Simbex

August 14, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Re: Request for Public Comment
Increasing Patient Access to Home Use Medical Technologies

CDRH Question: How can the FDA support the development of medical technologies, including digital health technologies and diagnostics, for use in non-clinical care settings, such as at home?

Simbex Response: Simbex is a Medical Device Design and Development company that provides engineering and strategy consulting to innovators. We specialize in medical device development for digital health, and many of our clients are developing products that are intended for use in home health applications. As such, we have closely observed the challenges and opportunities in supporting the development of medical technologies for non-clinical care settings, such as at home.

One area we frequently encounter as a consulting firm is the challenge faced by digital health innovators regarding coverage and reimbursement of their medical technologies. Despite receiving FDA approval, many medical technologies struggle to secure adequate coverage, particularly for home-use devices that do not fit into existing benefit categories. We understand that new pathways such as Translation Coverage for Emerging Technologies (TCET) are opening up to enhance the collaboration between regulators and payers such as the Centers for Medicare and Medicaid Services (CMS). We are encouraged by this and would like to see more programs that encourage parallel review of clinical evidence to support the availability and accessibility of medical technologies for all populations, irrespective of their geographic location or economic status. Encouraging pathways for discussion between regulatory agencies and payers can facilitate better alignment between regulatory approval and reimbursement, thus incentivizing companies and capital to invest in the development of cutting-edge home health technologies.

Another area where we have observed room for improvement is providing clarity around the regulatory process for low-risk devices. We often work with innovators who are developing medical devices that fall under the 510(k) exempt category and only require registering and listing with the FDA. This is a confusing process to navigate as a first-time entrepreneur. We theorize that clarifying the regulatory requirements for these devices would result in accelerated market access, reduced compliance burden, and encourage more companies to invest in developing medical technologies for non-clinical care settings.

Additionally, we have noticed a need for more guidance around Software as a Medical Device (SaMD) designed for use at home (most of the existing material is focused on SaMD for healthcare facilities). SaMD plays a vital role in the digital health revolution, particularly in home health applications where patients actively engage in self-monitoring and management of their health conditions. We believe that providing specific guidelines for home-use SaMD can ensure that these technologies adhere to robust data privacy and security standards while also offering interpretable outputs for patients and healthcare

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providers. By addressing these critical factors, we can increase access to SaMD for home use, enabling both patients and healthcare professionals to take advantage of these innovative tools for remote patient monitoring and care.

A growing trend that we have observed is the rapid influx of medical devices for use in home environments that contain artificial intelligence (AI) capabilities. By analyzing vast amounts of patient data, AI algorithms can provide real-time insights, enabling more accurate and early diagnoses, personalized treatment plans, and continuous monitoring of chronic conditions. This has the potential for transformative impact, but innovation in this space can easily outpace regulatory frameworks. Through our interactions with digital health innovators, we have witnessed the desire to leverage AI capabilities to enhance the effectiveness of medical technologies for patient treatment. However, we have also observed how existing regulatory requirements can sometimes limit the full potential of AI in these devices, hindering optimal patient care. Many of the innovators we collaborate with express the desire to leverage AI's potential to enhance the effectiveness of their products for patient treatment. However, they often find themselves constrained by existing regulatory requirements, leading to the need to compromise on the full potential of the AI portion of their products.

One prominent challenge our clients face revolves around data privacy and security. As AI-powered devices rely on sensitive patient information to provide personalized care, complying with data privacy regulations while ensuring data accessibility for AI algorithms can be intricate. Striking the right balance between data privacy and performance is essential to build trust among patients and healthcare providers. In addition to data security, the transparency of the training methods of AI algorithms is another obstacle that impacts our clients' product development process. AI models often produce complex outputs that are difficult to interpret, raising concerns about the clarity of decisions made by these devices, particularly in critical healthcare scenarios. Finding ways to create more trustworthy and interpretable AI models is vital to boost acceptance and adoption among healthcare professionals and patients. FDA guidance on best practices for AI development could help to standardize this evolving frontier.

Continuous learning, a fundamental aspect of AI, is crucial for device improvement over time. However, this continuous learning feature also introduces regulatory challenges concerning device validation and updates. Our clients often grapple with finding a balance between iterative updates that enhance device performance and ensuring that these modifications do not compromise safety and efficacy. This is an area that will require constant updating of regulations and we encourage the FDA to continue their focus in this space.

Despite these challenges, we firmly believe that encouraging responsible AI adoption is essential for fostering innovation in digital health and unlocking the full potential of AI-driven devices in non-clinical care settings. As a consulting firm, we advocate for collaboration with regulatory authorities, industry stakeholders, researchers, and patient advocacy groups to expeditiously bridge the gap between technological advancements and regulatory requirements. By actively engaging in dialogue with regulatory agencies, we are working to establish a supportive environment that enables digital health innovators to leverage AI capabilities to their fullest potential while adhering to stringent safety and

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efficacy standards. Addressing regulatory challenges, such as data privacy, algorithm transparency, and continuous learning, can help to empower effective innovation, ultimately enhancing patient treatment and improving the overall quality of care delivered in home health settings.

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