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COURT VACATES 60-DAY RULE FOR MEDICARE ADVANTAGE PLANS, CREATES UNCERTAINTY FOR SAME RULE APPLICABLE TO MEDICARE-ENROLLED PROVIDERS

Nearly a decade has passed since the U.S. Congress enacted the Patient Protection and Affordable Care Act (the "ACA"). Since March 2010, we have seen federal court rulings on numerous challenges to the ACA itself and the executive branch's efforts to enforce the ACA. One such challenge resulted on September 7, 2018 in the United States District Court for the District of Columbia categorically vacating the 60-Day Rule drafted by the Centers for Medicare & Medicaid Services ("CMS") that applies to Medicare Advantage ("MA") plans providing Medicare coverage to Medicare-eligible individuals through managed care plans. Interestingly, there is another 60-Day Rule that applies to health care providers enrolled in Parts A and B of the traditional fee-for-service Medicare Program. While the two rules exist in different places within the Code of Federal Regulations, the essence of the two CMS 60-Day Rules is the same; both rules implement the ACA mandate to return overpayments to the federal government within 60 days of overpayment identification. Since passage of the ACA, if an MA plan or a Medicare-enrolled provider fails to timely report and return an identified overpayment, they are in violation of the federal False Claims Act (the "FCA").

DISTRICT COURT RULING

In relevant part[1], the September 7 district court ruling scrutinized whether the CMS standard for when an overpayment is "identified" by an MA plan was unlawful due to inconsistencies with the express wording of the FCA (as amended by the ACA). The CMS definition for "identified" established that an overpayment is illegally retained by an MA plan if the plan "should have determined through the exercise of reasonable diligence" that the MA plan had received an improper overpayment. On the other hand, the FCA only imposes liability when an individual or entity "knowingly" submits to the government a false claim for payment. "Knowingly" is a term defined in the FCA to include false information about which a person:

1. "Has actual knowledge";
2. "Acts in deliberate ignorance of the truth or falsity of the information"; or
3. "Acts in reckless disregard of the truth or falsity of the information."

Including the "should have determined" standard in the CMS definition of "identified" created a more burdensome legal responsibility than that imposed by the FCA's "knowingly" standard. In fact, it imposes an affirmative obligation on the part of the MA plans and Medicare-enrolled providers to seek out such overpayments through "the exercise of reasonable diligence." In finalizing the 60-Day Rules, CMS stated that responsibility "at a minimum...would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." This concept of applying good faith and reasonable diligence essentially creates a negligence standard. The FCA is not a negligence-based statute but an intent-based statute. Therefore, the 60-Day Rules subvert the intent-based nature of the FCA to allow for liability due to negligent acts. Concluding that the "identified" standard in the 60-Day Rule was "obviously" inconsistent with the FCA standard, the court stated, "CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation." Therefore, the court vacated the 60-Day Rule at issue in the case.

IMPLICATIONS FOR MEDICARE-ENROLLED PROVIDERS

It is important to note again that this district court opinion only vacates the 60-Day Rule applicable to MA plans. Nonetheless, Medicare-enrolled providers subject to the Medicare Part A and Part B 60-Day Rule should incorporate this court's analysis into their compliance program activities. After all, the 60-Day Rule "identified" standard that the court disapproved of as inconsistent with the FCA is the exact same standard used in the 60-Day Rule applicable to Medicare-enrolled providers. Some of the takeaways from this opinion include:

1. Following the imposition of the 60-Day Rule, many organizations implemented broad and proactive audit practices to identify potential overpayments to avoid FCA liability. Before engaging in extensive audits or investigations, we would recommend discussing with counsel the obligations of the individual or entity to conduct such an audit and whether the audit should be narrowly tailored.
2. This decision is a district court opinion and does not have binding authority on other courts or jurisdictions. Therefore, it is important to

watch to see whether it is appealed and/or whether CMS proactively attempts to address the court's holding. In either case, it is important providers do not completely disregard their obligation to abide by the 60-Day Rule.

3. This court's ruling is significant, but the ultimate impact will not be fully known for a period of time.

If you have questions about this recent decision or other issues regarding the False Claims Act or the 60-Day Rules promulgated by CMS, please contact:

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[1] Before disapproving of the negligence standard and "identified" definition within the CMS 60-Day Rule, the district court also ruled that the CMS 60-Day Rule applicable to Medicare Advantage plans ensures that Medicare Advantage insurers are paid less to provide the same health care coverage to their beneficiaries than CMS pays for comparable patients under the fee-for-service programs. This disparity violates the statutory requirement that there must be "actuarial equivalence" between payments to Medicare Advantage plans and to traditional fee-for-service providers.