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February 23, 2026

Dear Department of Health & Human Services,

Better care at lower cost through patient-centered artificial intelligence regulatory sandboxes

Thank you for the opportunity to provide comments in response to the US Department of Health and Human Services (HHS) RIN 0955-AA13, *Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care.* On behalf of University of California Health (UC Health), we write to share policy proposals to strengthen the U.S. healthcare system and improve population health outcomes. UC Health serves millions of patients each year across urban, rural, and underserved communities and educates thousands of trainees. Our footprint spans six academic health centers and 21 professional schools. When developing and deploying artificial intelligence (AI) throughout the healthcare delivery system, we abide by a set of shared principles. Our recommendations are consistent with these principles, including that the use of AI should be transparent; accurate, reliable, and safe; fair and non-discriminatory; respectful of privacy and security; and accountable.

Over the past year, researchers and developers have advanced both the technology underlying AI tools and their applications to improve human health. Across UC Health, AI scribes have helped our clinicians provide better patient experience through a reduction in documentation burden. They have the potential to shorten appointment wait times and boost accessibility for patients by increasing clinicians' visit volumes. The greatest adoption of AI, and best outcomes from AI, have been seen in areas where health systems and industry innovators have consistent and streamlined regulatory frameworks with clear expectations and thus can implement new AI-enabled workflows safely and with strong oversight.

In the face of regulatory uncertainty, innovation stalls. Regulatory sandboxes[1] have emerged as a way for health systems and industry innovators to assess the benefits of new AI-enabled care models while maintaining safeguards, including monitoring, auditing, and accountability, until a more mature regulatory framework is implemented. Such sandboxes may provide a pathway towards piloting new uses of AI in service of our patients and communities. For example, Utah's regulatory sandbox framework recently enabled the first pilot of AI-prescribed medication refills, aiming to make care cheaper for patients while assessing clinical outcomes as part of a rigorous evaluation plan.

We acknowledge that such sandboxes are complex environments to establish. UC Health believes any regulatory sandbox framework must preserve existing patient protections and reinforce, not diminish, institutional accountability.

[1] *Winning the Race: America's AI Action Plan* (July 2025).

Sandbox models should establish clear clinical responsibility, formal governance oversight, ongoing safety and equity monitoring, and transparent reporting of outcomes and adverse events. Regulatory clarity should support responsible innovation while upholding patient safety, privacy, and nondiscrimination.

In this letter, we highlight two opportunities to improve health AI policy to make care more affordable and accessible while improving outcomes:

1. **Establish regulatory sandboxes to test new AI-enabled models of care.**
2. **Modernize restrictions on the use of AI-powered translation tools through a regulatory sandbox approach.**

1. Establish regulatory sandboxes to test new AI-enabled models of care. We recommend that HHS explore developing a pathway where health systems and industry innovators can propose, and after appropriate evaluation, register a new model of care to receive time-limited sandbox approval under a streamlined, consistent regulatory framework. To ensure public trust, regulatory sandboxes should include established guardrails, including defined safety metrics, real-world evidence generation plans, and transparent reporting requirements. Participating organizations should demonstrate data governance, clinical oversight, and patient engagement structures consistent with learning health system principles.

Health systems serve as the primary point of contact for patients and shoulder much of the responsibility for ensuring patients receive timely preventive care, diagnoses, and treatments. Given their obligation to improve patient outcomes while minimizing harm, health systems are understandably cautious about altering fundamental care delivery processes that may introduce new risks. On the other hand, *learning* health systems strive to learn from every patient and use those learnings to improve care for the next patient through changes to the care delivery process. Learning health systems are well-equipped to pair innovative care delivery models with robust evaluation plans to mitigate risks. In the absence of regulatory clarity, learning health systems narrow their scope to incremental changes to care delivery rather than developing new AI-enabled models of care.

Regulatory sandboxes facilitate innovation by mitigating the regulatory risks of testing new AI-enabled clinical workflows. For example, Utah's pilot of AI-prescribed medication refills was only possible because it was wrapped within a regulatory sandbox. While some have criticized whether AI-enabled refills are safe, the rigorous evaluation plan attached to the pilot will directly answer that question. The low cost to patients to obtain refills through this program will alleviate financial burdens and remove barriers to access. The recently announced Advanced Research Projects Agency for Health (ARPA-H) Agentic AI-Enabled Cardiovascular Care Transformation (ADVOCATE) program provides another example, striving to take AI automation to the next level by testing the safety of agentic AI tools in supporting patients with heart failure through actions typically considered within the purview of clinicians. While the ADVOCATE program has been wrapped within a regulatory sandbox with coordination from Food and Drug Administration, many health systems and industry innovators want to test similar models of care in other areas. Having a pathway where health systems and industry innovators can register new models of care to receive time-limited sandbox approval would facilitate higher-risk pilots where systems have regulatory clarity on specific use cases at the time of designing such pilots.

2. Modernize restrictions on the use of AI-powered translation tools through a regulatory sandbox approach. One area that is ripe for such a regulatory sandbox is the use of tools that translate text between languages. We recognize the key role that interpreters play in ensuring accurate in-person communication between clinicians and patients, and that translators play in

accurate translation of standardized documents such as consent forms. However, immediate translation services are often unavailable. As a result, certain communications (such as secure text messages) may be delayed, may occur in English (and rely on the patient to use online translation tools), or simply not take place. Safely exploring how to maximize use of readily available AI technology can both make care more accessible and reduce language-related medical errors for patients with limited English proficiency.

Currently, Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act require the use of interpreters for patients receiving services covered by the U.S. Department of Health and Human Services. If a covered entity uses “machine translation,” (i.e., AI), those translations must be reviewed by a qualified human translator to ensure accuracy “when accuracy is essential,” “when the source documents or materials contain complex, nonliteral or technical language,” or “when the underlying text is critical to the rights, benefits, or meaningful access” of individuals with limited English proficiency (45 CFR § 92.201(c)(3)).

Yet there has been a substantial shift in how people access healthcare, with many more touchpoints occurring via secure text messaging between patients and their care teams than ever before. Secure text messaging is used to address non-urgent concerns, and it is common for multiple short messages to be exchanged to address an issue. For brief messages, AI tools have been shown to be accurate in generating medical translations for a subset of languages, and patients have shown high satisfaction rates with the use of this technology in multiple studies. Since Section 1557 was enacted, substantial advances in neural machine translation have improved performance for many high-resource languages. However, because of regulations restricting the use of AI tools for translation remain, messages may be delayed or avoided altogether – leaving patients worse off. A sandbox-based approach could enable more consistent and practical use – paired with strong monitoring, auditing, and escalation to human review when needed – while preserving protections for patients**.** Clarifying and modernizing these regulations, if done thoughtfully in a phased, risk-based framework, will improve language access for patients with limited English proficiency and present a tremendous opportunity to improve access for these patients.

We appreciate your consideration of these recommendations.

Sincerely,

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