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

Dear Administrator Brooks-LaSure,

We appreciate the Centers for Medicare & Medicaid Services’ (CMS’) ongoing efforts to improve consumer protections in the Medicare Advantage (MA) program, particularly with respect to prior authorization, including last year’s final Part C & D rule\(^1\) and other relevant policy updates issued by CMS this year, including: the FAQ concerning the 2024 rule (February 6, 2024)\(^2\); the Interoperability and Prior Authorization Final Rule (CMS-0057-F, February 8, 2024)\(^3\); and, most recently, the Contract Year 2025 Medicare Advantage and Part D Final Rule (CMS-4205-F).\(^4\) Collectively, these efforts demonstrate the Biden Administration’s commitment to provide more meaningful oversight of MA plans.

However, we remain concerned about MA plans’ use of prior authorization, specifically their ongoing use of artificial intelligence (AI) and algorithmic software to guide coverage decisions. Plans continue to use AI tools to erroneously deny care and contradict provider assessment findings. Last year, a class action lawsuit was filed alleging that UnitedHealth Group unlawfully used an AI algorithm, nH Predict, to deny rehabilitative care to sick Medicare Advantage patients. The lawsuit cites an investigation suggesting that UnitedHealth Group pressured employees to use the algorithm to issue payment denials to Medicare Advantage beneficiaries and set a goal for employees to keep patient rehabilitation stays within 1 percent of the length of stay predicted by nH Predict.

We believe more detailed guidance is needed to protect access to care for Medicare beneficiaries and improve clarity for providers. We therefore urge CMS to take the measures outlined in the attached letter sent to CMS in November 2023, and we offer additional, specific recommendations for CMS to implement to ensure that the intent of the final rule and subsequent guidance is achieved for all beneficiaries.

- **Clarify the specific elements that must be contained in denial notices.**

We appreciate that the final Interoperability and Prior Authorization Rule will, as noted in your attached January 2024 letter, “require impacted payers, including MA organizations, to report certain metrics about their prior authorization processes, such as percentage of standard prior authorization requests that were approved, aggregated for all items and services.” While this will be a positive step forward, rather than aggregated data, we assert that more detailed information about denials is warranted, including by care setting/service/item, reason for denial, and outcome of each stage of the appeals process.

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\(^1\) 88 Fed Reg 22120 (April 12, 2023).
\(^3\) 89 Fed Reg 8758 (Feb. 8, 2024).
\(^4\) 89 FR 30448 (April 23, 2024).
We reiterate the request in the November 2023 letter that MA plans report prior authorization data including reason for denial, type of service, beneficiary characteristics (such as health conditions), and timeliness of prior authorization decisions. Such information is needed not only for AI tool oversight purposes, but to allow Medicare beneficiaries to make better informed decisions when comparing plan options.

We also recommend that denial notices should include person-specific details for why a service is denied or terminated that identifies what information is lacking, describes any internal criteria used to make the decision, cites the specific regulatory requirement that isn’t met, identifies the health professional who reviewed the request, and cites specific denial codes.

- Establish an approval process to review AI and algorithmic tools and their inputs to ensure the integrity of their use, and conduct a review of algorithm and AI tools currently being used.

  We believe CMS must be more proactive in monitoring plans’ use of AI and algorithm-driven tools. MA plans cannot be allowed to side-step oversight by claiming that these tools are mere “guidance.” Given that we do not know what inputs are used for the algorithms and AI tools currently being used, it is difficult to know the accuracy of the information they generate and whether the inputs comply with the regulations. Absent a prohibition on the use of such tools altogether, CMS should limit their use until a systematic evaluation can be conducted on how these tools are impacting care. This systematic evaluation should review a representative sampling of case files across MA plans comparing the output of algorithmic/AI tools used by the plans to actual coverage determinations including duration of coverage, number of units of service, and comparing the beneficiary profile to the tool’s generalized population.

- Prohibit the use of AI/algorithmic tools and software from use in coverage denials until a systematic review of their use can be completed.

  The November 2023 letter notes that “[g]iven concerns about the homogeneity of patient testing populations when developing AI or algorithmic software in other settings,” we urged CMS to “assess what data [plans are] relying on to make these determinations or assessment [and] [a]ssess whether plans are inappropriately using race/other factors in these algorithms.” We appreciate CMS’ concern outlined in the FAQs that use of AI or algorithmic tools “can exacerbate discrimination and bias” but we are disappointed that CMS defers to plans to, “prior to implementing an algorithm or software tool, ensure that the tool is not perpetuating or exacerbating existing bias, or introducing new biases.” We urge CMS to take a more affirmative role in prohibiting plans’ use of software or tools with discriminatory biases.

  Additionally, since the MA rule was finalized, plans have continued to use AI tools to determine whether care and services will be covered and the duration of care received. These tools apply a generalized need for care to an individual beneficiary’s situation, resulting in generalizations instead of person-centered approaches to care, which is antithetical to the mission of the Medicare program. CMS has shared that current AI tools are not able to self-correct when an incorrect decision is made, yet plans continue to use these tools exclusively. For these reasons, we believe that the use of AI and algorithmic tools should not be used for coverage denials until a systematic review of their use can be completed.

- Clarify how CMS distinguishes between uses of algorithms or software that account for individual circumstances and those that do not; specify what criteria, methods, or data will be used to
The November 2023 letter urges CMS to “assess how and to what extent initial prior-authorized AI determinations for services are adjusted to account for unanticipated changes in a patient’s condition (according to advocates and providers, initial determinations are not generally adjusted).” We appreciate the clarification in the February 2024 FAQ (Question 2) that with respect to MA plans using algorithms or artificial intelligence to make coverage decisions, an algorithm that determines coverage based on a larger data set instead of the individual patient’s medical history, the physician’s recommendations, or clinical notes would not be compliant with § 422.101(c). The FAQ states, “In an example involving a decision to terminate post-acute care services, an algorithm or software tool can be used to assist providers or MA plans in predicting a potential length of stay, but that prediction alone cannot be used as the basis to terminate post-acute care services. For those services to be terminated in accordance with § 422.101(c), the patient must no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient’s condition prior to issuing the notice of termination of services” [emphasis added].

We therefore recommend that CMS distinguish between uses of AI and algorithmic software that account for individual circumstances and those that do not, and we believe that more prescriptive guidance to plans in this area is critical to ensuring that beneficiaries are protected from wrongful care determinations. Additionally, advocates and providers report that MA plans often make an initial assessment about coverage and stick with that assessment rather than reassess or take account of an individual’s changing condition during a course of treatment. We therefore request clarification as to how CMS will monitor plan behavior to ensure that such reassessments are occurring. We also request clarification on how plans are required to communicate with providers and enrollees about such reassessments, including opportunities to provide input, feedback, and evidence.

- **Clarify when MA organizations are able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits.**

Question 1 of the February 2024 FAQ attempts to answer the question: “When are MA organizations able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits?” CMS states that “fully established” coverage criteria “includes established criteria in applicable Medicare statutes, regulations, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).” In your January 2024 letter, you note that: “CMS believes that permitting the use of publicly accessible internal coverage criteria in limited circumstances is necessary to promote transparent, and evidence-based clinical decisions by MA plans that are consistent with Traditional Medicare” [emphasis added].

We appreciate that CMS has tried to clarify when coverage criteria is clearly established and when external clinical criteria can be used to make coverage decisions. However, there still appears to be some ambiguity and confusion among plans, providers, and beneficiaries as to the distinction, despite CMS’ opinion that external criteria would be used in “limited circumstances.” Sub-regulatory guidance, including the Medicare Manuals, contain many important coverage rules, and while CMS has stated that they expect plans to consult sub-regulatory guidance, such authority has been removed from 42 C.F.R. §422.101(b)(2) as criteria that MA plans must follow in making coverage decisions. Accordingly, we urge CMS to revise §422.101(b)(2) to again articulate reference to Manuals and other sub-regulatory guidance and issue additional examples of permissible and impermissible use of “widely used treatment
guidelines or clinical literature” (using, e.g., case examples from the Office of Inspector General’s 2022 report, including stays in post-acute facilities, imaging, and injections).

- **Impose a minimum time period during which MA plans cannot issue a termination notice after their prior termination decision has been reversed by a Medicare contractor.**

Lastly, we are grateful that CMS is considering our suggestion of specific measures that could be used for monitoring MA organizations for future policymaking, as outlined in the November 2023 letter. We also urge CMS to finalize a provision in the proposed 2024 rule (CMS-4201-P) to impose a minimum time period during which MA plans cannot issue a termination notice after their prior termination decision has been reversed by a Medicare contractor (e.g., the Quality Improvement Organization). For example, an MA plan should have to meet a higher burden of proof demonstrating a significant change in beneficiary condition or need warranting a termination of coverage/services, particularly if the provider disagrees with the termination. CMS should consider a grace period of 14 days, at minimum, before a plan can issue another termination notice. This time period would allow a reasonable amount of time to reassess a beneficiary’s condition.

Medicare Advantage plans are entrusted with providing medically necessary care to their enrollees. We encourage CMS to incorporate the measures outlined above to protect Medicare beneficiaries and prevent future AI-related harms in health care.

Thank you for your attention to this important matter. We look forward to receiving your response and continuing to work together on ways to increase oversight of these AI tools in Medicare Advantage plans.

Sincerely,

Judy Chu  
Member of Congress

Jerrold Nadler  
Member of Congress

Elizabeth Warren  
United States Senator

Tina Smith  
United States Senator

Alma S. Adams, Ph.D.  
Member of Congress

Becca Balint  
Member of Congress
Bonnie Watson Coleman
Member of Congress