March 13, 2023

Submitted Electronically via www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 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

Dear Administrator Brooks-LaSure:

The Center for Medicare Advocacy (the Center) is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality healthcare. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with long-term conditions. The Center’s policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues. Additionally, the Center provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care. We appreciate the opportunity to submit these comments to the above referenced proposed rule.

Introduction/Overview

The Center welcomes CMS’ efforts to streamline and facilitate processing of prior authorization (PA) requests and improve interoperability. We strongly agree with CMS’ statements in support of health equity measures to increase access to health information for individuals with disabilities and individuals with limited or low health literacy. We further applaud CMS for addressing key issues relating to the overuse and misuse of prior authorization, including requiring specific reasons for denial, shortening timeframes for decisions, and requiring transparency from payers such as publishing data with respect to denial and appeal rates. This proposed rule would be an important step forward in the process of curtailing the misuse—and in some cases, abuse—of utilization management tools and strengthening transparency for individuals enrolled in impacted plans, particularly Medicare Advantage (MA) plans.
While the provisions of this proposed rule would apply to several programs including the Children’s Health Insurance Program (CHIP) Fee for Service (FFS), CHIP Managed Care, Medicaid FFS, Medicaid Managed Care, Qualified Health Plans on the Federally-facilitated Exchange (QHPs) and Medicare Advantage (MA), we focus our comments primarily on MA.

We also appreciate steps that CMS is taking elsewhere, including proposals in Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P), which is awaiting finalization. More is needed in order to provide adequate protection for managed care enrollees, however. As outlined below, we urge CMS to go further in order to curb the abuse of prior authorization as a cost-saving strategy.

Prior Authorization Misuse and Overuse

As the Center noted in our comments to the Medicare Part C & D rule (CMS-4201-P)¹, Medicare Advantage (MA) plans are entrusted with managing and providing for the health and wellbeing of their enrollees. Prior authorization (PA), a form of utilization management, is often touted by plans as a means of ensuring that enrollees do not receive unnecessary care. All too often, however, PA is used as a means to deprive enrollees of medically necessary care and services. Services and items that would be covered in traditional Medicare are routinely denied by MA plans.²

Our experiences concerning MA enrollees’ barriers to care are confirmed in two HHS Office of Inspector General (OIG) reports, one in 2018³ that found “widespread and persistent problems related to denials of care and payment in Medicare Advantage” plans. The report’s findings included that when beneficiaries and providers appealed preauthorization and payment denials, MA plans “overturned 75 percent of their own denials.” At the same time, “beneficiaries and providers appealed only 1 percent of denials to the first level of appeal.” As noted in the proposed rule, OIG issued another report in 2022⁴ that analyzed denials issued by 15 of the largest MA plans during one week in June 2019. Among the prior authorization requests denied by MA plans, OIG found that 13 percent met Medicare coverage rules – “in other words, these services likely would have been approved for these beneficiaries under original Medicare.” With respect to payment requests denied, OIG found that 18 percent met Medicare coverage rules and MA billing rules.

² See, e.g., STAT “Denied by AI: How Medicare Advantage plans use algorithms to cut off care for seniors in need” by Casey Ross and Bob Herman (March 13, 2023).
More recently in February 2023, the Kaiser Family Foundation issued a study\(^5\) analyzing the volume of Medicare Advantage prior authorization requests and approvals in 2021. The report found that 6% of MA prior auth requests were denied in full or in part. Overall, just 11% of denied prior auth requests were appealed; of those that were appealed, 82% resulted in the initial denial being either fully or partially overturned. Kaiser noted:

The high frequency of favorable outcomes upon appeal raises questions about whether a larger share of initial determinations should have been approved. Alternatively, it could reflect initial requests that failed to provide necessary documentation. In either case, medical care that was ordered by a health care provider and ultimately deemed necessary was potentially delayed because of the additional step of appealing the initial prior authorization decision, which may have negative effects on beneficiaries’ health.

These studies, and our experience, demonstrate that additional oversight of and rules concerning prior authorization are welcome and long overdue.

**Prior Authorization Documents and Process**

The proposed rule would require impacted payers to implement and maintain a Fast Healthcare Interoperability Resource (FHIR) Prior Authorization Requirements, Documentation, and Decision (PARDD) Application Programming Interface (API) to facilitate an electronic, more streamlined prior authorization process for providers than exists today. This system would allow a provider to query the payer’s system to determine if prior authorization is necessary for an item or service as well as the documentation requirements.

The PARDD API would be beneficial to providers and patients in several ways. Overall, it would reduce the administrative hurdles for providers that result in unnecessary delays in access to patient care. Many insurers currently require providers to call or send documents via fax machine to process prior authorization requests. These outdated systems slow down the prior authorization process and can require additional staffing to fulfill a payer’s requests, which further contributes to delays in patient care.

Streamlining provider workflow through an automated system is an essential element of improving care for patients. Administrative hurdles delay care for patients who are forced to wait days or weeks as providers navigate an inefficient and cumbersome process. The delays are not benign and can result in serious setbacks to patients needing care.

The Center supports the proposal for an automated process to increase transparency and ease the burden on providers requesting prior authorization on behalf of their patients.

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Reasons for Denial of Prior Authorization

The proposed rule would require impacted payers to provide a specific reason for prior authorization denials, regardless of the method used to send the request. Responses sent through the new automated system from the payer to the provider would have to include information about whether the payer approves the request, needs more information, or if the request is denied. If the request is denied, the proposed rule requires the payer to state the reasons for the denial. Existing regulations that require Medicaid managed care, CHIP, and Medicare Advantage plans to send a written denial notice would remain in place.

This proposed regulation would greatly benefit both beneficiaries and providers. The Center frequently hears from beneficiaries who are denied prior authorization without a clear reason. When an individual receives a denial that only cites that the item or service is considered “medically unnecessary” by the payer, it is impossible to understand the true reason for the denial and makes appealing the decision more challenging. Vague phrases like “the patient could be treated in a less intensive setting” are not an appropriate reason for denial of care. Such lack of specific support for such reasoning creates barriers for providers and patients seeking to appeal the decision, particularly in urgent situations. In these opaque processes, the power rests entirely with the payer to give further details so the provider can meaningfully address the denial reason. Too often, providers and patients are left to speculate the reasons for denial instead of receiving a clear response that allows for a reasonable chance at appeal.

While we support the requirement that any adjudicated authorization denial should specify the reason, that reason must be based on ascertainable standards that include any clinical criteria, processes, strategies, evidentiary standards, or other factors used to reach that decision. HHS should also strengthen requirements to help ensure that enrollees (and their providers) can access and evaluate clinical criteria, processes, strategies, evidentiary standards, or other factors used to support prior authorization documentation requirements through the API. Payers should have to provide enrollees and their providers with supporting documentation so they can understand and evaluate how to proceed. If payer denies a prior authorization for not being “medical necessary,” for example, the API should also make available documentation explaining the clinical basis for that decision.

The Center strongly supports this proposal and seeks to ensure its application is meaningful. The Center encourages CMS to provide specific examples of the term “specific reasons” for denial cited in the proposed rule and to provide examples of denial reasons that would not be sufficient for payers to use without more detail from the clinical record. CMS should consider going further in the final rule by requiring payers to state what specific clinical, medical, or functional evidence would be sufficient to warrant an approval of a given service.

Further, we urge CMS to consider prescribing specific definitions of “approval” and “denial” since some payers amend the prior authorization request and approve only a portion of what the treating physician prescribes. For example, a provider might prescribe eight physical therapy

sessions for a given patient submitting a prior authorization request. The payer may “approve” the request but only grant such approval for four physical therapy sessions, requiring that provider to submit another request for the same course of treatment. That decision is often considered an approval even though the payer denied the provider’s request for an appropriate course of treatment. This comes as close to the payer practicing medicine as any utilization review technique and it should be prohibited by these final regulations.

This issue intersects with the Medicare Advantage proposed rule (CMS-4201) which would prevent MA plans from subjecting a patient to prior authorization for an ongoing treatment after an initial authorization for a “course of treatment” has been granted. As in the MA proposed rule, the Center hopes that CMS offers more detailed definitions in the final rule that clarify what defines a course of treatment. The Center would like to ensure that providers and patients are the decision makers for courses of treatment and that plans do not inappropriately label amended prior authorizations as “approvals” both in communication to providers and patients and in public reporting of prior authorization data.

The Center strongly supports the proposed requirement to provide specific reasons for prior authorization denials and recommends CMS consider outlining specific definitions for and examples of terms such as “approval,” “denial,” and “specific reason for denial.”

Need to Improve Current Medicare Advantage Notices

As we noted in our comments to CMS’ proposed Part C & D rule (CMS-4201)\(^7\), the Medicare program is in need of enhanced notice requirements and oversight of Medicare Advantage (MA) plans. The following comments are excerpted from these earlier, submitted comments.

One of the findings of the above-referenced 2018 OIG report, in addition to a high rate of inappropriate clinical decisions made by Medicare Advantage (MA) plans, was that MA plans were responsible for “insufficient denial letters issued to beneficiaries and providers” and engaged in “insufficient outreach before issuing denials”. The report referenced CMS’ own audits of plans in 2015 that “cited 45 percent of contracts for sending denial letters with incomplete or incorrect information, which may inhibit beneficiaries’ and providers’ ability to file a successful appeal.” All too often, when MA plans deny or terminate care, across care setting, service, or item, they provide minimal, conclusory statements without justification. Statements such as “doesn’t meet Medicare coverage guidelines” or “not medically reasonable and necessary” gives plan enrollees and providers little information as to why services are denied or prematurely terminated.

In traditional Medicare, there is outside and independent oversight of provider decision-making by Medicare Administrative Contractors (MACs) via claims processing. In the Medicare Advantage program, there is no such routine oversight unless beneficiaries choose to appeal (most of whom do not do so, as highlighted by the OIG and Kaiser reports referenced above). The burden must be on the plan to “show their work” and adequately justify why

Medicare rules are not met. We therefore urge CMS to strengthen written notice requirements that MA plans must follow both when they deny care and when they terminate care that has been authorized. Otherwise, we will continue to see routine, knee-jerk denials without justification, and MA enrollee due process rights will be thwarted.

When an MA plan denies, discontinues or reduces care, Medicare rules currently require plans to issue a Notice of Denial of Medical Coverage or Payment (Form CMS-10003-NDMCP), also known as the Integrated Denial Notice (IDN). This form requires plans to “provide a specific and detailed explanation of why the medical services/items or Part B drug or Medicaid drugs were denied, including a description of the applicable Medicare (or Medicaid) coverage rule or applicable plan policy (e.g., Evidence of Coverage provision) upon which the action was based. A specific explanation about what information is needed to approve coverage must be included.” In our experience, these outlined elements of denial notices are viewed by plans as suggestions rather than requirements. All too often, people do not have enough information as to why their request was denied, including whether additional information is needed in order to have the request granted, and whether there is a clear error on the face of the denial (in other words, the wrong service or medical condition is referenced) so most people simply give up and do not appeal. All too often, people only receive a telephone call or other notification, not a written notice.

In addition to ramping up enforcement over plans to ensure they are both authorizing medically necessary care and providing adequate notices, CMS should enhance existing notice requirements. In order to better ensure that plans are providing the required information, we urge CMS to standardize MA denial forms in a manner that makes it more clear what information is required, and, correspondingly, makes it more clear when an MA plan has failed to provide the required information. For example, under current Medicare rules (in both traditional Medicare and MA), home health agencies, (HHAs), skilled nursing facilities (SNFs), hospice agencies and comprehensive outpatient rehabilitation facilities (CORFs) must provide a Detailed Explanation of Non-Coverage (DENC) to a beneficiary only if a beneficiary requests an expedited determination after receiving a Notice of Medicare Non-Coverage (NOMNC) when previously approved services are being terminated. The DENC requires the provider and/or plan to explain the specific reasons for the end of covered services, including a number of specific prompts.

In order to better ensure that MA plans actually do more than a cursory, perfunctory review of a request for covered services, a detailed notice and explanation of non-coverage should be required upfront, and designed in a manner to ensure that plans fill in the required data elements. The scope of information required in the DENC should be the default when initial denials (via prior authorization) are issued as well as notices of termination of previously approved services, regardless of whether a beneficiary chooses to appeal. This should be the standard across all care settings and services. This should not be considered a new “administrative burden” for plans, since (in theory) this type of review should already be happening when requests for

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coverage are made, and is already required under Medicare rules (even if such rules are not routinely followed).

**Extend Prior Authorization Rule to Cover Prescription Drugs**

While we recognize that the processes and standards of prior authorization for drugs differ from those for items and services, we urge CMS to include prescription drugs in future rulemaking on prior authorization. CMS should require impacted payers to include information about prior authorization for medications in the Patient Access API, Provider Access API, and Payer-to-Payer API. We also urge CMS to include beneficiary protections similar to those found in this rule, including timelines, specific reasons for denials, and public reporting on processing and denials. We also recommend creating guardrails around prior authorization for treatments that are already underway and for maintenance medications.

**Decision Timeframes for Prior Authorization**

The proposed rule would require MA organizations, Medicaid FFS programs, and CHIP FFS programs to provide notice of prior authorization decisions as expeditiously as a patient’s health condition requires but no later than 7 calendar days for standard requests and no later than 72 hours for expedited requests.

While we commend CMS for recognizing that the timeframe for prior authorization decisions must be regulated, and that these timeframes can mean the difference between receiving the service in a timely manner and delaying or even denying access to care, **we urge CMS to institute a shorter timeframe across all impacted payers for expedited or urgent requests and identify specific types of services that should always be considered for expedited review.** The need for emergent or expeditious access to health care services takes place every hour of every day and medical care must be available to respond to those emergencies, including on weekends and holidays.

An urgent request for prior authorization should be evaluated by the end of the day in which the request was made but in no event more than 24 hours from the time of the request, whether or not the request is made on a Friday of a business week. It is not appropriate for payers to decide a timeline for emergency medical care. Rather, those decisions should rest with trained providers treating patients in real time. The Center recommends shortening the timeframe for expedited prior authorization requests, requiring decisions to be made by payers on weekends and holidays, and requiring impacted payers to identify in the PARDD API which specific services qualify as expedited or urgent requests. Further, for non-urgent requests, the Center recommends a shorter timeframe of 72 hours for payers to respond to requests, rather than the seven days proposed in the rule.

**In short, the Center urges CMS to impose shorter timeframes for evaluating prior authorization requests and recommends that CMS considers a 24-hour timeframe for urgent requests and a 72-hour timeframe for non-urgent requests given the workflow**
solutions offered through this proposed rule and the proposed rule for Medicare Advantage plans (CMS-4201-P).

Additional Consumer Protections Needed

The Center urges CMS to require that MA plans and applicable integrated plans approve requests for prior authorization when the plans do not meet the required standard or expedited decision time frame (deemed approval). We do not believe that providers and enrollees should be required to follow up with a payer if the payer fails to respond to a prior authorization request within the time frame for standard and expedited requests, respectively. This policy leaves providers and, more importantly, enrollees in a potentially interminable cycle of pursuing plans for determinations. Rather, we urge CMS to require plans to deem approval for any prior authorization request to which a payer does not respond within the specified time frame. If CMS chooses not to follow this recommendation, in the alternative, we urge CMS to require that any failure by an MA plan or applicable integrated plan to provide notice of an organization determination within the same time frame (and without having requested an extension) shall constitute a deemed denial; in other words, an adverse decision that may be appealed. Such a deemed denial should trigger an automatic appeal to the next stage in the appeals process (Level 2) in which the beneficiary or health care provider may request a reconsideration determination by an Independent Review Entity—as is the case when an MA plan upholds its initial denial at the reconsideration stage (Level 1) or fails to issue a decision in a timely manner.

Public Reporting of Prior Authorization Decisions and Appeals

The proposed rule would 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. The data would be reported at the organizational level for Medicare Advantage, at the state level for Medicaid and CHIP FFS, at the plan level for Medicaid and CHIP managed care, and at the issuer level for QHP issuers on the FFE.

The Center strongly supports these data transparency requirements for all plans impacted by this rule. For an individual with a disability or chronic health condition seeking a new MA plan or QHP, for instance, that person would have the ability to research competing plans to assess their prior authorization practices before making a choice of plan. A publicly available resource would also serve to hold impacted payers accountable to enrollees, providers, and the public for its practices.

However, we urge CMS to require data reporting at a more granular level than in an aggregated format, particularly setting-specific data. Only with this level of specificity will patients and providers be able to assess which services are routinely denied, appealed, and overturned in favor of patients and providers. The Center is concerned that prior authorization denials in the post-acute care sector are more common than in other settings, as has been recognized by the above-referenced 2022 OIG report, and that these disparities in approvals
would be concealed in an aggregated data reporting requirement. A prospective enrollee or beneficiary will be able to make a more informed decision if they can compare multiple payers’ prior authorization metrics at the setting of care level.

Reporting aggregated data about approved and denied authorizations, as proposed, will mask cases where denials are targeted to a less common but particularly expensive services, or even by targeting individuals or groups of individuals with particularly high service needs. We recommend that HHS require plans to report on prior authorizations at the plan level and for specific categories of services, rather than overall aggregate rates. This would permit state and federal regulators to more easily link prior authorization practices with utilization rates for specific services -- an important oversight tool.

**We further urge CMS to further strengthen reporting requirements.** For example, at a minimum, we recommend that CMS add to its list of required reporting to include:

1. The total absolute number of prior authorization requests along with the absolute number of denials, extensions, and approvals, not just the percent that were approved or denied, for each category of services.
2. The total number and the percentage of appeals related to prior authorization denials; and
3. The average time between a prior authorization approval and the actual provision of the approved treatment or service.

The current list of required data refers only to percentages, but does not include the absolute numbers of PA requests, which are necessary to understand the scope of this utilization management practice.

As discussed at greater length in the Center’s comments to CMS’ Request for Information re: Medicare Advantage (CMS-4203-NC, published on August 1, 2022 at 87 Fed Reg 46918), currently, Medicare Advantage plans are required to disclose grievances and appeals information regarding the number of disputes and their disposition to any MA plan eligible individual who requests this information. In September 2020, in contravention of these requirements, however, CMS issued a memorandum to plan sponsors that revised the required data elements, informing plans that they do not have to report information about expedited or second level appeals. We urge CMS to rescind the September 2020 guidance and reinstate the previous reporting requirements.

In addition, as discussed in our MA RFI comments, in order to give both the government and the public more and better information concerning MA plan performance, **CMS should enhance reporting requirements for plans more broadly and make such information publicly**

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11§1852(c)(2)(C) of the Social Security Act and 42 C.F.R. §422.111(c)(3).
available. As CMS is aware, there is a proposed bill in Congress called the “Improving Seniors’ Timely Access to Care Act of 2022” (H.R. 8487 in the last session of Congress). If the bill is not enacted, we urge CMS to use the full extent of its authority to implement the transparency requirements outlined in the bill, in requiring plans to annually submit to the Secretary – and the Secretary to publish on its website on the individual plan level – the data elements found at (3)(A)(i)) of the bill’s text.

In addition, enrollees and beneficiaries must be able to understand this information in order to act upon it. Therefore, the Center recommends requiring impacted payers to present the data in a uniform, standardized format that is easily accessible and readable for all enrollees, particularly individuals with disabilities and individuals with limited or low health and data literacy.

Patient Access API

The proposed rule would add information about prior authorizations to the categories of data required to be made available to patients through the Patient Access API by impacted payers, no later than one business day after the payer receives the PA request. The information would include related administrative and clinical documentation for items and services.

The Center supports CMS’ efforts to enable patients to take an active role in their healthcare through information sharing. The Center strongly recommends CMS provide guidance on ensuring the Patient Access API is accessible and easy to use for individuals with disabilities and for individuals with limited or low health literacy.

Provider Access API

The proposed rule would require impacted payers to implement and maintain a Provider Access API to enable current patients’ information to be exchanged from payers to providers that are in that payer’s network, at the provider’s request. Patients would need to opt out through a mechanism maintained by the payer.

The Center supports the streamlining of provider workflows to ease the burden on patients to coordinate the transfer of electronic health information by establishing a Provider Access API.

Payer-to-Payer API

The proposed rule would require impacted payers to establish and maintain a Payer-to-Payer API to ensure data can follow patients when they change payers. The Payer-to-Payer API would facilitate the creation of a longitudinal health record for patients and would expedite care and reduce unnecessary burden and duplication when patients change plans.
The Center supports this increased data sharing, with permission by the patient, to ease the burden on patients to coordinate health record exchanges when changing from one plan to another and to reduce the inefficiencies of methods like phone calls and fax machines to secure prior authorization approvals.

**Enforcement Mechanisms**

The Center greatly appreciates CMS’ attention to solving critical issues in current prior authorization processes and CMS’ proposals to ensure that beneficiaries are able to access the medically necessary care to which they are entitled in a timely manner. These technological and system improvements will be a significant task for impacted payers to complete, implement, and maintain. The Center has concerns about the monitoring and oversight of impacted payers’ adherence to these new standards. Therefore, we encourage CMS to consider detailing the expected enforcement mechanisms for these new requirements in the final rule, to ensure that beneficiaries are able to see the full impact of these proposals reflected in practice.

**Conclusion**

We applaud CMS for recognizing the harms to beneficiaries posed by certain prior authorization practices and timeframes and the burdens placed on providers, and strongly encourage CMS to finalize this proposal and continue to guard against prior authorization as a mechanism to delay and deny medically necessary care, particularly for people with injuries, illnesses, disabilities, and chronic conditions that require rehabilitation care.

We appreciate the opportunity to submit these comments. For additional information, please contact David Lipschutz, Associate Director at DLipschutz@medicareadvocacy.org or (202)293-5760.

Sincerely

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