CMS Outlines New Standard for Challenging Medicare Payment Denials, Echoing Brand Memo on Force of Sub-Regulatory Guidance

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On October 31, 2019, the Office of General Counsel for the U.S. Department of Health and Human Services (HHS) issued an important memo from Kelly M. Cleary, CMS Chief Legal Officer, and Brenna E. Jenny, Deputy General Counsel, discussing the impact of the recent U.S. Supreme Court ruling *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019) on enforcement actions brought by the government ("Cleary Memo"). A copy of the Cleary Memo is available here.

On The Supreme Court in *Allina* held that HHS must go through notice-and-comment rulemaking for any rule, requirement, or policy statement that establishes or changes a "substantive legal standard" affecting Medicare benefits (*e.g.*, the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services).[1] By statute, Medicare rules are held to a higher procedural standard under the Social Security Act § 1871 relative to the Administrative Procedure Act (APA).[2]

The Cleary Memo expands on the holding of *Allina* and analyzes its impact on enforcement actions – most notably, overpayment actions based on audits – taken by HHS and CMS. Specifically, the Cleary Memo states that HHS and CMS cannot take enforcement actions based on sub-regulatory standards or manuals unless such guidance is closely tied to statutory or regulatory requirements.[3] If the guidance is not closely tied to statutory or regulatory requirements, then enforcement actions would be invalid as the underlying guidance was issued in violation of *Allina*.[4]

According to the memo, the agency may publish guidance documents based on a narrowly-worded statute to provide clarity without creating a new legal standard.[5] However, issuing rules in guidance documents based on a broadly-worded statute or regulation capable of be interpreted in many ways can be viewed as creating a new legal standard, requiring notice-and-comment rulemaking.[6] Ultimately, "the critical question is whether the enforcement action could be brought absent the guidance document."[7]

The Cleary Memo is significant for several reasons. First, it is an explicit acknowledgement of the limitations on CMS' enforcement authority involving sub-regulatory guidance. Second, it provides much needed certainty and consistency following the Brand Memo.[8] While the Brand Memo limited the ability of the DOJ to bring affirmative civil enforcement actions – like those under the False Claims Act (FCA) – based on "improper guidance documents" that did not go through APA notice and comment rulemaking,[9] the Brand Memo left the door open to other kinds of enforcement, including actions by the OIG and CMS.

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In the wake of the Cleary memo, providers may argue that unless FCA liability is alleged, an overpayment action based solely on guidance documents that change or create substantive legal standards would be improper. Indeed, any audit denials (and associated overpayment demands) based on sub-regulatory guidance are now potentially challengeable under *Allina* and the Cleary Memo, depending on whether the sub-regulatory guidance bears a close relationship to the statute or regulation. One particularly useful statement relates to enforcement actions based solely on Local Coverage Determinations (LCDs), which the Cleary Memo confirms are unsupportable.[10] This reinforces and reinvigorates a longstanding argument made by providers in LCD-related recoupment actions.

In addition, the Cleary Memo loosely defines the term "enforcement action" to include overpayment collections but not routine claims and cost report procedures, encouraging "consultation with the Office of General Counsel regarding questions about whether an action constitutes an enforcement action."[11]

Although the primary focus of the Cleary Memo is on the enforcement of Medicare payment rules, given the loose definition of "enforcement action," the memo may also have implications in other areas such as Medicare enrollment. The underlying Medicare statute interpreted by the Supreme Court in *Allina* requires notice and comment for any "substantive legal standard" affecting eligibility of an entity to furnish Medicare services—*i.e.*, eligibility to enroll as a Medicare provider or supplier. To the extent enrollment revocations or denials are based on sub-regulatory standards (*e.g.*, those found in the Program Integrity Manual), such standards are likewise subject to the holding in *Allina* and to the interpretation of that holding in the Cleary Memo. In other words, if the basis for the enrollment revocation or denial is a standard that is not "closely tied to a statutory or regulatory requirement," such an action is arguably in violation of *Allina* and improper.

Finally, though its focus is on CMS, the Cleary Memo embraces the Supreme Court's *Escobar* decision, and explicitly acknowledges that continued payment of claims by CMS with knowledge of a party's non-compliance with a law or regulation is strong evidence of a lack of materiality.[12] It goes on to note that guidance documents and payment history shed light on the question of materiality, which bolsters the existing position of FCA defendants about the importance of obtaining discovery from CMS on these issues to mount a defense.[13] Though this is not necessarily novel, and it was outlined in *Escobar*, CMS buying in to the Supreme Court's logic and holding may help strengthen a provider's ability to defend *qui tam* actions or seek much needed discovery that the DOJ has greatly sought to resist.

The Cleary Memo ultimately underscores the importance of verifying the basis of a government enforcement action and the standards upon which it bases the enforcement action. If an overpayment demand or other action is based on standards in guidance documents or manuals, it is important to determine whether those rules are closely tied to a narrowly worded statute or regulation and whether the enforcement action could be brought absent the guidance document or manual.

Endnotes/Citations

[1] *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1809 (2019).

[2] *Id* at 1819-20. Polsinelli previously issued an alert on the same potential impact of this case which can be found at https://www.polsinelli.com/intelligence/azar-v-allina-health-services.

[3] U.S. Department of Health & Human Services, Office of the General Counsel, Impact on Allina on Medicare Payment Rules (2019), p. 2. A rule is "closely tied to statutory or regulatory requirements" if it does not establish or change a substantive legal standard, but rather is "aiding in demonstrating that the standards in the relevant statutory and regulatory requirement have been or have not been satisfied." *Id.* (citing Justice Manual § 1-20.202).

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] U.S. Department of Justice, Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (2018).

[9] *Id.*

[10] U.S. Department of Health & Human Services, Office of the General Counsel, Impact on Allina on Medicare Payment Rules (2019) at p. 3.

[11] *Id.* at n. 1.

[12] *Id.* at p. 2.

[13] *Id.* at p. 3.