

CMS, FDA FACE WEAKENED AUTHORITY FOLLOWING SCOTUS' CHEVRON DECISION

Substantially weakening the power of federal agencies, the Supreme Court on June 28th overruled the longstanding *Chevron* deference precedent that has required courts defer to federal agencies' reasonable interpretations of statute, in its most consequential case of the term on the future of federal health policy. The decision clarifies that the court will not consider the change a reason to overturn previously decided cases that relied on *Chevron* reasoning.

In a 6-3 decision written by Chief Justice John Roberts and decided on ideological lines in the case *Loper Bright Enterprises et al. v. Raimondo*, the court decided agencies' interpretations will no longer receive deference over other interpretations in cases where the text of law is ambiguous. The liberal justices issued a dissenting opinion raising alarm about the decision's impact on complex technical health care regulations, including those involving artificial intelligence, CMS reimbursement and FDA drug approvals.

"What will the Nation's health-care system look like in the coming decades? . . . What rules are going to constrain the development of A.I.?" Justice Elena Kagan, writing in the dissent, asked. "In every sphere of current or future federal regulation, expect courts from now on to play a commanding role. It is not a role Congress has given to them, in the APA or any other statute. It is a role this Court has now claimed for itself, as well as for other judges."

The court majority clarifies that it does not intend to "call into question prior cases that relied on the *Chevron* framework. "Mere reliance on *Chevron* cannot constitute a 'special justification' for overruling such a holding, because to say a precedent relied on *Chevron* is, at best, 'just an argument that the precedent was wrongly decided,'" the decision says. "That is not enough to justify overruling a statutory precedent," it continues — although the decision itself overturns a significant statutory precedent.

Phillip Wallach, a senior fellow at the American Enterprise Institute, told *Inside Health Policy* before the release of the decision that the overturn of *Chevron* would require Congress to step up to change its lawmaking process and be clear about what it wants done. If lawmakers don't do so, Wallach said, much more power will be delegated to the federal judiciary, which includes a disproportionate number of GOP-appointed judges.

Health care attorney Robert Wanerman of Epstein, Becker & Green, also speaking before the decision was released, told *Inside Health Policy* agencies in a post-*Chevron* world would have to be more circumspect about providing rationale for their regulations if it could make court challenges about their reasoning easier. Wanerman said the end of *Chevron* would mean judges will be making decisions they're likely to be uncomfortable with, like deciding whether a drug is safe and effective.