If Centers for Medicare & Medicaid Services (CMS) leaders make decisions—even seemingly small ones—without input from stakeholders and the public, physicians and their Medicare patients may suffer substantial costs and other burdens, physicians told the U.S. Supreme Court.

In a friend-of-the-court brief that the Litigation Center of the American Medical Association and State Medical Societies filed on behalf of the AMA and the Medical Society of the District of Columbia in the U.S. Supreme Court, physicians told justices that “even ‘seemingly minor’ modifications in reimbursement determinations give rise to extreme financial consequences for providers and ultimately their patients.”

The brief calls on the court to require that the Department of Health and Human Services (HHS), which oversees CMS, follow the Medicare statute that requires notice-and-comment rulemaking even if it seems burdensome.

“Notice-and-comment rulemaking facilitates public input into agency decision-making, as well as greater transparency and clarity on the part of the agency and in this way provides an important check against unbridled administrative power,” the Litigation Center brief tells the court. “Because the administration of Medicare implicates the health of millions of Americans, fulsome opportunities for public input are essential.”

Medicare pays for 20 percent of health care in the United States, according to CMS data. Among physicians other than pediatricians, 96 percent told researchers that they saw at least some Medicare patients in 2016; 9.6 percent of all physicians reported that more than half of their patients were Medicare beneficiaries.

Lower court: HHS must get feedback must get feedback
The case before the U.S. Supreme Court, *Azar v Allina Health Services et al.*, stems from a lawsuit that challenges whether CMS had the right to skip the notice-and-comment rulemaking process when it changed the method used to calculate payments to hospitals to cover their additional costs for serving low-income patients. HHS’s own estimates show that the change affects between $3 billion and $4 billion in Medicare payments over nine years.

The U.S. District Court of Appeals for the District of Columbia Circuit found that CMS didn’t have the authority to change the formula at issue. The author of the opinion—then-judge, now U.S. Supreme Court Justice Brett Kavanaugh—wrote that Medicare could not issue any interpretive guidance without going through the notice-and-comment process. Kavanaugh has recused himself from the case before the high court.

The Litigation Center brief does not address the underlying question of how this hospital payment should be calculated. Instead, it focuses on how important it is to patients and physicians that HHS follow notice-and-comment rulemaking statute.

**Process promotes fairness, clarity**

Notice-and-comment rulemaking gives physicians, patients and others a chance to voice their opinions about the rules they will have to live under, lets stakeholders give CMS relevant facts and lets those expert stakeholders offer alternative solutions.

“This exchange of information enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated,” the brief states. It also “increases the likelihood of administrative responsiveness to the needs and concerns of those affected. After all, regulated entities and stakeholders are particularly likely to have valuable information regarding a proposed rule.”

**Real-world proof the process works**

The Litigation Center brief cites two real-world examples where HHS did not engage in notice-and-comment rulemaking that led to unclear rules that created unfairness and inconsistency for physicians and beneficiaries: the two-midnight rule to determine when a patient is considered an “inpatient” and national versus local coverage determinations.

As a comparison, the brief notes that regulations that undergo notice-and-comment rulemaking are of higher quality and have improved administrability. For example, HHS publishes a Medicare fee schedule annually that the AMA analyzes and comments on and HHS considers and incorporates the
AMA’s comments when drafting the final rule.

“This process permits efficient and centralized dialog between HHS, major stakeholders and the public and is accomplished within a matter of months. Through this back and forth … the final rules are better informed and more effective,” the brief tells the court. “More rather than less formal rulemaking for Medicare is warranted.”