Health Law Daily Wrap Up


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Medicare Advantage (Medicare Part C or MA) insurers have standing to challenge a CMS Final rule in district court, despite not having first sought administrative review. The U.S. District Court for the District of Columbia determined that CMS’ May 2014 Final rule (79 F.R. 29844) imposed a novel legal obligation on Medicare Advantage insurance companies, that there was “no viable path” for the insurers to seek administrative review, and that, even if they did, the rule placed burdens upon them that were so heavy as to practicably foreclose review. As a result, the district court denied HHS’s motion to dismiss (UnitedHealthcare Insurance Co. v. Price, March 31, 2017, Collyer, R.).

To "ensure[ ] actuarial equivalence" between Part C and regular Medicare plans, CMS adjusts average monthly Medicare beneficiary expenditures based on each particular Medicare Advantage plan’s beneficiary profile. Individual plans submit some of this information to CMS in the form of diagnostic codes provided by health care providers. CMS then uses the information to make adjustments to monthly payments. The agency recognizes that these codes may be inaccurate. Instead of requiring Medicare Advantage plans to conduct their own review of the underlying data they submit to CMS, the agency conducts periodic risk adjustment data validation (RADV) audits of sampled insurer data and extrapolates the results to calculate an average estimated error rate for the year.

Section 6402 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) required all insurers, including MA insurers, to return overpayments within 60 days of identification. Failure to comply is a False Claims Act (FCA) (21 U.S.C. § 3729, et seq.) violation. The 2014 Final rule clarified that an overpayment is considered "identified" at the time that an insurer determined, "or should have determined through reasonable diligence," that it received an overpayment. It further stated that "reasonable diligence" required "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of payments." Medicare Advantage plans operating under the UnitedHealthcare umbrella filed suit, alleging that the reasonable diligence requirement imposed a negligence standard for FCA liability, which is lower than the recklessness standard required by the FCA. They further alleged that the Final rule violated the requirement that CMS treat Part C insurers with actuarial equivalence to CMS by requiring the Medicare Advantage plans to review underlying medical charts to confirm diagnostic codes. The HHS Secretary filed a motion to dismiss, arguing that the plans lacked standing to challenge the Final rule.

Standing. Article III standing requires an injury in fact that is traceable to the defendant's actions and redressable by the court. The district court determined that the insurers adequately pleaded injury-in-fact, as the Final rule is actively in effect and applies to the insurers, and the insurers demonstrated sufficient harm caused by the required "proactive compliance activities." Furthermore, the injury was traceable to the Final rule, as the required due diligence was a new obligation requiring Part C plans to adopt and implement effective compliance programs to ensure accuracy and detect fraud. Finally, the court had the ability to redress the issue. It thus determined that the insurers had Article III standing.

It also determined that the insurers had statutory standing. Although the Medicare statute requires certain disputes to undergo the administrative procedure process outlined in 42 U.S.C. §§ 405 (b) and (g) before proceeding to judicial review, case law makes an exception where prohibiting judicial review would mean "no review at all." Specifically, the administrative procedure requirements do not apply where (1) no administrative route for reviewing a claim exists and (2) where the likelihood of severe sanctions for noncompliance is so great
as to cause parties to comply, thereby eliminating the path to review. Should the MA insurers violate the 60-day overpayment rule, the HHS Office of Inspector General (OIG) or a qui tam relator could bring an enforcement action against them pursuant to 42 U.S.C. § 1320a-7a. However, the OIG has stated that its rule does not interpret the CMS Final rule. As a result, any judicial review of the OIG rule would be unlikely to provide for judicial review of the CMS Final rule at issue. Furthermore, that path would require insurers to essentially commit uncorrected fraud by failing to repay overpayments, subjecting the insurers to potential civil monetary penalties and Medicare disbarment. The court noted that the administrative review requirement does not benefit from this type of "procedural quagmire." It thus determined that the Medicare Advantage insurers had statutory standing. It therefore denied HHS’ motion to dismiss.

The case is No. 16-cv-00157 (RMC).

