EPSTEIN BECKER GREEN

Health Care & Life Sciences

CLIENT ALERT

Supreme Court Expands the Scope of Public Participation in Medicare Policymaking

By Robert E. Wanerman and Stuart M. Gerson

June 2019

On June 3, 2019, the U.S. Supreme Court ruled in *Azar v. Allina Health Services* that the Medicare statute requires the Centers for Medicare & Medicaid Services ("CMS") to engage in public notice-and-comment rulemaking whenever there are substantive changes that affect Medicare eligibility, the scope of benefits, or reimbursement.[1] This decision expands the ability of interested parties to participate in the process of developing Medicare policies, and it narrows the scope of situations where CMS can publish and then rely on sub-regulatory interpretations or guidance in publications (including manuals or program memoranda) that lack any public participation.

Under the Administrative Procedure Act ("APA"), agencies such as CMS do not have to follow notice-and-comment rulemaking when they publish "interpretive rules," which are generally statements of policy or that inform the public of an agency's interpretations of existing law. Interpretive rules, which can be found in CMS manuals and other publications commonly posted on the agency's website, do not have the force of law like formal regulations, but they are relied on by CMS and its contractors and are commonly given weight in adjudications. The dividing line between interpretive rules and regulations is somewhat hazy, but many courts have determined that a regulation creates rights, assigns duties, or imposes obligations that are not stated in a statute, while an interpretive rule only clarifies an existing statute or regulation, or is intended to notify interested parties of the agency's interpretation of the laws it administers.[2] Nevertheless, Congress amended the Medicare statute in 1987 to require public notice-and-comment rulemaking when CMS "establishes or changes a substantive legal standard" governing Medicare benefits, payment, or the eligibility to participate in the Medicare program.[3]

---

[1] *Azar v. Allina Health Services,* No. 17–1484 (U.S. June 3, 2019), *available at* https://www.supremecourt.gov/opinions/18pdf/17-1484_4f57.pdf.

[2] *Id.* at 6; *see also La Casa Del Convaleciente v. Sullivan,* 965 F.2d 1175, 1178 (1st Cir. 1992), *available at* https://scholar.google.com/scholar_case?case=15256919552274163639&q=%22creates+rights,+assigns+duties,+or+imposes%22+&hl=en&as_sdt=3,39.

[3] 42 U.S.C. § 1395hh(a)(2), *available at* https://www.law.cornell.edu/uscode/text/42/1395hh.

The dispute in *Allina* involved a change to the calculation of patient days that can be used to determine the supplemental Medicare reimbursement that hospitals can receive when they treat a disproportionately high number of low-income patients, typically known as the "disproportionate share hospital adjustment" or "DSH." The change was not made through the annual Medicare rulemaking process, which includes an opportunity for public notice and comment; instead, the change was made through a posting on CMS's website with no input from parties outside of CMS. The net effect of the changes reduced each affected hospital's total Medicare reimbursement.

The hospitals challenged their Medicare DSH reimbursement and argued that under 42 U.S.C. § 1395hh(a)(2), CMS made a change to a substantive legal standard and bypassed the rulemaking process. Although the district court ruled that CMS's change to the Medicare DSH reimbursement formula was a permissible interpretive rule, the U.S. Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") reversed. The D.C. Circuit concluded that the text of 42 U.S.C. § 1395hh(a)(2) does not incorporate the APA's exemption of all interpretive rules from formal rulemaking; instead, it mandates notice-and-comment rulemaking whenever there is "any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'"[4]

The Supreme Court agreed that Congress had not incorporated the interpretive rule exception into the Medicare statute. The high court's decision turned on the finding that the term "substantive legal standard" in the statute is broader than the term "substantive rule" in the APA, and can include changes in agency policy that create or change duties, rights, or obligations under the Medicare program. As a result, when CMS fills a gap in a statute or regulation, it is potentially creating or changing a substantive legal standard. The Supreme Court rejected the government's arguments that (1) Congress had simply incorporated the interpretive rule exception into the Medicare statute, and (2) a change to the calculation of DSH reimbursement was just an interpretive rule that did not require notice and comment. In its discussion, the Supreme Court noted that if Congress had intended to incorporate the interpretive rule exception from the APA into the Medicare statute, it could have just cross-referenced the APA language.

The Supreme Court's decision potentially expands the opportunities for public participation in CMS decisions and restricts CMS's ability to rely on interpretive publications or website posts as the basis for determinations that affect Medicare providers and suppliers. As a result, this decision may open a new avenue for challenges to CMS actions that rely solely on sub-regulatory publications. Although the ruling applies only to the Medicare program, the change made through 42 U.S.C. § 1395hh(a)(2) could serve as a model for future legislation if Congress decides that it wants to expand the scope of public notice-and-comment rulemaking for other agencies.

---

[4] *Allina Health Services v. Price*, 863 F.3d 937, 943-44 (D.C. Cir. 2017), *available at* https://scholar.google.com/scholar_case?case=8318903007531297794&q=%221395hh(a)(2)%22&hl=en&as_sdt=3,39&as_ylo=2015.

* * *

This Client Alert was authored by **Stuart M. Gerson** *and* **Robert E. Wanerman.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

This document has been provided for informational purposes only and is not intended and should not be construed to constitute legal advice. Please consult your attorneys in connection with any fact-specific situation under federal law and the applicable state or local laws that may impose additional obligations on you and your company.

About Epstein Becker Green
Epstein Becker & Green, P.C., is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes. Founded in 1973 as an industry-focused firm, Epstein Becker Green has decades of experience serving clients in health care, financial services, retail, hospitality, and technology, among other industries, representing entities from startups to Fortune 100 companies. Operating in locations throughout the United States and supporting domestic and multinational clients, the firm's attorneys are committed to uncompromising client service and legal excellence. For more information, visit www.ebglaw.com.

If you would like to be added to our mailing list or need to update your contact information, please contact Whitney Krebs at wkrebs@ebglaw.com or 202-861-1845.

© 2019 Epstein Becker & Green, P.C. Attorney Advertising