July 14, 2025

Robert Francis Kennedy Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted via www.regulations.gov

RE: Recommendations for Commonsense Deregulation in HHS

Dear Secretary Kennedy:

ACHP appreciates the opportunity to provide recommendations for reducing regulatory burden, improving care delivery and unleashing innovation within the health care system. Our organization has long championed commonsense reforms that promote affordability, patient access and market competition. We applaud the Administration's commitment to restoring regulatory balance and advancing economic growth through the thoughtful reassessment of outdated and unnecessarily complex rules.

ACHP is the only national organization advancing a unique payer-provider aligned model of care that fosters competition and delivers high-quality coverage. Our member companies are nonprofit, community-based health plans that serve millions of Americans across nearly 40 states and the District of Columbia. Operating on margins of one to three percent, ACHP members remain in their markets when other carriers exit and lead the industry in driving administrative efficiency and innovation on behalf of patients.

With the Administration's focus on restoring the rule of law, reversing chronic disease and improving government efficiency, the Department has a historic opportunity to modernize outdated guidance, streamline implementation and ensure that regulatory actions deliver value to patients. ACHP and its member companies are eager to collaborate with the MAHA Commission to make meaningful impact on the health of America's children. In 2023, we launched the ACHP Chronic Disease Pledge, a ten-year commitment to reduce the incidence of diabetes, heart disease and childhood obesity in communities across the country. This commitment goes beyond slogans and is rooted in on-the-ground local solutions. ACHP is leading significant research on the utilization and adoption of continuous glucose monitoring (CGM) to help improve outcomes, facilitate better behavioral decisions and enhance quality of life for patients with diabetes. As agencies across the Department of Health and Human Services (HHS) work to implement Executive Orders 14219, 14212 and 14192, ACHP offers the following high-impact recommendations for immediate action.

High-Impact Recommendations for Regulatory Repeal and Reform under *Executive Order 14219 Restoring the Rule of Law, Federalism and Economic Growth by Reviewing Regulatory Actions*

- **Terminate the Medicare Prescription Payment Program created under the Inflation Reduction Act.** While ACHP supports the goal of reducing out-of-pocket costs, the program imposes significant administrative burden on health plans with minimal value for beneficiaries. Eliminating this requirement would reduce wasteful spending and allow plans to focus resources on care delivery.

- **Ensure consistent Part D coverage for transplant-related immunosuppressants**. Under Chapter 6 of the Medicare Prescription Drug Benefit Manual (PDBM), some self-administered transplant drugs are processed under Part B with different cost-sharing rules depending on whether the transplant was Medicare-covered. This fragmented coverage structure creates member confusion and operational inefficiencies. All transplant-related drugs should be covered under Part D.

- **Modify the 2025 Defined Standard Part D Benefit to eliminate incentives for high-rebate originator products.** Current policy design encourages plans to cover high-cost originators with larger rebates, undermining the use of lower-cost alternatives and increasing total program spending. Adjusting the benefit structure would promote value-based formulary decisions.

- **Remove restrictions against negative formulary changes during the benefit year**. Section 30.3.3.1 of Chapter 6 in the PDBM prohibits plans from adjusting formularies mid-year, even when pricing, availability or new evidence warrant changes. This restriction drives unnecessary costs for beneficiaries, plans and the federal government.

- **Finalize rulemaking to allow accumulator programs and clarify manufacturer coupon treatment.** ACHP urges HHS to issue final regulations resolving outstanding issues in *HIV+ Hepatitis Policy Institute v. HHS.* Plans need certainty that manufacturer assistance does not constitute cost sharing under the Affordable Care Act (ACA). This rule would support plan design flexibility and consumer cost transparency.

Advancing Chronic Disease Prevention under *Executive Order 14212, Establishing the President's Make America Healthy Again Commission*

- **Eliminate the fragmented vaccine coverage framework across Medicare Parts B and D.** Under Chapter 6, Section 10.14 of the PDBM, certain vaccines are reimbursed through Part B, while others are only available under Part D. This creates confusion for patients and providers and deters vaccine uptake. Centers for Medicare & Medicaid Services (CMS) should allow payment for all vaccines at any pharmacy or medical office and enable provider billing directly through CMS to simplify the immunization experience.

Reducing Red Tape under *Executive Order 14192, Improving Government Efficiency and Reducing Regulatory Burdens*

- **Align timelines for drug exception requests under ACA and Medicare Part D.** Section 156.122 under the ACA prohibits tolling and mandates a 72-hour review window from the time of initial request. In contrast, Part D allows timelines to begin upon receipt of a provider's supporting statement. This inconsistency leads to confusion and unnecessary administrative pressure. Aligning the timelines would streamline the process for providers, plans and beneficiaries.

- **Reverse IRA guidance counting Non-Covered Plan Pay toward True Out-of-Pocket (TrOOP) Costs under Enhanced Alternative plans.** Counting plan-paid amounts toward a beneficiary's TrOOP skews cost-sharing calculations and creates compliance risks. CMS should reverse this guidance and clarify that only member-incurred costs apply.

- **Update the Defined Standard Part D Benefit to use fixed copays instead of percentage-based coinsurance.** CMS already limits copays by tier in Enhanced Alternative plans. ACHP recommends extending this to the Defined Standard Benefit to simplify cost-sharing and improve consumer understanding of prescription drug costs.

We welcome the opportunity to support the Department's efforts to modernize health care regulation and advance practical reforms that improve outcomes, reduce costs and foster market competition. Please contact Michael Bagel, Vice President of Federal Affairs (mbagel@achp.org) to discuss these recommendations and collaborate on meaningful policy solutions.

Sincerely,

Ceci Connolly

Ceci Connoly
President and CEO
ACHP