NATIONAL HEALTH COUNCIL

July 14, 2025

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

RE: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make America Healthy Again

Dear Secretary Kennedy,

The National Health Council (NHC) appreciates the opportunity to respond to the Department of Health and Human Services (HHS) Request for Information (RFI) regarding proposed deregulatory initiatives under Executive Orders 14192 and 14219.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of more than 180 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

General Comments

As the leading voice for people with chronic conditions and disabilities and their family caregivers, the NHC supports efforts to improve the efficiency of government operations and reduce administrative burdens that do not meaningfully contribute to patient care, safety, or health outcomes.

The NHC supports the principle that regulatory frameworks should be regularly evaluated and streamlined where appropriate. When carefully designed and appropriately implemented, the removal of unnecessary regulatory requirements can improve the patient experience, reduce inefficiencies within the health system, and support innovation. However, any such actions must be guided by a commitment to maintaining access to care, protecting patient rights, preserving program integrity, and advancing high-quality treatment and service delivery. Given the breadth of the regulatory scope contemplated in this RFI, it is essential that patients, caregivers, providers, and other affected stakeholders are engaged early and meaningfully to help anticipate and mitigate any unintended consequences.

While the NHC does not propose specific deregulatory actions in response to this RFI, we offer the following principles to guide HHS in evaluating deregulatory opportunities:

- **Patient-Centered Review**: Regulatory review processes should prioritize the impact on patients, evaluating whether a given requirement meaningfully supports care delivery, outcomes, or safety, rather than focusing solely on perceived burden.
- **Stakeholder Engagement**: Any changes to existing regulations should be informed by robust and inclusive consultation with patients, caregivers, providers, payers, and community-based organizations.
- **Patient Protection and Access Safeguards**: Deregulatory actions must not create disproportionate barriers to care or increase risks to patient safety, continuity of care, or affordability.
- **Evidence-Based Justification**: Proposed deregulatory changes should be supported by clear, data-driven evidence of cost savings or improvements in care delivery and should be designed to minimize disruption to patients and providers.

Feedback on Specific Areas of Inquiry

Question 1: What HHS regulations and/or guidance meet one or more of the seven criteria in E.O. 14219? Should they be modified or repealed? What would be the impact of this change, especially the costs and savings?

The NHC does not propose specific regulations for modification or repeal under E.O. 14219 at this time. However, we recommend that HHS apply a patient-centered framework when evaluating whether existing regulations impose significant costs that are not justified by corresponding benefits. In the context of health care, such costs should be considered not only in fiscal terms but also in relation to their potential impact on access to services, continuity of care, and health outcomes.

Stakeholder engagement is essential to this evaluation process. Regulations that affect service delivery models or innovation pathways should be reviewed in close consultation with patients, caregivers, providers, and other relevant stakeholders to ensure that any changes do not inadvertently disrupt care, reduce patient protections, or diminish system effectiveness.

Question 2: What regulations should we reconsider as we look to achieve some of the policy objectives outlined in Executive Order 14212, "Establishing the President's Make America Healthy Again Commission," to focus on reversing chronic disease?

Efforts to reduce the burden of chronic disease should prioritize policies that strengthen access to coordinated, preventive, and person-centered care. While streamlining regulations may support this objective in some cases, it is important that such actions do not compromise the regulatory structures that underpin care quality, program accountability, or sustained access to essential services.

The NHC encourages HHS to approach any deregulatory proposals in this area with a clear understanding of their potential impact on patients managing chronic conditions. Regulatory requirements and HHS programs that support prevention, public health

capacity, and chronic disease surveillance should be maintained or refined—not eliminated—if they are instrumental in achieving long-term health outcomes.

Question 3: For general deregulatory consideration under E.O. 14192, are there additional HHS regulations and/or guidance that are confusing, duplicative, obsolete, overly punitive, or impede innovation and care access?

While the NHC does not offer specific regulations for repeal at this time, we encourage HHS to review regulatory frameworks that may create duplicative, conflicting, or unnecessarily complex requirements—particularly where federal and state obligations intersect. Simplifying such requirements can improve administrative efficiency and reduce burdens on providers without compromising the goals of public health programs.

Importantly, any efforts to streamline regulations should maintain core safeguards that protect patients, ensure access to comprehensive care, and support effective program oversight. The objective should be regulatory clarity and alignment, not the elimination of provisions that serve a meaningful role in advancing care quality or system integrity.

Question 4: What alternative approaches could achieve similar goals with less burden (e.g., state models or private-sector analogs)?

Alternative approaches—such as risk-based oversight models, streamlined documentation systems, and aligned quality reporting frameworks—may offer opportunities to reduce administrative burden while maintaining standards for care quality and safety. For instance, the use of standardized electronic reporting formats and health information technology tools to automate compliance processes could improve efficiency and reduce resource demands on providers, but CMS must also work to ensure that these tools do not hinder access to care for patients.

The NHC recommends that HHS pilot such models through targeted initiatives that include rigorous evaluation and input from patients, providers, and other stakeholders. Any alternative approach should be designed to function effectively across a wide range of care settings and populations, with attention to implementation feasibility and consistent access to services.

Question 5: Are there HHS regulations, guidance, or reporting requirements that are rooted in outdated technology? Can new technologies be leveraged to allow for rescinding or updating these policies? What are the cost implications?

Some existing data collection and reporting requirements rely on legacy or manual systems that place unnecessary administrative burdens on providers and limit the utility of data for program evaluation and public health monitoring. HHS should assess opportunities to transition toward modern, interoperable digital platforms that improve efficiency, reduce redundancy, and enhance data accuracy.

Any modernization effort should be accompanied by safeguards to ensure continuity of oversight, particularly in areas related to patient safety, program accountability, and monitoring of service delivery. Investments in digital infrastructure must also include protections for data privacy and security, and implementation strategies should account for variability in technological capacity across provider settings and geographic regions.

Question 6: Are there HHS regulations, guidance, or reporting requirements that are inconsistent with Executive Orders 14151, 14154, 14168, and 14213 or others issued by the President? Should they be modified or rescinded to make them consistent?

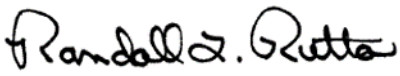
In reviewing regulations for consistency with Executive Orders, HHS should ensure that any modifications are guided first and foremost by considerations of public health outcomes and patient impact. Aligning regulatory frameworks to improve clarity and operational efficiency can be appropriate, provided such efforts do not undermine evidence-based policymaking or essential protections that support care quality and access.

The NHC recommends that all proposed regulatory changes—whether new, revised, or rescinded—undergo the formal notice-and-comment process. Robust stakeholder engagement remains essential to identifying potential unintended consequences and ensuring that regulatory revisions continue to serve the interests of patients and the broader health care system.

Conclusion

The NHC appreciates HHS' commitment to stakeholder engagement in the regulatory review process. As HHS considers potential deregulatory actions, it is essential that the perspectives of patients and their caregivers remain central to decision-making. We welcome continued dialogue with HHS to help ensure that any changes to the regulatory landscape support, rather than compromise, the health and well-being of individuals living with chronic conditions and disabilities. Please contact Kimberly Beer, Senior Vice President, Policy & External Affairs at kbeer@nhcouncil.org or Shion Chang, Senior Director, Policy & Regulatory Affairs at schang@nhcouncil.org, if you or your staff would like to discuss our recommendations in greater detail.

Sincerely,



Randall L. Rutta
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