FDA authorizes first Software as a Medical Device incorporating a patient-facing LLM

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Digital health company UpDoc announced that it received Food and Drug Administration approval for what the company describes as the first Software as a Medical Device ("SaMD") incorporating patient-facing large language models for medication management purposes. The UpDoc platform, designed on previously approved tools to assist in management of type 2 diabetes medication, integrates with electronic health records and existing clinical workflows and allows patients to submit information to produce treatment plans generated in accordance with clinician-defined protocols.

While this clearance indicates the FDA's willingness to authorize certain AI-enabled clinical tools, it does not establish a required approval pathway for all LLM-based healthcare products. Federal and state regulators continue to pursue multiple oversight approaches to regulating AI in health care, including an increasing number of states expressing interest in facilitating patient access to AI-enabled care through regulatory sandbox programs. Entities developing clinical and patient-facing AI technologies should consider governance and legal strategies calibrated to the specific intended use of the product at issue, as well as the implementation of protocols sufficient to demonstrate the safety, effectiveness, and reliability of the underlying AI technology.