MEMORANDUM

TO: Sirona Clients

DATE: October 17, 2024

RE: *Loper Bright* Implications for Health Policy

On June 28, 2024, the United States Supreme Court ruled in *Loper Bright Enterprises v. Raimondo* to overturn the 1984 *Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.* decision. The overturned policy, commonly referred to as the "Chevron Doctrine," played an important role in regulatory rulemaking for the last 40 years, and set the standard for courts to defer to administrative agencies' reasonable interpretations of ambiguous federal laws.

The "Chevron Doctrine" refers to the principle of judicial deference to administrative agencies' interpretation of federal statutes. If Congress had not made clear their intent on a specific issue, a federal agency could "reasonably interpret" the ambiguities in the law. Supporters of the Doctrine argued that it was appropriate for federal agencies, with experts in their respective areas, to interpret the law, whereas detractors argued that it gave too much power to unelected administrative employees.

The *Loper Bright* ruling limits regulatory agencies' discretion in implementing laws, and has already resulted in legal challenges in key policy areas such as health care, the environment, workplace safety, and consumer protections. In July 2024, the Supreme Court ruled that a six-year statute of limitations applies to challenges to agency rules under the Administrative Procedure Act (APA), which means that only rules that have been issued within the last six years may be subject to challenge on *Loper Bright* grounds.

This memo outlines health care regulations that may be at greater risk of legal challenge in the wake of the *Loper Bright* decision, and summarizes relevant lawsuits expected to be impacted by the decision. It also highlights legislation that has been introduced in response to the legal ruling.

Centers for Medicare and Medicaid Services

Affordable Care Act (ACA)

- ACA Section 2713 requires health plans to cover certain preventative services without a copay, as defined by the U.S. Preventive Services Task Force. HHS has detailed regulations and guidance about these services, including how contraceptive coverage should be implemented. This section of the law is already being challenged by Republican attorneys general arguing that ACA improperly delegates too much authority to non-elected bodies, and challenges the constitutionality of the government mandating no copays. The Loper Bright ruling offers another opportunity for legal challenge by allowing a challenge of the agencies' interpretation of the mandate.
- Nondiscrimination regulations, including Section 1557 of the ACA which prohibits discrimination on the basis of race, color, national origin, sex, sexual orientation, gender identity, age, or disability.
- HHS administers the Title X program through the Office of Population Affairs (OPA) to ensure funded projects comply with federal law. HHS has authority to develop regulations for Title X, including standards for the provision of family planning services and addressing issues such as client confidentiality and informed consent.

Medicare and Medicaid

- Minimum staffing requirements for nursing homes set by HHS through CMS for facilities that participate in Medicare and Medicaid.
- Medicare and Medicaid reimbursement regulations, including Medicare fee schedules, are set by CMS to determine how providers are paid for services to beneficiaries. CMS enforces compliance with reimbursement rules and has authority to take action against non-compliant providers.
- Interpretations of laws to prevent, detect, and respond to fraud and abuse in federal health care programs.
- Interpretation of the Inflation Reduction Act (IRA), including provisions which permit Medicare to negotiate the price for certain prescription drugs. HHS has authority under the IRA to oversee and manage the negotiation process for prescription drug prices under Medicare.
- The 340B program, a federal program established in 1992 that requires drug manufacturers to sell discounted outpatient drugs to certain health care organizations. Key aspects of the program are currently dependent on litigation.
- Implementation of the Medicaid Access Rule, which requires states to ensure that Medicaid beneficiaries have sufficient access to covered services, particularly in fee-for-service (FFS) Medicaid programs.
- Interpretation of the Medicaid Drug Rebate Program (MDRP), which helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.
- Interpretations of statutes and regulations governing the operation and oversight of Medicaid managed care organizations.

Food and Drug Administration (FDA)

- Decision making under the Federal Food, Drug, and Cosmetic Act allows the FDA to oversee the safety, efficacy, and security of various products, including food, drugs, medical devices, cosmetics, tobacco products, biologics, and radiation-emitting products. Examples of policy areas that could be challenged include:
    - FDA's regulation of compounded drugs, through the Compounding Quality Act;
    - The regulation of Software as a Medical Device and guidance regarding machine learning for medical device development; and
    - FDA's enforcement and oversight of flavored e-cigarette products.
- Development of new drugs and medical devices through the review of new drug applications, overseeing of clinical trials, and post-market surveillance.
- The process and evidence used to determine FDA approval of medications can be questioned along with the approval itself, for example, regarding the medication abortion drug, mifepristone.

Expected Impact to Health Litigation

Lawsuits Filed Post-Loper Bright Decision

The lawsuits listed below were filed after the Supreme Court's decision in *Loper Bright,* and have all challenged agency regulations on the grounds of exceeding statutory authority, misinterpreting statute, and/or violating Congressional intent. Courts will now have the responsibility to interpret laws and regulations even for complex and technical topics that had previously been deferred to agency expertise.

- Hackensack Meridian Health filed a lawsuit against HHS on June 28 regarding CMS's formula for disproportionate share hospital (DSH) payments.

- The University of North Carolina Hospitals at Chapel Hill, University of Chicago Medical Center, Bridgeport Hospital, Greenwich Hospital and Yale New Haven Hospital filed a lawsuit against HHS on July 12 alleging underpayment from the federal government to hospitals for graduate medical education.
- The Association for Molecular Pathology filed a lawsuit against the FDA on August 19 regarding the FDA's decision to regulate lab-developed tests.
- Texas filed a lawsuit against HHS regarding the HIPAA Privacy Rule Final Rule, which restricts state law enforcement agencies investigative authority.
- Shannon Medical Center and 79 other hospitals filed a lawsuit against HHS on September 9 regarding CMS' DSH payments. The lawsuit takes issue with the Part C Days Final Rule that allowed HHS to retroactively reduce DSH payments.
- Twenty states filed a lawsuit on October 8 over CMS's rule establishing minimum staffing standards for nursing homes.
- Owensboro Health filed a lawsuit against HHS on October 14 regarding the Administration's determination that the clinic was ineligible for volume-based Medicare compensation.

Lawsuits Filed Pre-Loper Bright Decision

These lawsuits were filed before the Supreme Court's decision in *Loper Bright*, but are expected to be impacted by the ruling:

- Three lawsuits: Americans for Beneficiary Choice v. HHS, filed May 13, 2024, Amerilife v. HHS, filed May 29, 2024, and Council for Medicare Choice v. HHS, filed May 15, 2024, are challenging an HHS rule that restricts compensation for field marketing organizations that provide support for independent insurance agents and brokers.
- The American Health Care Association filed a lawsuit against HHS on May 23, 2024, over CMS's rule establishing minimum staffing standards for nursing homes.
- Several lawsuits have been filed by the pharmaceutical industry against HHS over the Inflation Reduction Act's (IRA's) Medicare drug price negotiation provisions, including:
    - *AstraZeneca Pharmaceuticals LP et al. v. Becerra et al.*, filed May 2, 2024.
    - *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Department of Health and Human Services et al.*, filed on August 18, 2023.
    - *Janssen Pharmaceuticals, Inc. v. Becerra et al.*, filed on June 18, 2023.
    - *Bristol Myers Squibb Co. v. Becerra et al.*, filed on August 25, 2023.
    - *National Infusion Center Association et al. v. Becerra et al.*, filed June 21, 2023.
    - *Novo Nordisk et al. v. Becerra et al.*, filed September 29, 2023.
    - *Novartis Pharmaceuticals Corporation v. Becerra et al.*, filed September 1, 2023.

Legislative Response to *Loper Bright*

Various pieces of legislation have been introduced with new policies that would add to or change the current legislative and rulemaking process. It is unlikely that these bills will pass this year, which will leave reform of the rulemaking process on the table for the 119th Congress.

Examples of introduced legislation include:

S. 4692 - Upholding Standards of Accountability Act

On July 11, 2024, Sen. Cassidy (R-LA) introduced the Upholding Standards of Accountability Act (S. 4692). The legislation aims to "rein in the executive branch and ensure federal agencies are held accountable to Congress" through:

- Requiring the head of a federal agency signing a major rule to testify about the rule before the committee of jurisdiction within 30 days of the rule being published;
- Requiring each person nominated to a Senate-confirmed position to testify before the committee of jurisdiction prior to Senate confirmation;
- Improving cost-benefit analyses by requiring federal agencies to conduct retrospective reviews of such analyses for major rulemakings within five years of each rule's effective date;
- Clarifying that federal agencies are permitted to communicate with Congress at all times regarding proposed rules; and
- Requiring timely, substantive responses to congressional oversight from federal agencies.

S. 4749 - The Stop Corporate Capture Act

On July 23, 2024, Sen. Warren (D-MA) and 10 cosponsors introduced the Stop Corporate Capture Act (S. 4749). Rep. Jayapal (D-WA) and 76 cosponsors introduced companion legislation (H.R. 1507) in the House on March 9, 2023. The legislation aims to codify the original Chevron doctrine and strengthen the rulemaking process by:

- Streamlining the White House's review period for regulations, creating a 120-day time limit for review;
- Authorizing agencies to reinstate rules that are rescinded by Congress through the Congressional Review Act;
- Reforming agencies' cost-benefit analysis to emphasize public benefits of a rule, including non-quantifiable benefits like promoting human dignity, securing child safety, and preventing discrimination;
- Creating an Office of the Public Advocate to help members of the public participate more effectively in regulatory proceedings;
- Strengthening agency procedures for notifying the public about pending rulemakings;
- Providing the public with greater authority to hold agencies accountable for unreasonable delays in completing rules;
- Requiring agencies to respond to citizen petitions for rulemaking that contain 100,000 or more signatures;
- Requiring all rulemaking participants to disclose industry-funded research or other related conflicts of interest;
- Requiring any submitted scientific or other technical research that raises a specified corporate conflict of interest be made available for independent public review;
- Bringing transparency to the White House regulatory review process by requiring disclosure of changes to draft rules during that process and the source of those changes;
- Requiring agency officials to provide justification when the regulatory review process ends with a rule being withdrawn; and
- Establishing financial penalties for corporate special interests that knowingly submit false information during the rulemaking process.

S. 4987 - The Restoring Congressional Authority Act

On August 2, 2024, Sen. Wyden (D-OR) introduced the Restoring Congressional Authority Act (S. 4987). This legislation would codify the original Chevron doctrine and give Congress the ability to contradict judicial rulings that undermine Congressional law and intent by:

- Amending Section 706 of the Administrative Procedure Act to codify judicial deference to public agencies as they implement federal laws;
- Requiring courts to consider congressional intent when reviewing the reasonableness of an agency's interpretation of a statutory provision and define how congressional intent will be expressed; and
- Providing an identical timeframe as the Congressional Review Act for a new fast-track mechanism for Congress to overturn decisions by appellate courts to invalidate an agency rule based on a determination that the agency's interpretation of the statutory provision was not reasonable.

Conclusion

The *Loper Bright* decision will impact how agencies and Congress approach rulemaking and legislation in the future. Possible implications could include agency general counsels and leadership exercising more caution when undertaking rulemaking and changing rules over time, as well as being more exhaustive in drafting rules and agency justifications for rules. Further, courts challenges will make legislation in certain areas (listed above) more difficult. Bipartisan legislation with input and technical assistance to avoid ambiguity will become increasingly important. Members of Congress will rely more heavily on the policy expertise of outside lobbyists, and may also consider hiring staff with additional expertise.

Sirona Strategies previously held a webinar on the Chevron Doctrine, aimed at preparing health care leaders and stakeholders to respond to this landmark rulemaking. The webinar can be found here.