ALLIANCE for CONNECTED CARE

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RE: Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper

Dear Dr. Tarver and Dr. Abramson,

The Alliance for Connected Care is pleased to provide feedback on the Considerations for the Regulation of Generative AI-Enabled Medical Devices discussion paper. The Alliance has consistently urged federal policymakers to recognize AI-enabled care as a natural evolution of connected care and to avoid creating new technology-specific barriers where existing clinical standards and regulatory frameworks can appropriately address patient safety. FDA should similarly ensure that its approach to GenAI-enabled devices preserves longstanding distinctions between medical-device functions and the broader delivery of health care, while allowing technologies to evolve as clinical capabilities and care models advance.

The Alliance for Connected Care ("The Alliance") is dedicated to improving access to care through the reduction of policy, legal, and regulatory barriers to the adoption of connected care capabilities, including telemedicine, remote monitoring, and AI-enabled care. Our members are leading healthcare and technology organizations from across the spectrum, representing health systems, health payers, technology innovators, and patient and provider groups, including clinician specialty and patient advocacy groups seeking to expand high-quality care through connected care technologies.

Our overarching position is that FDA should preserve existing statutory distinctions between regulated medical-device functions and non-device software functions, while applying risk-based, proportionate oversight to GenAI-enabled functions that meet the definition of a medical device. The use of GenAI, should not, by itself, determine a function's regulatory status. For functions subject to FDA oversight, regulatory expectations should reflect intended use, clinical consequences, degree of autonomy, and the effectiveness of available safeguards. The agency is in a critical position to establish a framework that accommodates dynamic technologies without unnecessarily applying regulatory approaches designed principally for static products.

In advance of our detailed comments, the Alliance:

- **Supports a function-based, risk-proportionate approach**. FDA oversight should reflect intended use, degree of autonomy, clinical consequences, and the demonstrated effectiveness of available safeguards, including meaningful clinician review, rather than the use of generative AI itself.
- **Urges the FDA to evaluate GenAI in the clinical workflow in which it is designed to operate**. For regulated GenAI-enabled device functions, evaluation should account for the environment in

which the technology is intended to operate, including clinician participation, established clinical protocols, escalation pathways, and other safeguards.

- **Cautions the FDA from conflating non-device AI-enabled care with regulated medical-device functions**. Care coordination, patient engagement, documentation, administrative support, and other AI-enabled care-delivery activities should continue to be assessed according to their specific intended functions and applicable statutory exclusions. These activities should not become subject to medical-device regulation solely because increasingly capable GenAI or agentic technologies support their delivery. Conversely, an AI-enabled function intended to independently perform a regulated medical purpose should remain subject to appropriate FDA oversight.
- **Urges the FDA to use flexible, real-world evidence pathways**. Evidence requirements should reflect the intervention's actual risk and should make use of real-world evidence generated through normal clinical practice where appropriate.
- **Encourages regulation of GenAI to not only evaluate specific risks/functions but also broader implications of its availability**. These include the potential to increase access to care, supplement provider shortages, identify and reduce diagnostic errors, capture missed patient engagements, etc. An imperfect capability must be weighed against a patient unable to access care.
- **Encourages the creation of clear, workable delineations and regulatory tools to manage shared responsibility between foundation model developers and device deployers.** Clear, proportionate regulation can give developers and healthcare organizations confidence in the standards governing these tools and allow beneficial technologies to reach clinical practice more quickly. Responsibilities should correspond to each actor's control over design, validation, implementation, monitoring, maintenance, and risk mitigation.

The Alliance offers the following detailed comments on risk assessment, competency-based premarket evaluation, postmarket monitoring, lifecycle accountability, and agentic AI systems.

Assessment of Risk for GenAI-Enabled Devices

The Alliance cautions FDA against assuming that patient-facing GenAI-enabled technologies are inherently high risk or establishing a blanket requirement for clinician review of every patient interaction. Whether a patient-facing function constitutes a medical device should be determined under existing statutory standards, including its intended use and applicable exclusions. For patient-facing functions that are medical devices, the appropriate level of oversight should reflect the nature of the clinical information or recommendation, potential consequences of error, degree of autonomy, and effectiveness of available safeguards. Human oversight may be essential for certain high-risk functions, but direct clinician review should not be presumed necessary for every interaction or every device function.

The Alliance generally supports FDA's proposed two-axis framework based on the degree of device activity and the consequences of an incorrect output. In applying this framework, FDA should consider both the magnitude and likelihood of potential patient harm, along with the device's intended use, clinical context, and effectiveness of available safeguards. Additionally, risk should be evaluated both at the level of individual clinical actions and cumulatively across an episode of care, recognizing that the ability to identify and correct an error before harm occurs can materially affect its consequences. Notably, in this circumstance there is both risk from under-escalation and over-escalation. Failure to escalate a critical care need presents a potentially serious patient-safety risk, while unnecessary escalation can create access

and workflow challenges; these consequences should be evaluated according to their respective clinical significance rather than weighted equally.

Patients with complex acute or chronic conditions may require ongoing access to clinical expertise, but not every interaction requires direct clinician involvement. Patient engagement, health literacy, remote care, and access can be improved substantially through appropriately designed AI-enabled technologies. Some of these capabilities may operate outside FDA's medical-device framework, while others may involve regulated device functions that support clinical care. For functions subject to FDA oversight, evaluation should focus on the nature and consequences of the clinical activity, the evidence supporting its intended use, and the effectiveness of applicable safeguards, rather than assuming that every patient-facing interaction requires clinician review.

For GenAI-enabled care escalation functions, the Alliance encourages FDA to work with clinicians who routinely balance the risks of under-escalation and over-escalation through established clinical protocols, risk stratification, professional judgment, and ongoing patient reassessment. Clinical practice does not require escalation for every concern, but knowing the appropriate intervention based on the severity of symptoms, individual patient risk, and available care pathways is vital to the correct decision. Evaluation of GenAI-enabled escalation functions should reflect these established principles, including comparison against clinically appropriate decisions, consideration of patient outcomes, and recognition of the role of longitudinal monitoring and follow-up. FDA should avoid evaluation standards that incentivize unnecessary escalation or presume that direct clinician involvement is necessary for every patient interaction.

Importantly, the Alliance recognizes that AI-enabled escalation functions may present different regulatory considerations depending on their intended use. A capability that facilitates communication or routes information according to established operational procedures may differ from a function intended to analyze patient-specific clinical information to identify a medical emergency or recommend treatment. Where an escalation function constitutes a medical device, FDA should assess whether the underlying clinical protocols, performance evidence, and opportunities for clinician intervention sufficiently mitigate the risks associated with the function. Clinician involvement should be recognized as an important safeguard where meaningful, but should not substitute for appropriate validation of the regulated device function itself.

As FDA evaluates the benefits and risks of GenAI-enabled medical devices, it should consider both the risks introduced by the technology and the consequences of delayed, unavailable, or unaffordable care. These technologies may reduce costs, expand clinical capacity, and improve access where timely care is otherwise limited. As you know, it is common for patients to turn away from the health system if it is not able to meet their needs immediately. For regulated device functions, these considerations should inform the selection of clinically appropriate comparators and the assessment of potential patient benefits, while preserving evidentiary requirements necessary to establish safety and effectiveness. A technology need not demonstrate perfect performance to provide meaningful clinical benefit, but its performance must be supported by evidence appropriate to its intended use and potential consequences of error.

Competency-Based Approach for Premarket Evaluation of GenAI-Enabled Devices

The Alliance generally supports FDA's proposed competency-based approach in principle, so long as the framework is flexible, risk-based, and tailored to the intended use of regulated device functions. Importantly, competency-based evaluation should not alter the threshold determination of whether a software function constitutes a medical device under existing law.

For GenAI-enabled functions that are medical devices, FDA should recognize that clinical services are often delivered through integrated care models in which clinicians, established clinical protocols, escalation pathways, and other safeguards contribute to patient safety. Evaluation should therefore consider how a device performs within its intended clinical workflow rather than assessing its technical capabilities in isolation. The relevance of clinician oversight should depend on its demonstrated ability to mitigate the specific risks associated with the device, including whether clinicians have sufficient information, time, and authority to recognize and address inappropriate outputs.

- For regulated device functions with lower clinical risk and effective safeguards, retrospective analysis of real patient data, clinician adjudication, simulation, shadow deployment, and evidence from established clinical validation and quality assurance processes may provide sufficient evidence of safety and effectiveness, depending on the intended use and applicable regulatory requirements. These approaches may be particularly relevant for certain technologies supporting remote patient monitoring, chronic disease management, clinical communication, and care escalation. Experience with clinical laboratory validation illustrates the importance of recognizing existing quality assurance processes and avoiding duplicative regulatory requirements that could limit access to specialized services, while maintaining appropriate evidence of device safety and effectiveness. The appropriate level of evidence should be determined by the function's clinical risk and the effectiveness of its safeguards, rather than the presence of clinician supervision alone.
- For regulated device functions presenting greater potential for patient harm, including functions that independently direct consequential clinical decisions or treatment, more rigorous evidence may be appropriate. Greater scrutiny may also be warranted where clinician review is nominal, unlikely to identify errors, or unable to prevent harm before a recommendation is acted upon. FDA should evaluate the practical effectiveness of clinical oversight rather than relying solely on whether a human is formally involved in the workflow.

For example, an AI-enabled device that identifies potential deterioration in a remotely monitored patient's condition and alerts a clinical care team may warrant different evidentiary requirements than an autonomous device that initiates treatment without clinician involvement. However, the risk associated with an alerting function will also depend on the severity of the condition being monitored, the consequences of missed or inaccurate alerts, the timeliness of clinical review, and the availability of effective safeguards. These considerations should inform the appropriate level of clinical validation rather than assuming that all clinician-supervised monitoring functions carry minimal risk.

The Alliance encourages FDA to adopt a technology-neutral approach to evaluating GenAI-enabled devices, focusing on intended use, clinical performance, patient safety, and real-world outcomes rather than the specific tools or algorithms used to deliver care. For technologies intended to augment clinical judgment, evaluation should consider the performance of the clinician-AI team within the intended workflow, rather than the AI system in isolation. As referenced above, these outcomes should be measured

against real-world scenarios – including those in which there are barriers or delays in patient access that would be addressed by the expansion of the capability. This approach will provide the flexibility necessary to accommodate continued technological innovation while maintaining appropriate patient protection.

Real-world evaluation should reflect how patients interact with these technologies over time. Individuals managing complex chronic conditions may generate frequent monitoring data, symptom reports, or questions that do not necessarily require direct physician intervention. Evaluations should therefore assess whether GenAI-enabled technologies appropriately distinguish routine needs from clinically significant changes that warrant escalation. Clinical evaluation should reflect the distribution of routine real-world interactions, while safety-focused benchmarking should deliberately emphasize less common, high-risk scenarios in which errors could result in significant patient harm.

Existing care delivery models rely on multidisciplinary care teams, standardized clinical protocols, remote patient monitoring, and established escalation pathways to manage patients safely and effectively. For example, where a device's safe use depends on clinician review, testing should consider whether clinicians can reliably recognize inaccurate or inappropriate outputs, obtain the information necessary to exercise independent judgment, and intervene before patient harm occurs. The presence of a clinician in the workflow should not, by itself, be considered sufficient evidence that the relevant risks have been mitigated. As such, the Alliance encourages FDA to adopt a proportionate approach that recognizes the value of real-world evidence, supports clinically appropriate escalation, and avoids unnecessary regulatory barriers to technologies that improve patient access, engagement, and continuity of care.

Postmarket Monitoring Approaches

The Alliance generally supports a flexible, risk-based regulatory framework. Unlike traditional medical devices, some GenAI-enabled technologies have the potential to continuously improve through real-world experience, clinician feedback, and advances in clinical knowledge. Requiring these systems to remain frozen at a particular point in time could prevent beneficial improvements, perpetuate known limitations, and ultimately compromise patient safety.

The Alliance encourages FDA to allow robust postmarket monitoring to support greater flexibility in the type and extent of premarket evidence required, where appropriate to the device's clinical risk and demonstrated safeguards. The level of acceptable premarket uncertainty should be proportionate to the device's intended use, degree of autonomy, potential consequences of errors, and demonstrated ability to detect and mitigate emerging risks. Devices operating within established clinician-supervised workflows may be particularly well suited to greater reliance on postmarket monitoring when the effectiveness of those safeguards has been established and the consequences of errors can be appropriately managed. However, clinician supervision alone should not justify reduced premarket evidence requirements for functions presenting substantial risks of patient harm.

We encourage FDA to recognize continuous learning from clinician review and corrections as a fourth monitoring approach**.** When clinicians review, modify, reject, or override AI-generated outputs, those actions can provide valuable signals about system quality, clinical appropriateness, and opportunities for improvement. Such feedback should be systematically captured and analyzed, with appropriate consideration of the clinical context and whether the clinician's modification reflects an actual error, a patient-specific judgment, or a difference in clinical practice. This approach could be particularly valuable

for AI-enabled technologies supporting longitudinal care, remote monitoring, clinical decision support, and patient engagement.

The Alliance supports a collaborative approach to postmarket monitoring that draws on the expertise of developers, clinicians, healthcare institutions, professional societies, and standards-setting organizations. However, meaningful clinical oversight requires time, expertise, and resources that may not be equally available across healthcare settings. FDA should consider these practical constraints when evaluating proposed monitoring approaches and encourage manufacturers to provide the information and tools necessary for safe implementation and oversight. Monitoring expectations should remain proportionate to clinical risk and should not create unnecessary barriers for smaller or regional providers.

AI software and applications can involve multiple actors with control over different phases of the lifecycle, including foundation-model development, device design and validation, deployment, local configuration, monitoring, maintenance, and modification. Without clear regulatory expectations, this distribution of control can create gaps in information sharing, risk management, and corrective action.

Although questions of civil liability may fall outside FDA's jurisdiction, clearer allocation of regulatory responsibilities can reduce uncertainty for manufacturers, model developers, health care organizations, and clinicians. FDA should clarify the obligations of each regulated actor when agentic systems incorporate third-party foundation models or tools, while avoiding requirements that inappropriately transfer product-related responsibilities.

The Alliance encourages FDA to clearly assign responsibility to the parties that control each risk and are best positioned to prevent harm. Device manufacturers should remain accountable for product design, validation, safety, effectiveness, labeling, change management, and applicable postmarket obligations. Healthcare organizations should remain accountable for the safe implementation within their control – such as clinical operation of these technologies within their care environments, including appropriate oversight and monitoring of deployment-related risks. Where product-related and deployment-related risks intersect, FDA should clarify expectations for shared risk management, information sharing, and corrective action, while preserving each party's responsibilities under existing law.

FDA should provide greater clarity on how existing regulatory tools can support appropriate information sharing, lifecycle accountability, and modifications to GenAI-enabled devices. There are a number of reasonable steps FDA can consider to facilitate these interactions that have been discussed in FDA public meetings.

- FDA should promote risk-proportionate, clinically meaningful labeling and transparency that enables clinicians and healthcare organizations to understand a device's intended use, material limitations, performance characteristics, and necessary safeguards. Transparency expectations should reflect the clinical function and risk as well as any need for specialized training.
- FDA should leverage existing regulatory pathways, including Predetermined Change Control Plans (PCCPs), to accommodate modifications to GenAI-enabled devices without unnecessary additional submissions. Where a regulated agentic function relies on a third-party foundation model, manufacturers should have appropriate controls to evaluate material model updates before they affect clinical use. FDA should clarify when such updates constitute device modifications, when

they may be addressed through a PCCP, and what proportionate validation, notification, monitoring, and rollback capabilities are appropriate.

- FDA should encourage clear information-sharing and safety-reporting arrangements among device manufacturers, foundation-model developers, and healthcare organizations, while building on existing adverse-event reporting and quality-management systems. Expectations should reflect each actor's control over the relevant information, avoid duplicative reporting obligations, and clearly distinguish manufacturers' product-related obligations from healthcare organizations' responsibilities for safe clinical deployment.

Regulatory ambiguity can leave healthcare organizations uncertain about their responsibilities and potential liability when deploying AI-enabled technologies, particularly where product-related and deployment-related risks overlap. FDA should also make clear that clearance or authorization provides a reasonable basis for health care providers to rely on the device's disclosed performance within its authorized use. Regulatory uncertainty can deter adoption, especially among organizations with limited resources. Clear, proportionate regulation that establishes manufacturer accountability alongside healthcare organizations' responsibility for safe clinical deployment can support confidence in these technologies and allow beneficial innovations to reach patients more quickly.

Agentic AI Systems

The Alliance encourages FDA to adopt a function-based, risk-proportionate approach to agentic AI that recognizes both the potential risks of increased autonomy and the opportunities these technologies present to improve care coordination, clinical follow-up, and patient outcomes.

FDA should first determine whether the individual functions performed by an agentic system constitute medical-device functions under existing law. The ability to autonomously perform multiple steps, interact with external tools, or operate within a clinical care environment should not, by itself, establish that every function within the system is a regulated medical device.

For functions that qualify as medical devices, FDA should assess risk based on the nature and immediacy of clinical actions, the potential consequences of errors, reversibility, and the effectiveness of available safeguards. For example, an agent that autonomously schedules follow-up appointments, collects information, or facilitates communication with a care team may perform functions that are not medical devices, while a function that independently interprets clinical data to make diagnostic or treatment decisions may warrant FDA oversight. The regulatory status and appropriate oversight of each function should depend on its specific intended use, not simply its integration into an agentic system.

As mentioned above, these systems should be evaluated across episodes of care, rather than on individual interactions. A capability that can recognize deterioration, support appropriate adjustments within its authorized scope, and escalate to a provider when needed should be evaluated differently from a tool that provides an isolated recommendation without the ability to respond to subsequent patient needs.

Where an agentic system includes regulated functions, FDA should recognize that meaningful human oversight may be accomplished through established clinical protocols, defined escalation thresholds, ongoing performance monitoring, and the ability of clinicians to intervene when warranted. Requiring clinician review of every intermediate step should not be presumed necessary when other safeguards have

been demonstrated to manage the relevant risks effectively. This flexibility is particularly important for remote monitoring and longitudinal care models designed to identify patient needs and support timely intervention between clinical encounters.

The Alliance appreciates FDA's consideration of these comments and welcomes continued engagement as the agency develops a risk-based, least-burdensome, and lifecycle-oriented approach to GenAI-enabled medical devices. We encourage FDA to preserve flexibility for beneficial innovation while establishing clear expectations for evidence, monitoring, transparency, escalation, and accountability. Please feel free to reach out to rikki.cheung@connectwithcare.org with any questions or to schedule a conversation with our membership.

Respectfully submitted,



Executive Director