Morgan Lewis

FAST BREAK: ALLINA

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January 28, 2020

Agenda

- *Azar v. Allina Health Services*
  - Background & Summary
- CMS Chief Legal Officer Memorandum
  - What does the Medicare agency say about the decision?
- Post-Decision Legal Landscape
  - What does the decision mean for Medicare providers?
- A look at the bigger picture
  - Interplay with Court decisions considering agency deference (e.g. *Kisor v. Wilkie*)
- Questions

AZAR V. ALLINA HEALTH SERVICES

Background

- The Administrative Procedure Act relationship to the Medicare Act
  - APA rulemaking requirements do not apply to public benefit programs like Medicare
  - Informal relationship before the 1980s
- Congress amended the Medicare Act to solidify the rights of regulated parties in the Medicare program
  - 42 U.S.C. § 1395hh
  - Sometimes referred to as the "Mini-APA" or Medicare APA
  - Specific ties to APA adjudication standards in appeal statutes (e.g., claims appeals, PRRB appeals)

Background

- *Allina I* :
  - Challenge to CMS 2004 rulemaking on calculation of Medicare DSH because of insufficient notice relating to Part C days
    - Proposed rule sought to include Part C days in the Medic*aid* fraction (because such patients are not entitled to Part A as required for inclusion in the Medi*care* fraction)
    - Final rule decided to include the Part C days in the Medicare fraction instead.
    - "Agency pulled a surprise switcheroo…" (*Allina v. Sebelius*, 746 F.3d 1102, 1108 (CADC 2014)
      - Medicare Act Rulemaking Requirement at 42 U.S.C. § 1395hh(4)
        - Rule must be logical outgrowth of proposal
        - Codification of APA judicial doctrine

Background

- *Allina II*
  - In 2014, CMS issued Medicare DSH SSI Ratios (i.e. Medicare Fraction) for hospitals *FY 2012* cost reports that *included* Medicare Part C Days
    - Posted a website update including the new Medicare Fractions that would be used for such year
  - CMS had not formally proposed to include Part C days in the Medicare Fraction until the FFY 2014 rulemaking cycle (Aug. 19, 2013)
  - Allina led the challenge to the CMS modification to the Medicare Fractions without following proper rulemaking authority
- DC Circuit found that Medicare Act required notice and comment
  - Broke with several other courts of appeal to do so

The Supreme Court Decision

- The Supreme court relied upon the plain language of the Medicare Act itself, which requires CMS to provide advance notice and a chance to comment on any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. §1395hh(a)(2).
- The question is one of what is a "substantive legal standard?"
- The hospitals suggested that it is anything that imposes duties, rights, or obligations on a party, as opposed to *procedural* standards, which discuss means of enforcement of those standards
- The government argued that the difference is between "interpretive" and "substantive" standards, with the latter having the force and effect of law, and the former being guidance on how the agency is interpreting the law.

The Supreme Court Decision (cont'd.)

- The Court agreed with the hospitals for several reasons:
  - The Government's interpretation would render the statute internally inconsistent
    - Statements of policy expressly *not* substantive under APA; yet Medicare Act includes "statements of policy" in the rulemaking mix
  - The Medicare Act doesn't cross-reference the interpretive rule exemption from the APA
    - Congress drafts with a purpose
  - The Government's arguments regarding the legislative history were unconvincing
  - The Government's claim to the burdens of having to go through notice and comment rulemaking are overstated

The Supreme Court Decision (cont'd.)

- The dissent, however, made a number of important observations:
  - The Majority's limited holding (i.e. that the Medicare Act phrase "substantive legal standard" is distinct from the term "substantive rule" in the APA) stops short of defining the phrase "substantive legal standard"
  - The Majority's opinion does not clarify whether *any* impact on payment automatically turns a rule into a substantive rule
  - The Majority's opinion reopens for consideration all of the cases where a court held the agency's action acceptable on the basis that it was based on an "interpretive rule"

WHAT DOES THE DECISION MEAN?

The CMS Legal Memorandum

- How does CMS interpret the decision? -- October 31, 2019 Cleary Memo
  - Acknowledges that "Congress has imposed more stringent procedural requirements for certain Medicare rules that would otherwise apply under the APA"
  - Indicated that "Some of the payment rules [the agency] develops often form the basis for *enforcement actions*"
    - "Enforcement actions *may* include overpayment collections based on audits, but generally do not included routine claims and cost report procedures." (emphasis added).
  - If CMS intends to use particular guidance "in enforcement actions then the guidance must comply with *Allina*."

The CMS Legal Memorandum *(cont.)*

- "The critical question is whether the enforcement action could be brought absent the guidance document."
  - Is the guidance closely tied to a statute or regulation such that the "relevant payment norm" is determined by the statute or regulation?
  - Or does the guidance fill a substantive gap left by the statutory and regulatory payment scheme such that the guidance fills the payment norm?
- References/incorporates limitations announced by DOJ in Sessions announcement, Brand Memorandum
  - "Even a guidance document issued consistent with *Allina* may not be used as sole basis for an enforcement action…"
  - May be used to evidence materiality/scienter

The CMS Legal Memorandum *(cont.)*

- *Allina* does *not* prohibit CMS from "enforcing payment provisions in its contracts or agreements, provided that those provisions, if in the form of a guidance document, are expressly referenced as an obligation of the party to the contract."
- May be used to prove scienter or materiality
- Not applicable to LCD process (though enforcement based solely on LCDs generally unsupportable)
- Not applicable to the Stark Advisory Opinion process or MSSP process, which have specific statutory directives regarding issuance

Allina Key Take Aways

- NOT a license to ignore CMS Guidance.
- Medicare Program "Interpretive rules" now *are* susceptible to challenge
  - Court dissent suggested that decision may lead "to legal challenges to the validity of interpretive rules previously thought to have been settled"
  - Listed multiple PRM provisions previously decided as interpretive rules
  - Bad Debt "must bill" policy recent court example
- Case law will be need to be developed regarding what is a substantive vs. procedural rule
- More defenses available to providers in overpayment determinations
- Potential opportunities to challenge reimbursement adjustments/reductions based on sub-regulatory guidance

EXPANDING THE VIEW -- AGENCY DEFERENCE UNDER SCRUTINY

Kisor v. Wilkie, Secretary – Department of Veteran's Affairs

- Not a Medicare case, but important for administrative law governing all agencies
  - Basic legal question: ***How should a Court review an agency's interpretation of its own regulations?***

- Prior legal doctrine known as "*Auer* deference"
  - Generally a judicial "hands off" for an agency's interpretation of its own regulations unless it did not comport with the plain language of the regulation, or was otherwise "plainly erroneous."
  - Legal observers looked to this case to determine whether the court would modify this standard of review.

Kisor v. Wilkie, Secretary – Department of Veteran's Affairs (cont'd.)

- The Court did not overturn *Auer* deference
  - Nothing was presented by Kisor suggesting that the precedent of *Auer* and its deferential standard was "unworkable"
  - "Auer deference retains an important role in construing agency regulations."

- But…
  - "Even as we uphold it, we reinforce its limits."
  - "*Auer* deference is sometimes appropriate and sometimes not."

Kisor v. Wilkie, Secretary – Department of Veteran's Affairs (cont'd.)

- The Court therefore sought to remind courts of the limitations of the *Auer* doctrine and further develop the considerations for determining when such deference applies.
  - "Potent in its place but cabined in its scope."

- The Court began by providing a historical explanation of its legal basis for extending deference to agency regulatory interpretations
  - Grounded in a presumption of Congressional intent – Congress would want the agency to play the primary role in resolving regulatory ambiguities.
  - Agencies are more grounded than courts in the policy concerns affecting the regulated parties.
  - Benefits of uniformity of interpretation.

Kisor v. Wilkie, Secretary – Department of Veteran's Affairs (cont'd.)

- But deference only arises when a regulation is "genuinely ambiguous"
  - Court – "We mean it."
  - After all standard tools of interpretation have been exhausted.

- Moreover, "not all *reasonable* agency constructions of those truly ambiguous rules are entitled to deference."
  - If genuine ambiguity exists the agency's reading must still be reasonable – i.e., come within the zone of ambiguity identified by the court.
  - Interpretation must be the agency's "authoritative" or "official position."
  - It must "implicate the agency's substantive experience."
  - It must reflect "fair and considered judgment."

Kisor v. Wilkie, Secretary – Department of Veteran's Affairs (cont'd.)

- So where does the decision leave us? The Court described it well:

"The upshot of all of this goes something as follows. When it applies, *Auer* deference gives an agency significant leeway to say what its own rules mean. In doing so, the doctrine enables the agency to fill out the regulatory scheme Congress has placed under its supervision. But that phrase "when it applies" is important—because it often doesn't…this Court has cabined *Auer's* scope in varied and critical ways---and in exactly that measure, has *maintained a strong judicial role in interpreting rules*. What emerges is a deference doctrine not quite so tame as some might hope, but not nearly so menacing as they might fear."

October 9, 2019 Executive Orders

- Promoting the Rule of Law Through Improved Agency Guidance Documents
  - Publication of guidance documents, review of guidance documents, establish procedures for issuing guidance documents

- Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication
  - Guidance documents may not be used to impose new standards of conduct on persons outside the executive branch except as expressly authorized by law or as expressly incorporated into a contract

The Road Ahead…?

- Judicial scrutiny of agency action appears to be on the rise…

…while simultaneously…

- CMS is increasingly stepping in to drive elements of Medicare/Medicaid program policy in the "gaps" left by Congress
- Legal challenges likely to increase…

- QUESTIONS?

Thanks!

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Gregory N. Etzel concentrates his practice on the representation of hospitals and other healthcare providers in a variety of complex legal transactions and regulatory litigation. Prior to joining Morgan Lewis, Greg spent four and a half years in-house as the vice president of legal affairs at The University of Texas Medical Branch (UTMB), providing legal counsel and representing the entire institution on a wide range of issues involving strategic initiatives, hospital and medical school operations, transactions, litigation management, public information, and international affairs.

Thanks!

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

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"Labor Issues in the Healthcare Industry"

Featuring Doug Hart

- February 27 3:00 PM (EST)