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When The Government Misinterprets Its Own Medicare Rules

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Howard J. Young


Albert W. Shay


Holly C. Barker

The crush and complexity of Medicare regulation make it increasingly difficult for providers and the government to understand and comply with applicable law. And so the Tenth Circuit recently mused "[w]hat happens if we reach the point where even these legislating agencies don't know what their own 'law' is?"[1]

The Caring Hearts Personal Home Service Inc. v. Burwell decision reminds us of the mind-numbing complexity of the Medicare program and importance of independent judicial review beyond the administrative agency appeal process, which increasingly has that "rubber stamp" feel. Observing early on its opinion that there are "about 37,000 separate guidance documents" on the Centers for Medicare & Medicaid Services website, "and even that doesn't purport to be a complete inventory,"[2] the Caring Hearts decision also serves as an important reminder that health care providers, even when trying in earnest to comply with complex and frequently changing rules, face a daunting task.

CMS and its contractors, particularly in post-pay program integrity reviews, often apply the strictest of interpretations most favorable to Medicare. Providers are growing increasingly frustrated with a Medicare appeals system that accords extraordinary deference to the secretary's positions, even when those positions defy common sense. Federal courts are also highly deferential under long-established Chevron deference and Administrative Procedure Act standards (as was the district court in Caring Hearts), but sometimes the agency just gets it plain wrong.

In Caring Hearts, the Tenth Circuit vacated and remanded a Kansas District Court's 2014 decision affirming a roughly $800,000 extrapolated overpayment issued to Caring Hearts in connection with home health services provided to 24 patients. The disallowed services, provided in 2008 and early 2009, were found by the CMS to be noncovered on the basis that documentation failed to adequately support medical necessity or that patients were "homebound" (and thus qualified to receive home health services), or both.

The problem, however, was that CMS attempted to apply regulations adopted in 2010 to support its disallowance of services rendered on or before Jan. 31, 2009. Moreover, based on the regulations in effect at the time the services were rendered (and the statute itself), Caring Hearts could not reasonably have known that the furnished services were noncovered, according to the Tenth Circuit. Further, the Tenth Circuit held that 42 U.S.C. § 1395pp (commonly referred to by health

care reimbursement lawyers as “waiver of liability” or “limitation of liability”), permits the secretary to waive liability where the provider could not have reasonably been expected to know that services were noncovered under the “reasonable and necessary” mandate.

Notwithstanding the agency’s arguments to the contrary, the court highlighted CMS’s misreading of the waiver of liability statute, finding that it expressly applies to disputes involving whether a home health patient is homebound, and not just to disputes pertaining to medical necessity and custodial care. To the point, the Tenth Circuit again noted that the agency “seems to be unfamiliar with its own law.”

The Long Road to Vindication

The genesis of this case was a 2010 extrapolated overpayment determination to the tune of $855,643.51 based on a review of 30 claims by a program integrity contractor, with adverse findings on 24 home health claims submitted by Caring Hearts between Jan. 1, 2008, and Jan. 31, 2009. Caring Hearts challenged the findings and lost at every level of administrative review — i.e., redetermination by the Medicare administrative contractor, reconsideration by the qualified independent contractor, review by an administrative law judge, and further review of the ALJ’s decision by the Medicare Appeals Council.

Undeterred, Caring Hearts appealed the agency’s final decision to the District Court for Kansas. The district court upheld the secretary’s determination in its entirety, deferring to the agency’s final administrative decision under a “substantial evidence in the record as a whole” standard and determining the secretary applied the correct legal standard.[3] Caring Hearts again appealed to the Tenth Circuit. On May 31, the provider’s perseverance finally paid off.

The Tenth Circuit’s Decision

The issue on appeal to the Tenth Circuit boiled down to whether, under 42 U.S.C. § 1395pp (waiver of liability), Caring Hearts could have reasonably known that services furnished in 2008 and early 2009 were noncovered at the time based on the regulations in effect at that time. The answer was a resounding, “no.” The court acknowledged the vast and complicated regulatory framework governing Medicare coverage, and even gave an indirect nod in dicta to the Chevron deference standard it would normally apply to an agency’s regulatory interpretation of a statute, but marveled nonetheless at the agency’s inability to accurately identify the applicable law in effect when the claims were submitted.

With respect to those claims disallowed based on the agency’s position that the patient did not meet Medicare’s “homebound” standard, CMS had concluded that Caring Heart’s documentation failed to establish that leaving home would “require a considerable and taxing effort” for the patient, even with an assistive device. However, that was not the standard in 2008 when the services at issue were furnished. Instead, the governing regulation provided that “[g]enerally speaking, a patient will be considered homebound if they [sic] have a condition due to an illness or injury that restricts their ability to leave the place of residence except with the aid of supportive devices such as crutches, wheelchairs and walkers ...”

The court found the difference between these two standards to be significant. Citing by way of example a patient who “lived” for all intents and purposes in his wheelchair, the court observed that the patient would have certainly qualified as homebound under the standard in effect in 2008 when the services were furnished, irrespective of any question as to whether the patient would have qualified for home health services under current regulations (a question carefully avoided by the court).[4]

The Caring Hearts decision also provides helpful guidance to providers that face Medicare audit challenges related to the sufficiency of medical record documentation. With respect to the medical record support for services for which CMS disputed medical necessity, the agency again applied a version of the governing regulation not in effect at the time the services were furnished. In 2008, the relevant regulation provided as follows: "services must be considered under the accepted standards of medical practice to be as specific, safe and effective treatment for the beneficiary's condition." The regulation was revised in 2010 to impose more onerous documentation and evidentiary requirements: "[d]ocumentation of objective evidence or clinically supportable statements of expectation that the patient can continue to progress toward the treatment goals and is responding to therapy ..."

In addressing this issue, the court noted that back then, the standard focused on whether the "provider's physical therapy services were consistent with accepted contemporary standards of medical practice," and that "nowhere does CMS's opinion suggest the doctors who prescribed the care in this case defied accepted medical standards."[5] With respect to whether services were "skilled" (an element, if you will, of medical necessity), CMS remarkably once again applied a regulatory provision not in effect at the time the services were rendered that required more extensive documentation than the regulations in effect at the time.

Typically, courts lend a great deal of deference to an agency's interpretation of the laws it administers, but that deference only goes so far. Here, the Tenth Circuit appears to empathize with a frustrated provider and join in its exasperation with the agency:

> This case has taken us to a strange world where the government itself — the very "expert" agency responsible for promulgating the "law" no less — seems unable to keep pace with its own frenetic rulemaking. A world Madison worried about long ago, a world in which the "laws are so voluminous they cannot be read" and constitutional norms of due process, fair notice and even the separations of powers seem very much at stake. But whatever else one might say about our visit to this place, one thing seems to us certain: an agency decision that loses track of its own controlling regulations and applies the wrong rules in order to penalize private citizens can never stand.

Going perhaps one step further and in an unusual move, the Tenth Circuit seems to invite Caring Hearts on remand to the district court to seek legal fees from the secretary to help make amends — "Indeed, we would not be surprised if — should Caring Hearts bring an otherwise eligible application for costs and fees under the Equal Access to Justice Act, 28 U.S.C. § 2412(d) — CMS were to accept on remand that its positions in this case were not "substantially justified.'" The court's implied message is that the agency didn't just get it wrong, it got it really wrong. With the agency's repeated misapplication of the law not only before the Tenth Circuit, but at every level of the administrative appeal process, Caring Hearts should seek some level of solace from finally, after years of litigation, prevailing.

Conclusion

While of limited precedential value given the narrow set of facts, the Tenth Circuit's decision in Caring Hearts is an eloquent and sharp criticism of the regulatory rubric governing U.S. federally funded health care programs. The Tenth Circuit is not the first to take note of the complexity of Medicare's governing statutes, regulations and subregulatory guidance. Courts have on a number of occasions commented on the overwhelming complexity of the Medicare system, describing it as "labyrinthine" and more

colorfully as a law that reads as though it was "written by James Joyce and edited by E.E. Cummings."[6] Another oft-quoted observation by the Fourth Circuit in a Medicare appeal offers this:

> Medicare and Medicaid are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.[7]

But what are the larger implications of a Medicare system with which the regulating agency itself cannot keep pace? Although Caring Hearts was not a False Claims Act case — it was a long-litigated overpayment determination arising from a program integrity audit — theories of FCA liability premised on similar allegations of regulatory noncompliance and government or qui tam relator overreach are not uncommon. With its focus on due process, provider knowledge of Medicare requirements, and proper notice in the face of exceedingly complex rules and regulations, this Tenth Circuit opinion serves as a stark and colorful reminder of the challenges the government has in proving fraud-based liability arising from a "knowing" failure to comply with highly technical and frequently evolving requirements.

—By Howard J. Young, Albert W. Shay and Holly C. Barker, Morgan Lewis & Bockius LLP

Howard Young and Al Shay are partners and Holly Barker is an associate in Morgan Lewis' Washington, D.C., office. Young previously served as senior attorney and deputy branch chief with the Office of Inspector General.

[1] Caring Hearts Personal Home Services Inc. v. Sebelius, 2016 WL 3064870 at 1 (10th Cir. May 13, 2016).

[2] Id.at *2 (citing Jessica Mantel, Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State, 61 Admin. L. Rev. 343, 353 (2009)).

[3] Caring Hearts Personal Home Services Inc. v. Sebelius, 2014 WL 4259151 at *16 (D. Kan. 2014).

[4] 2016 WL 3064870 at *3.

[5] Id. at *5.

[6] See Catholic Health Initiatives Corp. v. Sebelius, 657 F.3d 1, 17 (D.C. Cir. 2011) (artfully describing the burden and challenge that is the Medicare statute) and Ne. Hosp. Corp. v. Sebelius, 657 F.3d 1, 17 (D.C. Cir. 2011)).

[7] Rehab. Ass'n of Va. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994).