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2024 Final Rule: CMS Announces More Changes to Medicare Advantage but Declines to Reform the "60 Day Rule"

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On April 5, the Centers for Medicare & Medicaid Services ("CMS") released the 2024 Medicare Advantage and Prescription Drug Benefit Programs Final Rule ("Final Rule"), which will be codified at 42 C.F.R. Parts 417, 422, 423, 455, and 460. The Final Rule adopts a host of reforms aimed at improving health care access, quality, and equity for Medicare beneficiaries that receive coverage through Part C ("Medicare Advantage" or "MA") and prescription drug benefits through Part D. As discussed below, the Final Rule also has some notable omissions compared to what CMS previously proposed in December ("Proposed Rule," published at 87 Fed. Reg. 79452 (2022)). The Final Rule is effective **June 5, 2023**.

Part C Reforms

Pursuant to the Final Rule, if an MA plan prior authorized an item or service or made a pre-service determination of coverage or payment, the MA plan may *not* later deny coverage for lack of medical necessity and may not reopen the decision, except for "good cause" (as defined in 42 C.F.R. § 405.986) or "reliable evidence" of fraud or "similar fault" (as defined in 42 C.F.R. § 405.902). To limit interruptions in care, MA plans will be required to:

(1) grant prior authorizations that cover an entire course of treatment, plus a 90-day transition period when a beneficiary, mid-treatment, switches to or between Medicare plans;

(2) implement electronic medical record interoperability capabilities related to processing prior authorizations; and

(3) provide certain notifications to beneficiaries when the network terminates their providers.

See Final Rule at pp. 7-8.

The Final Rule defines a "course of treatment" based on the treating provider—i.e., "a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan." See id. at p. 270.

The Final Rule contains a number of reforms to promote health equity under MA, including adding to the Star Ratings Program a health equity index reward to incentivize quality care for patients with certain social risk factors ("SRFs").[1] *See id.* at p. 504. The SRFs include low-income subsidy, dual eligibility (meaning eligible for Medicare and Medicaid) and disability. *Id.* at p. 673. To promote equity in access to care between MA and traditional Medicare (*i.e.*, Medicare Parts A and B), MA plans will also be required to comply with traditional Medicare's general coverage and benefit criteria. Determinations of medical necessity will need to follow national coverage determinations, local coverage determinations, or, where none are applicable, plans must follow publicly available, evidence-based coverage criteria. *Id.* at p. 8. We note, however, that an MA plan may elect to offer, as a Medicare benefit, coverage for post-hospital skilled nursing facility care without a prior qualifying hospital stay that is required under traditional Medicare.

To promote parity between behavioral health and physical health services, the Final Rule extends MA care coordination and network adequacy requirements to include behavioral health care. Final Rule at p. 12. MA plans will be required to have a Utilization Management Committee that conducts annual reviews of policies to ensure compliance with the foregoing. *Id*. at 8. Finally, the Final Rule targets informational barriers to care, especially for older and diverse beneficiaries, by:

(1) prohibiting potentially misleading advertisements that refer generally to MA without naming a particular MA plan;

(2) promoting digital health literacy; and

(3) imposing cultural competency and linguistic accessibility requirements on MA plans.

See id. at 6-7, 98-99.

With respect to digital health literacy, MA plans will be obligated to offer to beneficiaries education about digital health so that they may access benefits furnished through telehealth when their provider is at a different location. *Id.* at 116.

Notable Omissions from Proposed Rule

CMS declined to adopt previously proposed amendments to the standard for "identified overpayments" under Medicare Parts A, B, C, and D. If finalized, the amendments would have aligned the Medicare standard with the standard for liability under 31 U.S.C. § 3729(b)(1)(A) of the False Claims Act ("FCA"). *See* Proposed Rule at 79559. The Social Security Act requires "a person" who has received an overpayment to report and return the overpayment no later than 60 days after being "identified." *See* 42 U.S.C. § 1320a-7k(d)(2) ("60 Day Rule"). A "person," for purposes of Parts C and D, includes a Medicare Advantage Organization and, for purposes of Parts A and B, includes providers and suppliers. *See* Proposed Rule at 79559. Any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation under the FCA. *Id*.

Under existing rules, the standard for "identifying" an overpayment is "reasonable diligence," such that an MA plan is on the hook for any overpayments it has determined or should have determined through "reasonable diligence." *See* 42 C.F.R. § 401.305(a)(2). However, in *United Healthcare Ins. Co. v. Azar*, the United States District Court for the District of Columbia held that the "knowledge" standard under the FCA is a more demanding standard of care than the "reasonable diligence" standard under the 60 Day Rule. 330 F. Supp. 3d 173, 191 (D.D.C. 2018). The Court specifically reasoned that "Congress clearly had no intention to turn the FCA, a law designed to punish and deter fraud, into a vehicle for either 'punish[ing] honest mistakes or incorrect claims submitted through mere negligence' or imposing 'a burdensome obligation' . . . rather than a 'limited duty to inquire." *See UnitedHealthcare Ins. Co*., 330 F. Supp. 3d at 191 (citing *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274-75 (D.C. Cir. 2010) (quoting S. Rep. No. 99-345, at 6, 19 (1986)).

Although CMS indicated in its Proposed Rule that it would incorporate the FCA's knowledge standard of actual knowledge, deliberate ignorance, or reckless disregard, the Final Rule contains no such reform. *See* 31 U.S.C. § 3729(b)(1)(A); Final Rule, *in passim*. We also note that, interestingly, in the *UnitedHealthcare* case, the Court opined that CMS did not have the authority to apply a more stringent standard to impose FCA consequences and, thus, such a change would require action by Congress. *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 191. The Court also held that the 60 Day Rule imposed a burdensome definition for "identified" without adequate notice to insurers. *See id*. (We discuss the Supreme Court's denial of writ of certiorari challenging the 60 Day Rule in a previous blog post.)

Nonetheless, CMS made clear that it intends to address previous proposals that are not addressed in the Final Rule. CMS also noted that they did not address comments received on provisions of the Proposed Rule that are not addressed in the Final Rule (*e.g.*, the 60 Day Rule) with the understanding that they will address them in a subsequent rulemaking document, as appropriate.

At Proskauer, we will stay up to date on any such rulemaking. Subscribe to our Health Care Law Brief to stay tuned.

[1] CMS is also reducing the weight of patient experience related measures and eliminating the 60-percent rule (*i.e.*, the "disaster adjustment" for extreme and uncontrollable circumstances). Together, these changes to the Star Ratings Program are expected to result in a ten-year savings of $6.41 billion, or "0.10% of the private health baseline." *See* Final Rule at p. 14.

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