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Health Regulators Likely To Tread Carefully Post-Chevron

By **Theresa Schliep**

Law360 (June 28, 2024, 9:37 PM EDT) -- The demise of Chevron deference at the U.S. Supreme Court on Friday will likely encourage or fortify challenges to agency rulemaking on matters of health policy in the U.S., from Medicare reimbursement decisions to FDA rules on laboratory-developed tests.

The decision, representing a historic shift in power from regulators to the courts, also risks making the agencies that oversee health and medicine more cautious, potentially slowing action during public health emergencies and chilling dialogue between agencies and industry players, experts warned.

The Supreme Court's decision to do away with Chevron deference — a doctrine that instructed courts to yield to reasonable agency interpretations of federal rulemaking — represents a sea change in the canon of administrative law.

Eliminating Chevron will transform how courts — especially the lower courts and the D.C. Circuit, which routinely reviews disputes over agency actions — analyze agency policy.

While opinions vary on precisely how seismic the ruling will prove to be, the decision will likely especially impact the work of the U.S. Food and Drug Administration, U.S. Department of Health and Human Services, and Centers for Medicare & Medicaid Services, which issue reams of guidance every year and oversee highly technical and scientific areas of the law.

"For entities that are regulated — hospitals, physicians, laboratories, etc. — it now means that it's going to be much, much easier to challenge an agency regulation," Robert E. Wanerman, an Epstein Becker Green member and expert on healthcare and administrative law, told Law360.

Yet some experts cautioned this power shift may make agencies behave prophylactically and move more slowly, taking time to issue guidance that they can defend in court. It thus may take longer to respond to public health emergencies, when speed is of the essence, Wanerman added.

"If there's another pandemic, it will be difficult for HHS writ large to respond," he said. "It will be harder for agencies to publish regulations since they are going to have to parse statutory language in much more detail than they did in the past."

Eliminating Chevron risks making an already risk-averse FDA "much more risk-averse, to cause serious delays because they have to do that extensive review to determine if they can issue regulation," said Dr. Reshma Ramachandran, a professor at Yale School of Medicine.

Doing away with Chevron has long been a target of the conservative legal movement, which sees the doctrine as one reason federal agencies have swelled in size and accumulated power. While some legal scholars blame Chevron deference for paralysis in Congress, others regard the doctrine as a way to allow subject-matter experts to respond with haste to rapidly changing advancements in technology, as well as environmental problems like climate change.

Writing for the 6-3 majority, Chief Justice John Roberts said the doctrine has resulted in judges acceding too much deference to agencies' evaluation of the law, even when courts have a better reading of a statute. Such deference is a violation of the Administrative Procedure Act, the bedrock law governing how agencies issue guidance, Justice Roberts wrote.

"At best, our intricate Chevron doctrine has been nothing more than a distraction from the question that matters: Does the statute authorize the challenged agency action?" Justice Roberts wrote. "And at worst, it has required courts to violate the APA by yielding to an agency the express responsibility, vested in 'the reviewing court,' to 'decide all relevant questions of law' and 'interpret ... statutory provisions.'"

Rather than complete deference to agency action, Justice Roberts embraced so-called Skidmore deference, which generally looks to the persuasiveness of an agency's justification for a given approach to an issue.

And the chief justice suggested courts have a role in interpreting even highly technical matters, writing that "delegating ultimate interpretive authority to agencies is simply not necessary to ensure that the resolution of statutory ambiguities is well-informed by subject-matter expertise."

Some attorneys, like Thomas H. Barnard, a Baker Donelson Bearman Caldwell & Berkowitz PC shareholder with expertise in healthcare fraud investigations, view the demise of Chevron as a bit of a restoration of the usual order, shifting the task of evaluating statutes to the courts.

Yet Barnard and others said there will be a period of uncertainty following the decision, during which ambitious plaintiffs will test the bounds of the court's decision. Indeed, the ruling could impact pending litigation, such as the legal challenge over a controversial FDA rule addressing laboratory-developed tests, according to Sonia Nath, a Cooley LLP partner and head of its life sciences and healthcare regulatory practice group.

Other pending cases, like litigation over a regulation on minimum staffing requirements for nursing homes deemed a "nightmare" by nursing home trade groups, might benefit from the Chevron ruling.

Chevron's demise may give the clients of Jacob J. Harper, a Morgan Lewis & Bockius LLP healthcare partner, more of a fighting chance when they get into court. When challenges over reimbursement disputes exit administrative proceedings and make it to federal court, providers are typically hamstrung in challenging CMS' posture on some statutory issues, as Chevron would require the courts to defer to the agency.

But with Chevron no longer in place, those providers can now dispute an agency's legal stance in federal court, giving them another "tool in the toolbox," according to Harper.

"With Chevron overruled, we have more options available," Harper said. Yet he cautioned it's far from

an "automatic win" for providers since CMS' interpretation will still be subject to some amount of respect.

And experts cautioned not all healthcare regulations will be completely vulnerable post-Chevron. Chevron deference applied to rulemaking done through the formal APA process, and Justice Roberts attempted to assuage fears that rules previously deemed safe by the courts on Chevron grounds may be newly open for challenges.

Cooley's Nath said the FDA is still owed some amount of deference for its scientific conclusions, and she doesn't think drug approval or exclusivity decisions will be too impacted.

Still, Harper said the decision is a bit of a "double-edged sword," at least for CMS. Agencies may have to behave more cautiously overall, and Harper said he worries "we're going to lose some of the dialogue between agencies and regulated parties."

Nath said where she sees the potential for "deleterious impacts" is in the "day-to-day" business of the FDA. Eliminating Chevron will cause some uncertainty for agencies including the FDA, and taking away certainty is "a real fear" for industry, she added.

--Additional reporting by Jeff Overley, Juan Carlos Rodriguez and Madeline Lyskawa. Editing by Philip Shea and Dave Trumbore.
