HEALTH INNOVATION ALLIANCE

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The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Office on Science and Technology Policy (OSTP) *Regulatory Reform of Artificial Intelligence* request for information. We believe that this administration has the opportunity to supercharge AI innovation and adoption and ensure America leads the artificial intelligence race. We applaud OSTP for taking the first step to reform and eliminate regulations to unencumber innovation and progress.

HIA is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the commonsense use of data and technology to improve health outcomes and lower costs. As a group, we are actively engaged in policy discussions regarding the implementation of AI within the health care sector and are at the forefront of advocating for the innovation and adoption of new health technologies. We believe AI is a critical part of the future of health care and the federal government should wield its vast authority to incentivize and eliminate regulatory barriers to ensure the American health care system leads the world in its adoption.

General Comments

For 18 years, HIA has been a leader in federal policy related to health care technology. We believe that artificial intelligence (AI) models present opportunities to make significant strides toward improving the American health care system. From accelerating novel drug discoveries through AI-created problem solving that has already figured out protein folding – a biological process that had eluded scientists for over 50 years – to cleaning up the processes surrounding care delivery, coverage, and payment, AI can help us break through some of the health care industry's most entrenched problems. This is only possible if the federal government provides the

necessary leadership to create an environment conducive to innovation – both through supporting development and adoption of these technologies, while also balancing appropriate safeguards and streamlining regulatory oversight. This administration can take meaningful steps to provide that balance by:

- Creating a strong federal regulatory framework for AI to provide nationwide predictability for innovators
- Enforcing existing information blocking requirements
- Realigning current health AI certification frameworks to a risk-based approach
- Ensure the FDA's predetermined change control plans process for AI/ML enabled medical devices is used to its fullest potential
- Revising federal authorization processes, like FedRAMP, to minimize burden for innovators

Preserving U.S. Leadership in Healthcare AI: Avoiding Global Regulatory Pitfalls

The United States currently leads the world in healthcare innovation, particularly in the integration of artificial intelligence (AI) within the pharmaceutical and biotechnology sectors. As global adoption of AI accelerates, HIA urges OSTP and other agencies to ensure that America does not replicate the regulatory missteps emerging in other nations.

The European Union and the European Commission are advancing Annex 22, a regulatory framework under the Good Manufacturing Practice (GMP) guidelines. Annex 22 defines stringent requirements for AI and machine learning in the manufacturing of active pharmaceutical ingredients and medicinal products. The proposal heavily favors static, highly explainable models while explicitly limiting or excluding generative AI systems from safety-critical processes. In particular, the proposal contains a categorical prohibition of GenAI/LLMs in critical good manufacturing practice (GMP) applications, which represents a significant departure from technology-agnostic and risk-based norms.

While well-intentioned, frameworks like Annex 22 pose a serious threat to innovation. They impose rigid restrictions that undermine the flexible, iterative processes essential to modern AI development and deployment. Instead of enabling progress, they risk locking healthcare systems into outdated technological paradigms—discouraging the very advances that could improve safety, quality, and efficiency across the pharmaceutical lifecycle. Not only will this impact the EU, it could have global ramifications as companies try to comply with Europe's requirements.

HIA believes the United States must take a more balanced, forward-looking approach. As federal agencies consider new AI regulatory structures, it is crucial to support explainability and safety while also allowing for the responsible development and deployment of generative and adaptive AI systems. These models hold enormous potential—not only to transform healthcare delivery, but also to reduce administrative burdens, accelerate drug development, and unlock insights that are otherwise beyond human capability. The U.S. cannot make the same mistake of

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implementing blanket bans on GenAI/LLM solutions – this will hamper our competitiveness in this sphere.

In addition to learning from the pitfalls of other nations, OSTP and others must also recognize the broader geopolitical context. As countries like China aggressively pursue AI-driven advancements in healthcare and life sciences, the U.S. cannot afford to impose unnecessary regulatory constraints that slow progress. If America's regulatory posture becomes overly restrictive, we risk ceding both technological and strategic leadership in one of the most consequential domains of this century. Similarly, we should engage with our allies in the EU and elsewhere to encourage innovation-friendly regulatory frameworks and modifications to overly restrictive regulations like Annex 22, in order to stay on the cutting edge of development with our partners.

Regulatory frameworks should reflect a clear understanding: overregulation not only stifles innovation—it endangers our global competitiveness and national security. The future of healthcare depends on our ability to harness the full potential of AI. This administration must lead with principles that support innovation, ensure safety, and preserve our position at the forefront of global scientific advancement.

Centralizing a Federal Framework

HIA believes that one of the most significant barriers to AI innovation today is the absence of a centralized federal regulatory framework. In the current landscape, regulation is being determined on a state-by-state basis, creating a fragmented and inconsistent approach across the country.

Health care is already a hyperregulated industry, and numerous existing authorities are already governing the use of technology in health care, making this issue even more pronounced. Multiple authorities already oversee AI use in health care, and the introduction of disparate state laws only adds to the complexity – subjecting technologies to inconsistent and, at times, arbitrary regulations. This patchwork of state laws discourages companies from introducing AI solutions in certain markets due to the risk of conflicting legal requirements, and drags down innovation and deployment broadly due to increased compliance burden. To unencumber AI adoption on a national level, we believe that federal leadership is necessary to develop a framework that reduces various obstructions put up by state laws. Most notably, the difficulty of complying with 50 different standards for AI development and deployment slows existing industry leaders and serves as a barrier to the entrance of new innovators.

As AI tools continue to be developed for use in clinical settings, trustworthy training data becomes even more crucial. Agencies should build incentives to maintain intellectual property guardrails by encouraging the use of appropriately licensed, trustworthy training data and resources. This type of action can only be truly effective at the federal level, and would standardize requirements across the country to promote patient safety and model effectiveness.

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To foster innovation and ensure the responsible deployment of AI nationwide, HIA strongly advocates for the development of a cohesive federal framework. Federal leadership is necessary to promote patient safety, responsible innovation, and trusted AI tools. Such a framework would streamline oversight, prevent state-level regulations from becoming obstacles to progress, and support the safe and efficient integration of AI technologies across the whole country.

HTI-1 Final Rule (ONC) and Predictive Decision Support Interventions (Predictive DSI)
The HTI-1 (Health Data, Technology, and Interoperability) Final Rule was issued by Assistant Secretary for Technology Policy / Office of the National Coordinator for Health IT (ASTP/ONC) to update the certification program, enhance algorithmic transparency, and refine information sharing and information blocking policies. However, HIA believes the information blocking requirements of this rule and other successive rules are not being properly enforced.

This final rule was established to reduce information blocking, yet it still occurs due to non-compliance with existing rules and the fact that requirements do not apply to all entities that possess data that is needed for true interoperability. We believe that information blocking is a serious problem that has not garnered enough attention and needs to be reassessed regarding enforcement and expansion of current regulations and rules. For AI tools to be most effective, especially when attempting to assist patients and clinicians, they need to have the whole view of the necessary data. Due to lack of compliance with existing information blocking requirements, AI tools are unnecessarily limited in their utility due to lack of access to existing information that is siloed away.

We suggest that the HHS OIG meaningfully enforce information blocking requirements with the tools they are already given – namely civil monetary penalties. It is unclear if this tool has been used at all, so it is difficult to ascertain whether additional enforcement powers are needed. This step would go a long way to making AI tools more efficient, as well as marking a massive shift towards true interoperability.

The ASTP/ONC Certification Program, created by the HITECH Act of 2009 and found at 45 CFR Part 170, is another area that should be examined. The program certifies EHRs, patient portals, APIs, public health reporting modules, and other health IT solutions, in order for them to be able to be used for the purposes of serving any federal health program. While certification is optional, in reality it is essentially a requirement – hospitals and other sites of care will not bifurcate their technology solutions for federal health program recipients and those covered by private insurance or without coverage.

The ASTP/ONC HTI-1 Final Rule modified the certification program to include a new set of certification criteria that has attached significant new requirements around AI tools. Specifically, the rule replaced existing clinical decision support (CDS) certification criteria with decision support intervention (DSI) and predictive decision support intervention (PDSI) certification criteria. The definition of what constitutes PDSI is ambiguous at best, which raises many questions and constitutes a compliance problem for health IT vendors. In general, PDSI includes

technology that supports decision-making based on algorithms or models derived from training or example data, producing outputs like prediction, classification, recommendation, evaluation, or analysis. This includes virtually any AI that is included in any health IT module seeking certification. Thus, if there is an AI component of a health IT module, numerous requirements apply, including but not limited to:

- Source attribution: made available to a set of end users
- Developers must perform risk analysis and risk mitigation for PDSI tools
- Real world testing requirements, under §170.405

This said, we believe the PDSI certification criteria are well intentioned, and many of the requirements are already industry best practices that most health IT vendors adhere to on their own. However, the current certification criteria for PDSI is entirely built upon a function-based approach: that is, "if it looks like AI, then these requirements apply". We believe this fundamental basis of the regulatory structure is misguided and should be amended. Just because something "looks like AI" does not mean that it is inherently more likely to cause harm than any other process. Rather, regulation, including the PDSI certification criteria, should be built on a risk-based approach. ASTP/ONC should take a risk-based approach and specifically limit PDSI to express clinical related models that make clinical decisions impacting patient clinical care.

In addition, if the ASTP/ONC could limit and refine source attribute expectations for PDSI (currently, 31 source attributes must be listed for PDSI models), that would further streamline PDSI model development. Clarity on the definitions of "supports decision making" and "supplied by" as part of the HTI-1 Final Rule would also be useful to health IT developers and vendors. One potential avenue to streamline source attribution would be to introduce a "Federal Model Card" that describes an AI model's key characteristics. This would ease the burden associated with certification and align with private sector practices already widely in use.

The ASTP/ONC HTI-1 Final Rule notes that source attributes are not intended to require the disclosure of confidential or proprietary information. However, third parties that are not subject to ASTP/ONC requirements on their own are sometimes reluctant to provide health IT vendors the information necessary for certification processes, citing concerns about sharing proprietary information. If third party industries had transparency requirements that mirrored source attributes there would be less pushback on sharing the information and all necessary information would already be gathered and formatted in a usable format, which would expedite the process for covered health IT developers. Additionally, whether the information for source attributes is reqested of third parties or developers themselves, much of it could be considered proprietary. Any innovator would be wary of submitting proprietary information, potentially stifling innovation in this sphere.

Given that there are many issues with the certification criteria as it currently stands, another avenue for action would be to eliminate the criterion altogether. While well-intentioned, the certification of these technologies was not structured well and has limited utility for clinicians and patients – rather it represents a complex structure dreamed up by Washington technocrats.

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Finally, there should be greater clarity on the overlap and/or distinctions between the ASTP HTI-1 Rule PDSI analysis and requirements and FDA non-device clinical decision support software guidance. Currently these differing requirements are not aligned to one another, creating a difficulty for health IT developers and vendors. As AI continues to be considered within regulatory structures, we urge OSTP and other agencies to align new requirements with existing ones, especially those in use at the FDA. One example of a way to do this now would be to standardize transparency requirements or for ASTP/ONC to provide a perspective on whether all PDSI are FDA non-device clinical decision support.

FDA Regulation of AI-enabled Medical Devices

FDA has the existing predetermined change control plan (PCCP) structure for AI-enabled medical devices so that a device may be approved for iterative changes post-clearance. This allows AI-enabled devices to evolve within bounds over time, rather than have to go through an entire approval process each time it is modified. However, the flexibility and value of this pathway is not reaching its full potential at the present time. FDA has been reticent to agree to a wider variety of evolutionary pathways for AI-enabled devices, limiting the utility of the PCCP pathway. Obviously, there need to be appropriate safeguards and guardrails for AI/ML models to evolve when used in a medical device, but FDA also needs to allow room for innovators to innovate. The FDA has spent appreciable resources in standing up the PCCP pathway, and should continue to engage with stakeholders to make the process work to its fullest potential.

Another development in the realm of regulation of AI-enabled medical devices is that foreign governments have begun implementing plans to expand regulation to software solutions that have not historically been considered medical devices. A prime example is the United Kingdom's move to deem AI medical scribe technology as a medical device. This is problematic because the UK is taking a technology-specific approach to a use case that can be achieved via multiple means – scribe in the room; scribe off shore; AI scribe – and for a non-medical device indication of use. This type of structure represents an overreach of existing medical device regulatory structures and a significant barrier to deployment of proven AI solutions. We urge OSTP to ensure the same mistake is not replicated by the FDA in the future.

FedRAMP Certification

The FedRAMP certification process exists for a reason, in that software and cloud solutions need to be vetted before they are used by federal agencies. However, the current system is inflexible. Through the current process, as innovators attempt to incorporate AI features, there are significant recertification processes that are required, which can impede and hinder innovation. Under current NIST guidelines, these certification processes do not allow enough room for innovation and will severely impact the way novel technologies will be developed and used. One potential option would be for OSTP to encourage agencies to consolidate the myriad of data centers that are agency-specific, and engage with commercial cloud providers that are already certified. Not only would this lessen certification bottlenecks, it would also enable agency access to more sophisticated AI tools that are on offer from private cloud providers.

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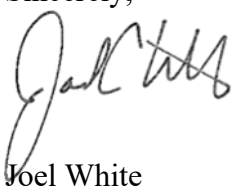
Conclusion

We thank OSTP for the opportunity to respond to this RFI, and we look forward to working with you to reform current regulations and establish a new framework to bolster AI and continue innovation in the healthcare sector.

Sincerely,



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