily. However, we reiterate our caution that transparency and shopping cannot take the place of oversight and we must not rely on patients to correct bad actors through plan selection.

CMS notes that it may propose in future rulemaking to use these data to help develop quality measures to incorporate into quality star ratings. We support using prior authorization data to inform quality determinations for MA plans, though we have grave concerns that the star ratings program is currently of little utility for most consumers.

9. "Gold-Carding" Programs for Prior Authorization

CMS notes that it encourages payers to adopt gold-carding approaches that would allow prior authorization exemptions or more streamlined reviews for certain providers who have demonstrated compliance with requirements and seeks comment on how CMS and other payers could ensure that such programs benefit diverse populations, including individuals in rural areas, individuals with disabilities, individuals with chronic illnesses, small and minority providers, and providers who disproportionately serve minority and underserved communities. We support the use of gold-carding approaches to lessen the burdens of prior authorization, but we caution CMS that MA insurers in particular could use such techniques to lessen burdens for healthier and therefore less expensive enrollees and fail to reduce burdens for more disadvantaged populations that MA might be less

interested in keeping enrolled. We would encourage CMS to closely monitor gold carding to ensure that it does not show a bias toward wealthier, healthier enclaves, or providers with certain specialties that are more likely to reflect healthier patients.

Conclusion

Thank you again for the opportunity to provide comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Counsel for Federal Policy at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

Fred Riccardi
President
Medicare Rights Center