DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

UNITED STATES Regulatory

Category Name	Medical Device—includes Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD)		
Responsible Regulatory Agency	Food and Drug Administration (FDA), specifically the Center for Devices and Radiological Health (CDRH)		
Product Risk Classifications	**Exempt Medical Devices** Class I Exempt, Class II Exempt, or Enforcement Discretion (including COVID-19 public health emergency (PHE))	**Class II** Pre-market Notification 510(k) or De Novo pathways	**Class III** Premarket Approval (PMA)
Regulatory Review	Exempt from a marketing submission: Most Class I and some Class II devices are 510(k) exempt devices, but must register and list. Enforcement discretion devices may not be required to register and list. Enforcement discretion is a risk-based decision by FDA to decline enforcing certain regulatory requirements and is not specific to a classification.	510(k): Marketing submission required to demonstrate substantial equivalence to predicate device. General controls are required. Special controls may also be required, which may require a clinical trial (see regulation to determine requirements). De Novo: Marketing submission required to demonstrate reasonable assurance of safety and efficacy. General controls are required. Prospective clinical trial generally required.	PMA: Most stringent market submission application to demonstrate safety and effectiveness. General controls are required. Prospective clinical trial generally required.
Pre-Submission Opportunities	513(g) can be submitted to confirm the regulatory pathway, but is not required: *Timeline: 60 days* *Cost: $2,530 small business* / $5,061 standard*	Pre-submission strongly recommended, especially for De Novo: *Timeline: 70 days* *Cost: no charge* 513(g) may be submitted to confirm regulatory pathway. Breakthrough Devices request may be possible for highly innovative products: *Timeline: 60 days* *Cost: no charge*	Pre-submission strongly recommended. Pre-IDE should be submitted for feedback on significant risk clinical studies. 513(g) may be submitted to confirm regulatory pathway. Breakthrough Devices request may be possible for highly innovative products.
FDA Guidelines To Be Met	General Controls, which includes establishment registration and medical device listing (21 CFR Part 807), Quality System regulation (21 CFR Part 820), and labeling requirements (21 CFR Part 801) prior to marketing the product. Exempt devices under COVID-19 PHE are subject to other requirements.	General Controls, as outlined in the prior column. Special Controls, as determined by FDA. Special Controls are specific to each device and relevant predicates. May include performance standards, premarket data requirements, post-market surveillance, patient registries, special labeling requirements, and adherence to other guidelines.	General Controls and premarket authorization required, which will specify any conditions to approval.
Other Relevant Guidelines	**Health Insurance Portability and Accountability Act (HIPAA):** protects the privacy and security of certain health information. **Federal Trade Commission Act (FTC Act):** prohibits deceptive or unfair acts, including false or misleading claims about apps' safety or performance. **FTC's Health Breach Notification Rule:** requires certain businesses to provide notifications following breaches of personal health record information.		
Product Recognition	Exempt Medical Devices: FDA Listed (if there is a product code) Exempt devices under COVID-19 PHE do not list	510(k): FDA Cleared De Novo: FDA Granted	PMA: FDA Approved
Approximate Timing For Process Completion	Immediate	510(k): 177 calendar days De Novo: 235 calendar days	PMA: 243 calendar days
Cost	$5,672 annual registration fee; no charge for listing	Annual registration fee + 510(k): $3,186 for small business* / $12,745 standard De Novo: $28,114 for small business* / $112,457 standard	Annual registration fee + $93,714 for small business* / $374,858 standard + Annual Fee for Periodic Reporting $13,120 standard/$3,280 SB*

*Small businesses are < $30M in gross receipts or sales

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UNITED STATES Reimbursement

		Exempt DTx Medical Devices/ Enforcement Discretion *Through the use of a unique device identifier (UDI) code.*	Regulated Medical Devices (Class II & Class III) *Products may or may not require a prescription.*
Public Insurance Coverage	• Medicare generally does not pay for software-only products due to no existing appropriate benefit category. Medicare Advantage has more flexibility in product coverage (about 40% of Medicare recipients have Medicare Advantage). • Medicaid programs and Medicaid managed care plans can consider fee-for-service product coverage pathways or coverage via specific benefit programs (i.e., CHIP, EPSDT) on a state-by-state basis. • Department of Defense (i.e., Veteran's Affairs) is beginning to cover some DTx products with a hardware component.		
Private Insurance Coverage	**Unit by Unit or Fee-for-service**	Pharmacy benefit — yes Medical benefit — yes	Pharmacy benefit — yes Medical benefit — yes
	Manufacturer as the provider *(Durable Medical Equipment (DME) or a credentialed provider)*	Yes, but limited	Yes
	Provider reimbursement *CPT® (Current Procedural Terminology) codes (i.e., Remote physiologic monitoring (RPM), Remote therapeutic monitoring (RTM))*	Yes, but limited	Yes
	Device & Drug Combination or Companion Products	Yes, but limited	Yes
Private Insurance Coverage & Employer-Sponsored Healthcare	**Programmatic Spend**	Yes, through direct negotiation Examples include: per member per month (PMPM)/per employee per month (PEPM) models, per engaged member per month (PEMPM) models, value-based contracts, unit x unit	
Consumer-Funded	**Out of pocket**	Yes, a possible pathway	Yes, even though initial authorization for the product or a prescription could be required

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Note: This document represents pathways that continue to evolve. It does not provide legal advice.

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