

CMS Proposes Artificial Intelligence Limits and Utilization Management Guardrails for Medicare Advantage

December 18, 2024

On December 10, 2024, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule with technical changes for the Medicare Advantage (MA) Program and the Medicare Prescription Drug Benefit Program for Calendar Year 2026 (Proposed Rule). Citing the growing use of Artificial Intelligence (AI) within the healthcare sector and reports that the use of AI may lead to “algorithmic discrimination” that exacerbates inequalities within healthcare, CMS proposes, for the first time, new guardrails that must be adopted by MA plans when using AI to manage patient care. CMS also proposes several reforms addressing utilization management (UM) techniques adopted by MA plans, including requirements for such plans to conduct and report detailed analyses on the use of prior authorizations. Notably, the Proposed Rule primarily modifies MA regulations, without direct application to the Medicare Part D prescription drug program.

A summary of key provisions follows below.

Proposed Guardrails for MA Plans Adopting AI and Automated Systems to Manage Patient Care

CMS states the purpose of its proposed AI guardrails is to ensure that the “use of AI does not result in inequitable treatment, bias, or both within the health care system, and instead is used to promote equitable access to care and culturally competent care for all enrollees.” With this consideration in mind, CMS proposes several regulatory safeguards that MA plans must adopt when using AI to manage patient care. CMS proposes the following:

- **Equitable Use of AI.** CMS proposes to revise existing MA regulations to state explicitly that MA plans that use AI or “automated services” do so in “a manner that preserves equitable access to MA services.”
- **Automated Systems Defined.** CMS proposes to broadly define “automated systems” to mean “any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both.”
- **AI Defined.** CMS clarifies that for the purpose of MA regulations, and consistent with the existing statutory definition at 15 U.S.C. § 9401(3), “artificial intelligence” means “a machine-based

system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to – (A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action.”

- **Patient Care Decision Support Tools Defined.** CMS proposes to define “patient care decision support tool,” consistent with the existing definition at 45 C.F.R. § 92.4, as “any automated or non-automated tool, mechanism, method, technology, or combination thereof used by an MA organization to support clinical decision making in its health programs or activities.”
- **Application of Antidiscrimination Provisions to AI Tools.** CMS emphasizes the continued application of current statutory and regulatory antidiscrimination provisions to AI tools used by MA plans in coverage decisions. Current requirements prevent MA Plans from denying, limiting, or conditioning the coverage or furnishing of benefits to patients on the basis of any factor related to health. CMS highlights that MA plans are bound by these rules even if they use AI tools to manage beneficiaries and/or third parties to fulfill their obligations and responsibilities. CMS specifically suggests that MA plans utilizing AI systems to manage beneficiaries should (1) ensure they understand and recognize biased inputs within any AI or automated system; (2) create and follow a process of regularly reviewing their automated systems to ensure they are operating in a nondiscriminatory way; (3) not use outputs with a known discriminatory bias (e.g., expected utilization or predictability of payment or both) in automated systems.
- **Public Disclosure and Transparency in Application of Utilization Management Measures.** CMS proposes several reforms addressing internal coverage criteria adopted by MA plans and reiterates that MA plans “are responsible for ensuring that usage of AI tools complies with internal coverage criteria” used in utilization management techniques. Among other reforms, CMS proposes to require MA plans to conduct detailed analyses on the use of prior authorizations and to report transparency data regarding their application of prior authorization and other utilization management techniques.

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