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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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June 30, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

As Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I write concerning the Supreme Court’s decision in *Loper Bright Enterprises v. Raimondo*, and the significant changes that federal agencies will make to their rulemaking and other processes in its aftermath. For 40 years, Congress and federal courts have ceded their respective responsibilities to write and interpret statutes to federal agencies. Under the Court’s decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, courts were required to give broad deference to agencies’ interpretations of ambiguous provisions in statutes.¹ The Court has now overturned that deference, reinforcing that Congress and the courts are responsible for writing and interpreting the laws, respectively; not agencies.² The Court held that such deference defies the Administrative Procedure Act, and that agency interpretations are no longer entitled to deference.³

This decision is an opportunity for executive agencies to re-examine their role relative to Congress, and to return legislating to the people’s elected representatives. For too long, *Chevron* deference has let agencies make broad decisions governing a diverse country of over 330 million people. Instead of engaging in the hard work of making tradeoffs and building coalitions needed to legislate, unelected agency bureaucrats exploit statutes to impose policy decisions that exceed their authority from Congress and exercise discretion far outside their core expertise and purpose.

Such unfettered agency power by the unelected is a perversion of the Constitution. *Loper Bright* makes clear that no agency is above the law or should be afforded special treatment when its authority is challenged. Moreover, the Court has separately confirmed that agencies need clear, specific statutory authorization from Congress to take action on issues of “vast ‘economic and

¹ *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

² *Loper Bright Enterprises v. Raimondo*, No. 22-1219, 2024 WL 3208360 (U.S. June 28, 2024).

³ *Id.* at *3.

political significance.”⁴ Agencies cannot seize broad power based on authorities that Congress intended to be exercised narrowly—subtle, vague, or ambiguous statutory provisions provide no foundation for sweeping action.⁵ Even then, Congress cannot delegate its Article I legislative powers to agencies.⁶

Congress is the most politically accountable branch in our government, and should be responsible for making the most important policy decisions that affect the American people. The Court also makes clear that Congress makes law, not agencies. When the Executive Branch does make law, such as promulgating new regulations, it does so to implement the laws Congress makes and only within the clearly established guardrails that Congress sets. In *Loper Bright*, the Court makes clear that the role of federal courts is to “independently interpret the statute and effectuate the will of Congress subject to constitutional limits.”⁷

Despite the Court’s decision, given your agency’s track record, I am concerned about whether and how the Department of Health and Human Services (“HHS” or the “Department”) will adapt to and faithfully implement both the letter and spirit of this decision. I, alongside colleagues in both Houses of Congress, worked to pass the No Surprises Act to protect patients from surprise medical bills.⁸ In implementing the statute, the Department cast aside clear congressional directives and key parts of the statute that Congress carefully negotiated. As a result, HHS has been sued over multiple aspects of its implementation, specifically regarding the calculation methodology and deference to the Qualified Payment Amount (QPA) within the independent dispute resolution framework. A federal court invalidated the Department’s QPA methodology and payment determination rules on multiple occasions.⁹ The Department could have responded to the court decisions by moving forward with new guidance and enforcement that is *consistent* with the law. Instead, the Department spent time and resources appealing the decisions and delaying necessary enforcement actions surrounding the QPA methodology, prolonging uncertainty for providers and patients across the country.

Further, the Department has yet to implement the Advanced Explanation of Benefits, a critical provision that Congress included in the statute to provide patients with the estimated cost of a

⁴ See *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)).

⁵ See *Whitman v. Am. Trucking Ass’n, Inc.*, 531 U.S. 457, 468 (2001) (“Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.”).

⁶ See, e.g., *Gundy v. United States*, 588 U.S. 128, 135 (2019) (“Congress, this Court explained early on, may not transfer to another branch ‘powers which are strictly and exclusively legislative.’” (quoting *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42-43 (1825))).

⁷ *Loper Bright*, 2024 WL 3208360 at *2.

⁸ Consolidated Appropriations Act, 2021, Division BB, Title I. P.L. 116-260 (2020).

⁹ See 587 F.Supp.3d 528 (TMA I), 587 F.Supp.3d 528 (E.D. Tex. 2022); *Texas Med. Ass’n v. U.S. Dep’t of Health & Hum. Servs.* (TMA II), 654 F.Supp.3d 575 (E.D. Tex. 2023); *Texas Med. Ass’n v. U.S. Dep’t of Health & Hum. Servs.* (TMA III), No. 6:22-CV-450-JDK, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023).

scheduled service and accompanying out-of-pocket costs before they receive care. The dereliction of duty by the Department to implement this provision in a timely manner comes at patients' expense. The Court's *Loper Bright* decision reiterates that Congress (not agencies) writes statutes, and should prompt the Department to comprehensively implement the No Surprises Act as Congress intended.

In another egregious example, HHS has been an active participant in an interagency working group led by the National Institute of Standards and Technology that seeks to reinterpret the Bayh-Dole Act's criteria for the use of march-in rights to apply to drug prices. The resulting draft framework received significant, widespread negative feedback. Exercising march-in rights on the basis of a product's price directly conflicts with congressional intent, as publicly affirmed by the law's bipartisan authors, and how the statute has consistently been interpreted in response to previous march-in petitions during presidential administrations of both parties.¹⁰

Moreover, HHS has consistently failed to provide timely or satisfactory responses to oversight requests, hindering Congress' ability to make informed policy decisions and hold agencies accountable for implementing the laws Congress writes. I have been investigating the treatment of unaccompanied children and the sponsor vetting process at HHS' Office of Refugee Resettlement (ORR) for over a year, but have faced repeated stonewalling by HHS throughout the process. As the agency tasked with the custody and care of unaccompanied children (UC), your disregard of numerous congressional oversight letters and other inquiries into the well-being of children is alarming. I have sent four letters requesting information on topics such as the level of care given to UC in ORR custody, the process by which sponsors are screened prior to gaining custody of a child, and data on the bed capacity at individual ORR facilities. Each response was delayed for months, incomplete, or simply restated publicly available information.¹¹ Additionally and separately, the Department refused to brief my staff regarding the scientific justification for the proposed re-scheduling of marijuana. This proposal would have significant ramifications for public health and safety, yet your agency refuses to discuss it with congressional staff.

Agency responses to congressional oversight are not optional. Constructive dialogue between Congress and Executive agencies is critical to both branches serving the American people and fulfilling their respective constitutional responsibilities. To facilitate this dialogue, agencies cannot simply shrug off oversight or side-step legitimate inquiries by providing only the information the agency wants to share. Congress is constitutionally mandated to perform oversight over federal agencies, and HHS must change its perspective to be more accountable to Congress moving forward.

¹⁰ See, e.g., Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab. & Pensions, et al. to Dr. Monica Bertagnolli, Dir., Nat'l Insts. of Health (March 4, 2024), https://www.help.senate.gov/march-in_nih_finalpdf.

¹¹ See, e.g., Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ. Lab. & Pensions, to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (May 16, 2024), <https://www.help.senate.gov/2024-05-16-letter-from-sen-cassidy-to-sec-becerra-re-oversight-of-orr>.

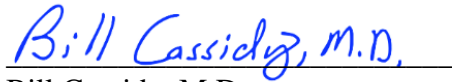
To understand how HHS will abide by and implement the Court's new framework, I ask that you answer the following questions, on a question-by-question basis, **by July 19, 2024**:

1. How will HHS change its current practices to enforce the laws as Congress writes them, and not to improperly legislate via agency action?
 - a. Will HHS be conducting a systematic, action-by-action review of its ongoing activities to identify opportunities where the Department needs to make changes to comply with or otherwise account for the decision?
 - b. Will HHS pause or stop any existing rulemaking activities in light of the Court's decision? If so, what rule(s) is HHS halting? If not, why does HHS feel it is legally able to continue existing rulemakings without considering the impacts of the Court's decision?
2. How does the HHS plan to facilitate greater congressional involvement in policy issues under the agency's purview? Please be as specific as possible with respect to oversight responses, regular briefings, trainings and seminars, and other actions you plan to take.
3. What are your current policies about when your staff may or may not provide briefings to congressional staff? Where are such policies codified?
4. How do you plan to increase the Department's responsiveness to oversight and technical assistance requests from Congress?
 - a. For example, how do you plan to streamline the Department's process for clearing technical assistance to reduce response times to congressional requests?
5. Moving forward, will you commit to providing a substantive response to congressional oversight requests within 30 days of receipt of the request? If not, why not?
6. How does the *Loper Bright* decision alter the Department's interpretation of its authority with respect to how arbitrators should make payment determinations under the No Surprises Act?
7. How does the *Loper Bright* decision alter the Department's interpretation of its authority to specify the QPA methodology under the No Surprises Act?
8. Does the Department intend to revise any pending proposed rules regarding the IDR process in light of the *Loper Bright* decision?
9. When does the Department intend to implement the Advanced Explanation of Benefits provision that Congress required in the No Surprises Act?

10. Please explain the specific statutory authority that the National Institutes of Health, a sub-agency of HHS, would have to use price as a justification to use march-in rights for drug patents.

Thank you for your prompt attention to this important matter.

Sincerely,

Handwritten signature of Bill Cassidy, M.D. in blue ink, underlined.

Bill Cassidy, M.D.

Ranking Member

U.S. Senate Committee on Health,
Education, Labor, and Pensions