HHS

Hart Health Strategies Inc.



July 1, 2024

Supreme Court Overturns Chevron Doctrine

The Supreme Court struck down the four-decade old legal precedent known ▲ as the Chevron deference in a 6-3 ruling along ideological lines on Friday. The decision, which comes in response to litigation concerning fishing industry regulation, strips federal agencies of their ability to interpret ambiguous laws passed by Congress. Under the Chevron deference doctrine, judges would defer to regulators when congressional intent was ambiguous. Writing in the majority opinion, Chief Justice John Roberts states that courts may no longer "defer to an agency interpretation of the law simply because a statute is ambiguous." Roberts argued that Chevron cannot be reconciled with the *Administrative Procedure* Act, which governs judicial review of agency actions. In her dissent, Justice Elena Kagan contends that the ruling will "flip the script," so that courts, rather than federal agencies "will wield power when Congress has left an area of interpretive discretion." However, the opinion makes clear that the Chevron doctrine was directed at questions of law and statute, but that the *Administrative Procedure* Act directs that courts provide deference to agencies in matters of policymaking and factfinding.

The Chevron decision will have significant implications for both federal agencies and the role of the court system in future federal regulations. While the high court stated that past decisions relying on the Chevron doctrine will remain intact, experts expect a wide range of recent regulations will now be challenged now that the Chevron doctrine is no longer in place, including but not limited to environmental regulations, like those related to auto pollution limits and power plant emissions, as well as regulations related to net neutrality, non-compete agreements, online privacy, and independent contractor status.

The Supreme Court ruling is also expected to result in a significant increase in litigation challenging health care related regulations. Because the **Affordable Care** *Act's* (ACA) preventive health coverage requirements do not spell out specific services, and the *Inflation Reduction Act's* Medicare drug price negotiations program does not specify certain processes, both may be prominent targets for litigation. Experts have also called into question the

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vulnerability of the National Institutes of Health's (NIH) clinical trial regulations.

Justice Kagan's dissent specifically warns of the impact this decision will have on federal agencies dealing with complex scientific questions, writing "When does an alpha amino acid polymer qualify as a 'protein'? I don't know many judges who would feel confident resolving that issue...But the FDA likely has scores of scientists on staff who can think intelligently about it, maybe collaborate with each other on its finer points, and arrive at a sensible answer." While the Food and Drug Administration's (FDA) authority over individual product approval decisions is based in statute – and thus will not be impacted by the high court's Chevron decision – experts have warned that the agency's overall decision-making process could slow, increasing the time it takes to bring new drugs and medical devices to market. The FDA's recent laboratory-developed test regulation, along with its breakthrough device designation, have both been identified as rules that could be particularly vulnerable to legal challenge. On the whole, all agencies across federal government must now devote more time and resources to support the legal standing of any regulatory decisions being made.

The decision is also likely to have a significant impact on legislative advocacy. The deference afforded to agencies via the Chevron doctrine was only applicable when Congressional intent was not clear and "the statute is silent or ambiguous with respect to the specific issue." The ruling now places greater emphasis on both more precise text as well as more express delegations of agency authority where Constitutionally permissible.

Appropriations Update

Appropriators in the House of Representatives advanced their fiscal year (FY) 2025 Labor-Health and Human Services spending bill out of subcommittee last week. The \$185.8 billion measure amounts to an 11% cut to currently enacted funding levels. The bill includes \$8.5 billion for the U.S. Department of Health and Human Services (HHS), a 7% cut. The Centers for Disease Control and Prevention would receive \$1.7 billion, a 22% decrease. While funding for the NIH would remain flat at \$48 billion, the bill proposes to restructure the research agency, reducing the number of centers from 27 to 15 while increasing congressional oversight of NIH operations. The bill includes anti-abortion measures like the Hyde Amendment, as well as a prohibition on funding for the Title X family planning program and gender affirming care. It also contains provisions to defund climate change, sex education, and gun violence programs. Full committee markup of the bill is scheduled for July 10, with Ranking Member Rosa DeLauro (D-Conn.) stating that Democrats will "accept nothing less" than a 1% increase in spending. A summary of the bill is available here. Bill text is available here.

The House Appropriations Committee also advanced the FY 2025 Interior, Enviornment, and Related Agencies bill out of subcommittee. The spending measure totals \$38.5 billion, \$72 million below currently enacted levels, and includes significant cuts to the Environmental Protection Agency's budget. It would also bar funding for several Biden administration climate change and environmental justice initiatives. The FY 2025 Commerce-Justice-Science spending bill and Energy and Water Development spending bill were also advanced out of subcommittee.

The full House passed its FY 2025 State, Foreign Operations, and Related Programs appropriations bill (H.R. 8771) on Friday in a 212-200 vote. The bill reduces funding for the State Department and the U.S. Agency for International Development by 11%. The legislation would eliminate funding for the World Health Organization and other United Nations' entities. It also includes a provision barring funding for any global health organizations that promote or perform abortions, even if they use outside resources for such activities. The House also passed its FY 2025 funding bill for the Department of Homeland Security (H.R. 8752) and the Department of Defense (H.R. 8774) last week.

Despite the absence of a bipartisan agreement on topline spending levels, Senate Appropriations Chair Patty Murray (D-Wash.) has confirmed that her panel will begin moving ahead with their spending bills after the Fourth of July recess. Republican leadership in the House aim to pass all 12 annual appropriations bills on the House floor before the August recess. Lawmakers have until September 30 to fund the federal government, with senators seeking a slight increase in nondefense funding, while House Republicans are pushing for a 6% cut in spending. House Appropriations Chairman Tom Cole (R-Okla.) has indicated that a continuing resolution will likely be necessary to keep the government open beyond the end of the fiscal year.

Ways and Means Advances Four Health Bills

The House Ways and Means Committee favorably reported four health care related bills to the full House of Representatives last week.

- H.R. 2407, Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, was advanced 38-0.
- H.R. 8816, American Medical Innovation and Investment Act, was advanced 40-0.
- H.R. 1691, *Ensuring Patient Access to Critical Breakthrough Products Act*, was advanced 36-5. The Democrats voting in opposition to the bill raised concerns about device safety and restricting the Centers for Medicare and Medicaid Services' authority to set coverage guardrails.
- H.R. 4818, *Treat and Reduce Obesity Act*, was advanced 36-4. The Democrats who voted no expressed their disappointment in the limited scope of the legislation, which had been scaled back in an effort to lower the cost of the measure.

E&C Cancels Markup of Health Legislation

The House Energy and Commerce Committee canceled its scheduled markup last week. The panel had planned to consider 11 bills, including four health care related measures: H.R. 7188, Shandra Eisenga Human Cell and Tissue Product Safety Act; H.R. 3433, Give Kids a Chance Act of 2024; H.R. 670, Think Differently Database Act; and H.R. 7623, Telehealth Modernization Act of 2024. Committee leadership scrapped the markup after House Republican leadership expressed opposition to H.R. 8818, American Privacy Rights Act of 2024. The data privacy legislation is considered a career legacy effort for retiring Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-Wash.), who is retiring from Congress at the end of the year.

Lawmakers Urge Oversight of AI in Medicare Advantage

A bicameral group of lawmakers led by Sen. Elizabeth Warren (D-Mass.) and Reps. Judy Chu (D-Calif.) and Jerrold Nadler (D-N.Y.) are <u>calling</u> on the Centers for Medicare and Medicaid Services (CMS) to reign in the use of AI for prior authorization and coverage decisions by Medicare Advantage (MA) plans. The letter, also signed by 48 House and Senate Democrats and Senator Mike Braun (R-Ind.), highlights the need for more detailed guidance to protect access to care for Medicare beneficiaries and improve clarity for providers. The lawmakers specifically recommend that CMS:

- Clarify the specific elements that must be contained in denial notices.
- Establish an approval process to review AI and algorithmic tools and their inputs to ensure the integrity of their use, and conduct a review of algorithm and AI tools currently being used.
- Prohibit the use of AI/algorithmic tools and software from use in coverage denials until a systematic review of their use can be completed.
- Clarify how CMS distinguishes between uses of algorithms or software that account for individual circumstances and those that do not, specify what criteria, methods, or data will be used to determine this distinction, and clarify how this requirement will be enforced and communicated to plans.
- Clarify when MA organizations are able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits.
- Impose a minimum time period during which MA plans cannot issue a termination notice after their prior termination decision has been reversed by a Medicare contractor.

BIOSECURE Receives Favorable CBO Score

The Congressional Budget Office (CBO) has released its <u>score</u> of the *BIOSECURE Act* (H.R. 8333), finding that the legislation would not have a significant impact on federal spending. The legislation would prohibit Chinese biotechnology companies of concern from receiving federal contracts, grants, or loans and is aimed at blocking foreign governments from accessing Americans' health and genomic data. Both the House and Senate versions of the bill were advanced out of committee earlier this year.

Analysts Score Impact of Making Permanent Enhanced Affordable Care Act Tax Credits

CBO and the Joint Committee on Taxation (JCT) <u>estimate</u> that making permanent expanded tax credits under the ACA would increase the federal budget deficit by \$336 billion over the next decade, and result in the coverage of nearly seven million additional individuals through ACA marketplace plans during the same time period. According to CBO and the JCT, such a change would also result in a 3.5 million-person decrease in employer-based coverage. The analysis was requested by Republicans on the House Budget and Ways and Means committees who oppose the Biden administration's proposal to make permanent the enhanced refundable premium tax credits to purchase health insurance through the ACA marketplaces, which are currently set to expire at the end of 2025. In their letter to lawmakers, the analysts also estimate that a recent CMS regulation from making Deferred Action for Childhood Arrivals recipients eligible for the ACA marketplace will increase the deficit by \$7 billion over the next decade.

CMS Issues Proposed Rule on Suspect Billing Activity and ACO Reconciliation

The Biden administration is proposing a new <u>regulation</u> to shield health care providers from the impact of suspicious Medicare billing activity. The rule follows a major increase in spending on urinary catheters last year. The HHS Office of the Inspector General has reported on a fraud scheme involving scammers contacting Medicare enrollees, offering free services, and using the individual's enrollment information to bill the Medicare program for catheters. The proposed rule from CMS would exclude payments for two urinary catheter codes from the calculation of accountable care organizations' (ACO) 2023 financial performance.

Supreme Court Allows Emergency Abortions in Idaho, For Now

The Supreme Court has dismissed a pair of abortion related cases, *Moyle v. United States* and *Idaho v. United States*, as "improvidently" – or mistakenly – granted, without ruling on the merits of the dispute. The move reinstates the August 2022 district court preliminary injunction of an Idaho law that called into question physicians' ability to provide stabilizing care, including abortion, in an emergency setting. Idaho's law banned abortion except in cases to save the life of a pregnant woman. The federal *Emergency Medical Treatment and Labor Act* (EMTALA) requires treatment to stabilize patients with emergency medical conditions. The district court concluded that, under the Constitution, EMTALA preempts state law. The Supreme Court's dismissal of Idaho's challenge does not answer questions about whether doctors can provide emergency abortions elsewhere in the nation.

Durbin Recovering Hip Replacement Surgery

Sen. Dick Durbin (D-Ill.), 79, underwent hip replacement surgery on Thursday and will remain in his home state until cleared by his physician to return to Capitol Hill. Durbin was first elected to the Senate in 1996. He was reelected to a fifth term in 2020, and currently serves as chairman of the Senate Judiciary Committee.

Congressional Retirements and Resignations

Rep. Jamaal Bowman (D-N.Y.) lost the Democratic primary for New York's 16th congressional district last week. Bowman, who currently sits on the Education and Workforce and Science, Space, and Technology committees, was first elected to Congress in 2020 and is a member of the progressive group of Democrats known as "the squad." His more centrist challenger was George Latimer, a Westchester County Executive.

A running list of members of Congress who are retiring or seeking other office can be found below.

SENATE	
Stabenow (D), MI	Braun (R), IN
Cardin (D), MD	Romney (R), UT
Carper (D), DE	
Butler (D), CA	
Manchin (D), WV	
Sinema (I), AZ	
HOUSE OF REPRESENTATIVES	
Porter (D), CA	Mooney (R), WV
Lee (D), CA	Banks (R), IN
Gallego (D), AZ	Bishop (R), NC
Schiff (D), CA	Lesko (R), AZ
Slotkin (D), MI	Granger (R), TX
Allred (D), TX	Buck (R), CO (effective March 22, 2024)
Trone (D), MD	Burgess, MD (R), TX
Blunt Rochester (D), DE	Wenstrup, DPM (R), OH
Napolitano (D), CA	McHenry (R), NC
Wexton (D), VA	Johnson (R), OH (effective Jan. 21, 2024)
Kim, Andy (D), NJ	Ferguson, IV, DMD, PC (R), GA
Jackson, Jeff (D), NC	Curtis (R), UT
Sarbanes (D), MD	Luetkemeyer (R), MO
Blumenauer (D), OR	Lamborn (R), CO
Kilmer (D), WA	Bucshon, MD (R), IN
Spanberger (D), VA	Pence (R), IN
Kildee (D), MI	Duncan (R), SC
Phillips (D), MN	Armstrong (R), ND
Cardenas (D), CA	McMorris Rodgers (R), WA
Eshoo (D), CA	Gallagher (R), WI (effective April 19, 2024)
Manning (D), NC	LaTurner (R), KS
Nickel (D), NC	Graves (R), LA
Ruppersberger (D), MD	
Sablan (D), MP	
Kuster (D), NH	
Bowman (D), NY	

Hart Health Strategies Inc. Upcoming Congressional Hearings and Markups

Senate Health, Education, Labor, and Pensions Committee hearing "Why Is Novo Nordisk Charging Americans with Diabetes and Obesity Outrageously High Prices for Ozempic and Wegovy?" 10:00 a.m.; September 24

Recently Introduced Health Legislation

H.R.8798 — To amend subpart 2 of part B of the Social Security Act to promote community-based prevention services, and for other purposes; Sponsor: Carey, Mike [Rep.-R-OH-15]; Committees: House - Ways and Means

H.R.8801 — To amend the Public Health Service Act to provide more opportunities for mothers to succeed, and for other purposes; Sponsor: Fischbach, Michelle [Rep.-R-MN-7]; Committees: House - Ways and Means; Energy and Commerce

H.R.8806 — To direct the Comptroller General of the United States to carry out a study relating to the resiliency of Social Security and Medicare; Sponsor: Nunn, Zachary [Rep.-R-IA-3]; Committees: House - Ways and Means; Energy and Commerce

H.R.8816 — To amend title XVIII of the Social Security Act to provide for a cognitive impairment detection benefit under the Medicare program, and for other purposes; Sponsor: Buchanan, Vern [Rep.-R-FL-16]; Committees: House - Energy and Commerce; Ways and Means

H.R.8817 — To improve data collection and reporting for youth in residential treatment programs; Sponsor: Steube, W. Gregory [Rep.-R-FL-17]; Committees: House - Ways and Means

H.R.8818 — To provide Americans with foundational data privacy rights, create strong oversight mechanisms, and establish meaningful enforcement, and for other purposes; Sponsor: McMorris Rodgers, Cathy [Rep.-R-WA-5]; Committees: House - Energy and Commerce

H.R.8819 — To amend the Internal Revenue Code of 1986 to provide for a credit against tax, or refund of tax, for certain Federal insurance taxes for employees who are members of religious faiths which oppose participation in such insurance; Sponsor: Balderson, Troy [Rep.-R-OH-12]; Committees: House - Ways and Means

H.R.8820 — To amend the Internal Revenue Code of 1986 to provide an above-the-line deduction for long-term care insurance premiums and to reduce certain tax credits; Sponsor: Burlison, Eric [Rep.-R-MO-7]; Committees: House - Ways and Means

H.R.8821 — To ensure coverage for the treatment of infertility for certain conditions; Sponsor: Chavez-DeRemer, Lori [Rep.-R-OR-5]; Committees: House - Education and the Workforce

H.R.8832 — To direct the Secretary of Health and Human Services to issue guidance on payment under the Medicare program for certain items involving artificial intelligence; Sponsor: Schweikert, David [Rep.-R-AZ-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.8834 – To establish a Supply Chain Fraud and Theft Task Force; Sponsor: Valadao, David G. [Rep.-R-CA-22]; Committees: House – Judiciary

H.R.8839 — To require the Secretary of Health and Human Services to issue guidance to States on best practices for screening and treatment of congenital syphilis under Medicaid and the Children's Health Insurance Program; Sponsor: Caraveo, Yadira [Rep.-D-CO-8]; Committees: House - Energy and Commerce

H.R.8848 — To amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of affordable and safe drugs by wholesale distributors, pharmacies, and individuals; Sponsor: Schakowsky, Janice D. [Rep.-D-IL-9]; Committees: House - Energy and Commerce

H.R.8849 — To amend title XVIII of the Social Security Act to improve the national and local coverage determination processes under the Medicare program; Sponsor: Smucker, Lloyd [Rep.-R-PA-11]; Committees: House - Ways and Means; Energy and Commerce

H.Res.1325 — Supporting the designation of the month of June 2024, as "National Men's Health Month"; Sponsor: Carter, Troy A. [Rep.-D-LA-2]; Committees: House - Oversight and Accountability

H.R.8857 — To amend the Public Health Service Act to prohibit discrimination against health care entities that do not participate in abortion, and to strengthen implementation and enforcement of Federal conscience laws; Sponsor: Banks, Jim [Rep.-R-IN-3]; Committees: House - Energy and Commerce

H.R.8860 – To amend the Internal Revenue Code of 1986 to enhance the paid family and medical leave credit, and for other purposes; Sponsor: Feenstra, Randy [Rep.-R-IA-4]; Committees: House - Ways and Means

H.R.8861 — To amend the Federal Food, Drug, and Cosmetic Act to extend the destruction authority of the Secretary of Health and Human Services to articles that present a significant public health concern, and for other purposes; Sponsor: Higgins, Clay [Rep.-R-LA-3]; Committees: House - Energy and Commerce

H.R.8869 — To amend title XIX of the Social Security Act to require, as a condition of receiving Federal Medicaid funding, that States do not prohibit in vitro fertilization (IVF) services, and for other purposes; Sponsor: Perry, Scott [Rep.-R-PA-10]; Committees: House - Energy and Commerce