Welcome to *Washington Update*, the weekly e-newsletter on the latest health care happenings in the nation's capital that affect APG's members.

To our subscribers: *Washington Update* will not publish next week due to the July 4th holiday. It will return on July 12.

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In Rejecting Longstanding Legal Framework, Supreme Court Casts Vast Cloud Over Federal Regulations

In a decision with far-reaching implications for all federal regulatory agencies – including those charged with administering health-care statutes – the Supreme Court in a 6-3 vote this week rejected the longstanding "Chevron deference" framework compelling federal courts to defer to a federal agency's interpretation of an ambiguous or unclear statute that Congress delegated to the agency to administer. The decision now casts an enormous cloud over what dissenting Justice Elena Kagan termed the regulatory "warp and woof of modern government," and "is likely to produce large-scale disruption" as the executive branch, agencies, and lower courts struggle to understand the consequences.

In lawsuits brought by commercial fishing groups challenging a federal regulation, the Court reexamined its earlier 1984 decision and resulting framework through which courts defer, in certain circumstances, to agencies' reasonable interpretation of the statutes they administer. The majority opinion, written by Chief Justice John Roberts, said that the Chevron doctrine violated the law governing federal administrative agencies in its presumption that ambiguities in other laws "are implicit delegations of authority by Congress" to these agencies to interpret the ambiguities. "Agencies have no special competence in resolving statutory ambiguities. Courts do," Roberts wrote. Justice Neil Gorsuch concurred: "Today, the Court places a tombstone on Chevron no one can miss."

Scope of ruling: Although Roberts wrote that the Court's latest decision would not "call into question" the 70 prior Supreme Court and roughly 17,000 lower court decisions that relied on the Chevron framework," it clearly "threatens regulations in countless areas, including the environment, health care and consumer safety," the *New York Times* said. APG will monitor the near-term consequences for federal health care regulations of interest to member organizations and keep them apprised.

Preventive Services Mandated in Affordable Care Act Mostly Survive a Court Challenge – For Now

Health insurance plans and many Medicaid programs must maintain mandated coverage for preventive services at no cost to enrollees when those services have received an A or B grade from the United States Preventive Services Task Force (USPSTF) – at least for now. But in the wake of a complicated federal appeals court decision in a case involving these Affordable Care Act (ACA) mandates, multiple aspects of the lawsuit could be headed to the Supreme Court.

The Fifth Circuit Court of Appeals' decision came in a case brought by Texas individuals and Christian-based for-profit companies that contended that the ACA's preventive services mandate was unconstitutional. The plaintiffs also claimed that the related requirement to cover preexposure prophylaxis (PrEP) for HIV prevention violated their religious rights.

Implications: In what the appeals court accurately termed a "mixed bag" decision, it partly affirmed the lower court's decision against the preventive services mandate, agreeing that it was unconstitutional because of its linkage to USPSTF and the "unreviewable power" that the panel wields. But at the same time, the appeals court partly reversed other aspects of the lower court's ruling, overturning its nationwide injunction against preventive services mandate. It also sent a separate argument over coverage for contraception and vaccines back to the lower court for further review.

The clearest takeaway from the Fifth Circuit's decision is that, for the preventive services mandate to be constitutional, members of the USPSTF will now have to be nominated by the President and confirmed by the Senate, as required under the Constitution's appointments clause. The picture is muddier for contraceptive and vaccines coverage, as those ACA provisions are linked to decisions by other entities – namely, the recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration's approval of contraceptives, and the provision of other women's health services required by the federal Health Resources and Services Administration. For procedural reasons, the appeals court sent the dispute over these benefits and the underlying issues back to the lower court. Even as that action continues, however, plaintiffs or the federal government could still appeal other aspects of the case to the Supreme Court for consideration in next year's term.

Providers Will Soon Face Penalties Through Information Blocking Final Rule

Health care providers will soon have to comply with rules about sharing information with patients in a timely manner to avoid new penalties. The change stems from a federal final rule that establishes the specific disincentives – or penalties – for health care providers that have committed so-called information blocking as defined in the 2016 Cures Act.

The new disincentives, which will go into effect in 30 days, differ in their application to clinicians depending how they participate in Medicare, as follows:

- If they have committed information blocking, Medicare Shared Savings Program (MSSP) ACOs and the clinicians who participate in them may be ineligible to participate in the program for at least a year, starting in 2025.
- Physicians and group practices that commit information blocking and participate in traditional Medicare may be determined to not be meaningful electronic health record users. They would thus receive a zero score in the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category and be ineligible for a positive MIPS payment adjustment.

HHS indicated that information blocking regulations will continue to evolve through future rulemaking – for example, by establishing disincentives for the Medicaid and Marketplace plans.

Measures To Accelerate Value-Based Care Advanced In House Panel Hearing

Revamping the means of setting ACO spending benchmarks, lightening these organizations' reporting burden, and continuing the Advanced Alternative Payment Model (AAPM) bonuses beyond this year were among measures aired at a House hearing this week. Witnesses told members of the Ways & Means health subcommittee that such steps were essential to retain providers in alternative payment models, let alone to draw others into them.

Witnesses made the oft-voiced complaint that the current process of setting ACO benchmarks constitutes "a race to the bottom," as one witness put it, as ACOs that lower their spending are in effect penalized when their subsequent spending benchmarks fall – the so-called "ratchet effect." Rural providers, in particular, need APMs that are "simple and easy to both understand and implement" and that build on infrastructure that rural practices already have, such as existing electronic health record systems, said Sarah Chouinard, MD, chief medical officer of the rural health organization Main Street Health.

Rural concerns: Responding to Chouinard's comment that "every member of a rural care team needs to work at the top of his or her license," one panel member, Rep. Adrian Smith (R-NE), cited a bill he cosponsored that would allow patients receiving primary care from nurse practitioners, clinical nurse specialists, and physician assistants to be attributed to ACOs. Currently, Medicare beneficiaries are assigned to Medicare Shared Savings Program ACOs if they receive the plurality of their primary care services from the ACO's primary care physicians, or if they visit another of these types of practitioners but also receive at least one primary care service from a physician within 24 months.

In Case You Missed It

- The Supreme Court blocked the Purdue Pharma opioid settlement because it shielded the Sackler family from lawsuits, but also secured billions of dollars to address the opioid crisis.
- The High Court also allowed emergency abortions to resume in Idaho without ruling on whether the federal EMTALA law protects such procedures nationwide.
- The House Republicans' fiscal 2025 appropriations bill for the Departments of Labor, Health and Human Services, and Education

would cut the agencies' funding by 11 percent, eliminate the Agency for Healthcare Research and Quality, and eliminate funding for the Title X Family Planning program -- among other controversial measures that would set the bill on a collision course with the Democratic-controlled Senate.
- Interactions between Medicare drug price negotiation and changes in Part D benefits could actually raise out-of-pocket spending for 3.5 million Part D enrollees, says a new Milliman report sponsored by the pharmaceutical manufacturers' trade group, PhRMA.
- A draft framework for testing the quality of health care artificial intelligence tools was released by the Coalition for Health AI, which seeks public comment for the next 60 days before it finalizes the framework.
- CMS alerted pharmacists to the possibility of a late September national coverage decision for preexposure prophylaxis (PrEP) using antiretroviral drugs to prevent HIV and provided a FAQ.

APG Announcements And Offerings

- The next **APG ACO REACH Coalition** webinar will be Thursday, July 11, from 4:00 - 5:00 pm EDT. Members can register here.
- The next **APG Government Relations/Public Policy Forum** webinar will be Wednesday, July 17, 12:00 - 1:00 pm EDT. Members can register here.
- Want to get more involved in APG's Federal advocacy efforts? Join APG Advocates today.
- Mark your calendars now for **APG's Annual Fall Conference 2024,** November 11 – 13 in Washington, DC.

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