Weill Digital Health Series

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DIGITAL HEALTH: UNDERSTANDING THE FDA REGULATORY LANDSCAPE

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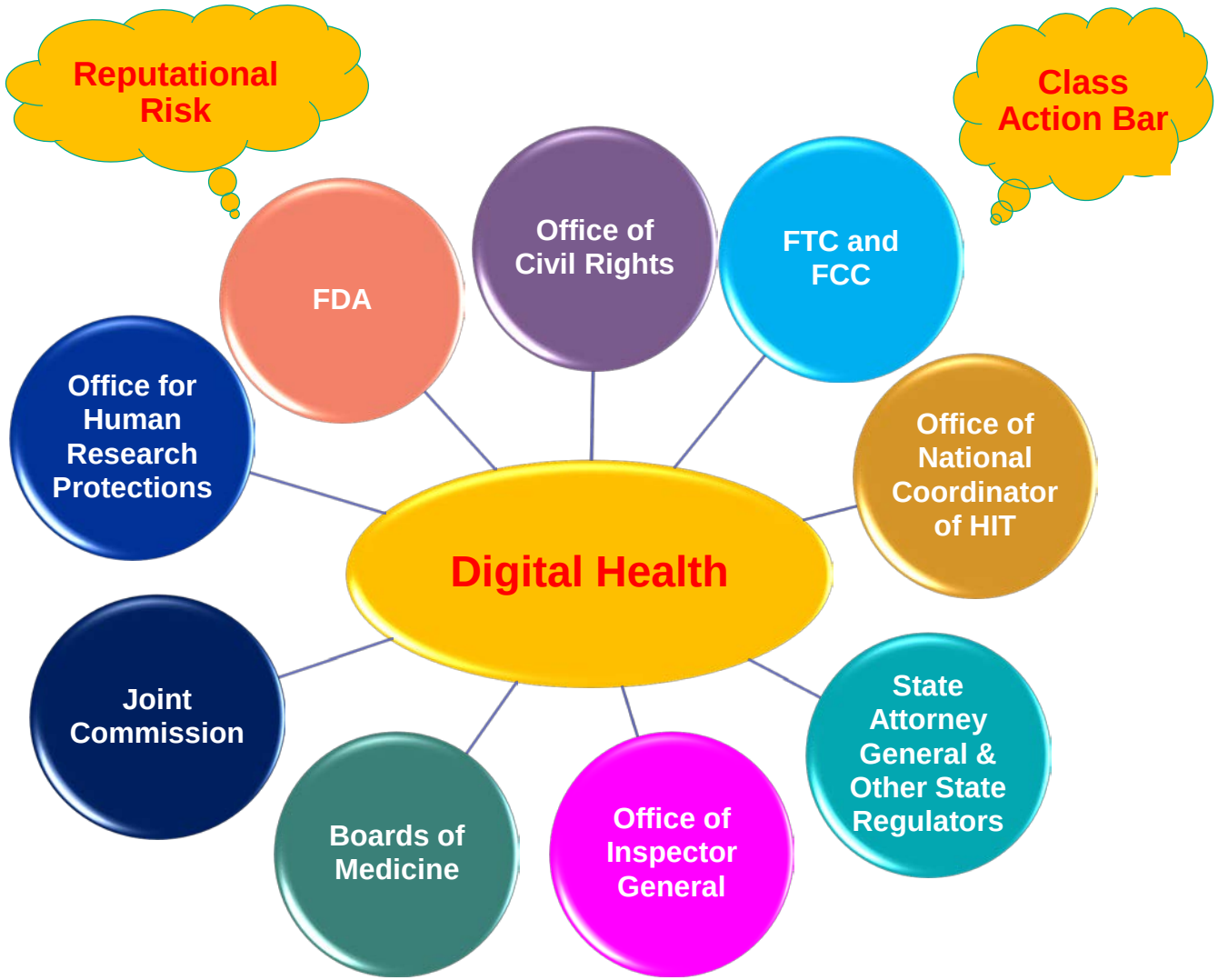
NEW PARADIGM FOR HEALTHCARE: THE “CONNECTED” PATIENT

Consumer/Patient
- Wearable Biometric and Behavioral Data tracking (Medication reminders, BP, Heartrate, etc.)
- Communication with HCP
- Control and Monitoring of Auxiliary Medical Devices

DIGITAL HEALTH – THE PERFECT STORM OF OPPORTUNITY AND RISK

- Opportunities
  - Advancing Patient Engagement in Care
  - Connecting HCPs to Underserved Patient Populations
  - Harnessing Data and Analytics to Improve Care
  - Innovative Collaborations & Partnerships
- Risks
  - Many Regulators with Divergent Priorities
  - Product Safety and Effectiveness
  - General Privacy and Security
  - Financial Relationships & Pricing
  - Slow Market Adoption



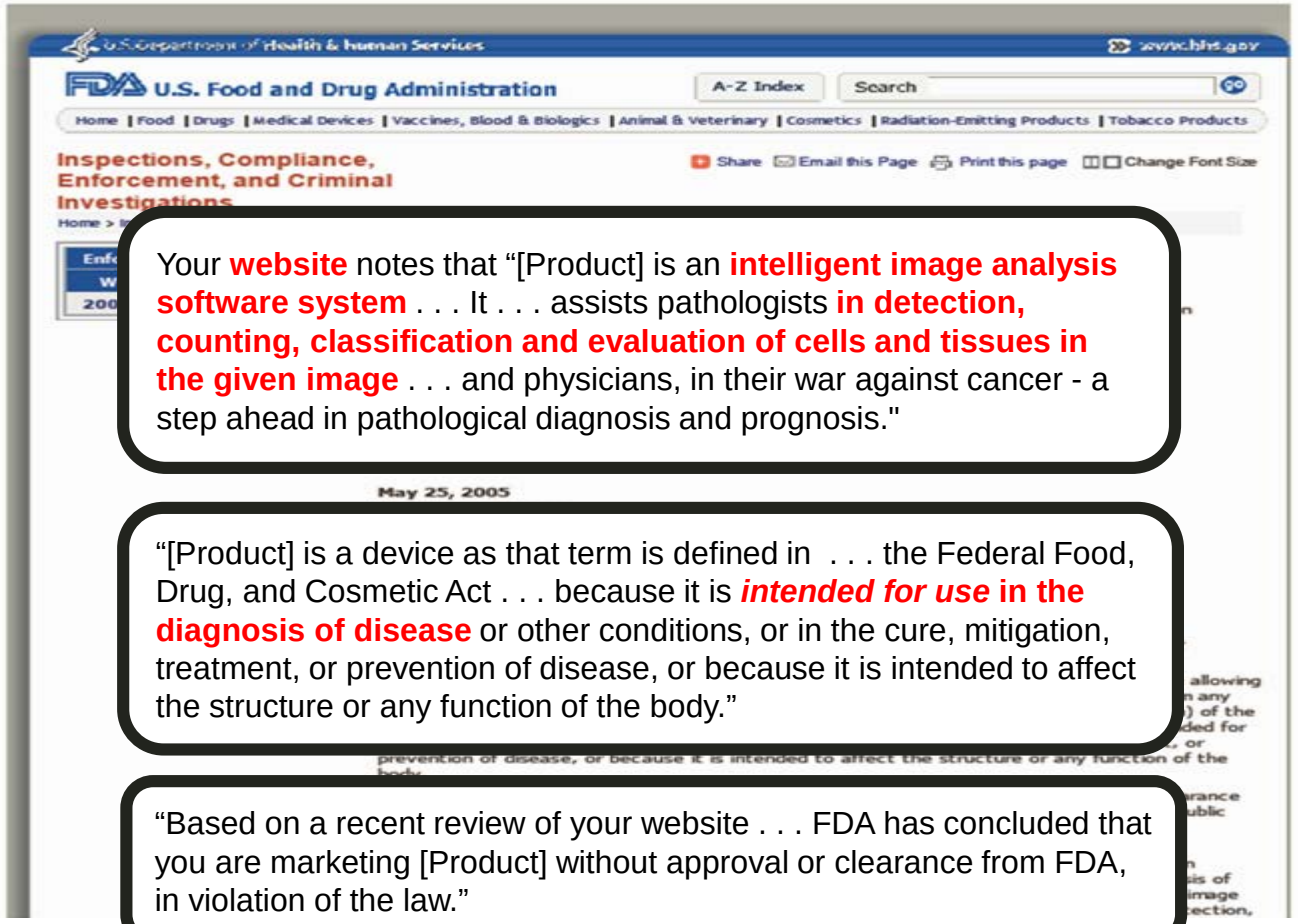
FDA'S DIGITAL HEALTH REGULATORY PRIORITIES

1. **New Market Pathways for Software as a Medical Device (SaMD)**
   - Breakthrough Device pathway increasingly available for digital health products
   - Digital Health Pre-Certification pathway designed to expedite the premarket review process
2. **Interoperability and compatibility of "connected" devices**
   - Emphasis on ensuring that connected devices are tested and validated to work and perform when connected to or through other devices, hardware, or software
3. **Cybersecurity and Privacy**
   - Recent recalls and safety issues related to data breaches and "hacking" of life-sustaining and other devices are prompting greater oversight of medical device cybersecurity
4. **Labeling, Advertising and Promotion**
   - Emphasis on ensuring that labeling and instructions for use are clear and appropriate, particularly for novel or innovative devices
   - Emphasis on preventing fraudulent "cures" or deception of consumers or healthcare providers
   - FTC and states stepping in to regulate health and wellness software

"INTENDED USE" DETERMINES REGULATORY STATUS OF A PRODUCT OR SOLUTION: *FDA WARNING LETTER EXAMPLE*

Intended use refers to the "objective intent" of the persons legally responsible for marketing the product, and is shown by labeling, promotional statements, other statements made by or on behalf of the marketer, actual knowledge

– *See* 21 C.F.R. § 801.4



Your **website** notes that "[Product] is an **intelligent image analysis software system** . . . It . . . assists pathologists **in detection, counting, classification and evaluation of cells and tissues in the given image** . . . and physicians, in their war against cancer - a step ahead in pathological diagnosis and prognosis."

"[Product] is a device as that term is defined in . . . the Federal Food, Drug, and Cosmetic Act . . . because it is ***intended for use* in the diagnosis of disease** or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or because it is intended to affect the structure or any function of the body."

"Based on a recent review of your website . . . FDA has concluded that you are marketing [Product] without approval or clearance from FDA, in violation of the law."

* FDA Warning Letter 5/25/2005

FDA'S CURRENT DIGITAL HEALTH PARADIGM IS BASED ON THE MEDICAL DEVICE FRAMEWORK

- A medical device is an "instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including **any *component, part, or accessory***"
  - ***intended for use*** in the *diagnosis*, *treatment*, *cure*, *mitigation*, or *prevention* of a *disease or condition*, or
  - intended to affect the *structure* or *function* of the body
  - which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is *not dependent upon being metabolized* for the achievement of its primary intended purposes
    - *See* 21 U.S.C. § 321(h)

THE CURES ACT CHANGED THE DEFINITION OF "MEDICAL DEVICE" TO CLARIFY SOFTWARE REGULATION

- Section 3060 - The term "device" **shall not** include a software function that is intended:

1. For **administrative support** of a healthcare facility (*e.g.*, billing, lab workflow, population health management, claims analysis, etc.);
2. For maintaining or encouraging a **healthy lifestyle** that is **unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition**;
3. To serve **as electronic patient record**s, including patient-provided information, so long as (a) the records are certified under ONC electronic health record standards; *and* (b) the EHR is not intended to interpret or analyze patient records, including medical images, for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
4. For **transferring, storing, converting formats, or displaying clinical laboratory test or other device data**, **unless** the function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or **unless** the function is intended to acquire, process, or analyze a medical image or signal from an *in vitro* diagnostic device or a pattern or signal from a signal acquisition system for the purpose of (a) displaying, analyzing, or printing patient medical information; (b) supporting or providing recommendations to HCP about prevention, diagnosis, treatment; and (c) enabling HCP to rely primarily on recommendation to make a clinical diagnosis or treatment decision about an individual patient

KEY FDA INTERPRETATIVE GUIDANCE

1. General Wellness: Policy for Low Risk Devices (Sept. 2019)

- Provides examples of low risk devices (including software) that are (1) not medical devices or (2) medical devices but not subject to medical device requirements because they are low risk (i.e., "enforcement discretion devices")

2. Clinical Decision Support Software (Sept. 2019)

- Clarifies FDA's interpretation of CDS functions that are medical devices (so called "Device CDS") and CDS functions that are not devices ("Non-Device CDS"). There are two categories of "Device CDS" functions; (1) regulated medical devices and (2) "enforcement discretion" devices that are effectively unregulated

3. Policy for Device Software Functions and Mobile Medical Applications (Sept. 2019)

- Identifies medical mobile applications that are (1) medical devices, (2) not medical devices, or (3) medical devices but are not subject to medical device requirements because they are low risk (i.e., "enforcement discretion devices")

KEY INTERPRETIVE GUIDANCE, CONT'D.

4. **Changes to Existing Medical Software Policies Resulting From Section 3060 (Sept. 2019)**
   - Clarifies that Medical Device Data Systems (MDDS) are not medical devices under the Cures Act. Suggests that an Application Program Interface (API) that merely enables medical device functions or the transfer medical device information is not a medical device
5. **Draft Guidance: Multiple Function Device Products: Policy and Considerations (April 2018)**
   - Clarifies that where systems contain both medical device and non-medical device functions, FDA intends to regulate only those device functions that are subject to premarket review or other medical device requirements in a multiple function device
6. **Prescription Drug-Use-Related Software: Request for Comments (November 2018)**
   - Describes proposed approach to regulating PDURS as drug labeling or promotional labeling depending on the output of the software and its relationship to safety and effectiveness of Rx drug

SOFTWARE REGULATION AFTER RESULT OF CURES ACT AND GUIDANCE

"Administrative" functionality (not a medical device)

- Admissions
- Billing and claims processing
- Practice and inventory management
- Scheduling
- Analysis of historical claims data to predict future utilization or cost-effectiveness
- Determination of health benefit eligibility
- Population health management
- Reporting of communicable diseases to public health agencies
- Reporting on quality measures

"General Wellness/Health Management (Not a Medical Device and/or Enforcement Discretion)

- Health information (*e.g.*, symptom trackers, medication reminders, etc.)
- Medical device data transfer and viewing
- "Most" clinical decision support (*e.g.*, clinical guidelines, most dosage calculators, etc.)
- Electronic communication (*e.g.*, provider-patient, patient-provider, provider-provider)
- Knowledge (clinical evidence) management
- Patient identification, matching, predictive analysis of disease progression

"Medical device" functionality (focus of FDA oversight)

Software as a Medical Device (SaMD)

- Digital Therapeutics
- Computer-aided detection / diagnosis
- Radiation treatment planning
- Robotic surgical planning and control software
- AI enabled algorithm using data to analyze and detect arrhythmia
- 3D devices and related software systems

KEY QUESTIONS FOR SAMD ANALYSIS

1. Is the product or tool intended for use in diagnosis, treatment (including “therapy”), medical care, or disease prevention?

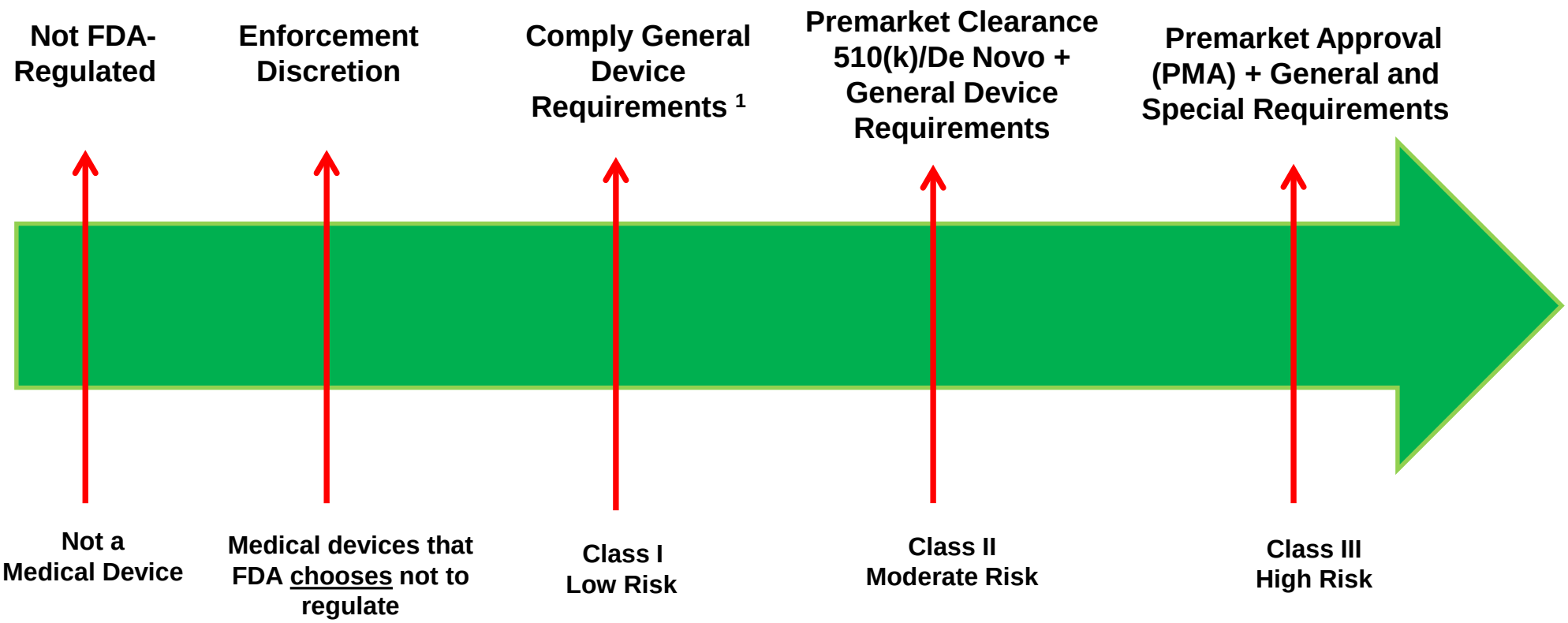
2. If yes, is the product software that is exempt from the medical device definition under Section 3060 of the Cures Act?
   - Administrative support, general wellness, EHR, Medical Device Data System (MDDS), or non-device clinical decision support
   - If it is one of these, then it is not a medical device

3. If not exempt under Section 3060, is the product subject to “enforcement discretion” under a relevant or applicable FDA guidance or enforcement policy?
   - If yes, then medical device requirements do not apply
   - If no, then product is likely regulated as a medical device

BASIC FDA REQUIREMENTS FOR SAMD

- If the software is a medical device under FDA laws:
  1. Determine the device classification / category (using applicable risk assessment guidance such as IMDRF risk classifications and FDA device classification regulations)
  2. Determine regulatory pathway to market (*e.g.*, register and list (for Class I devices), 510(k), *de novo* 510(k), premarket approval (PMA), Software Pre-Certification program)
  3. Implement processes to comply with the following "general control" requirements for SaMD
     - ❑ **Establishment Registration and Listing**
     - ❑ **Medical Device Quality System (including complaint handling, interoperability, and cybersecurity)**
     - ❑ **Labeling (and Advertising)**
     - ❑ **Corrections and Removals (*e.g.*, assess whether software updates, patches, etc. trigger recalls, field actions, etc.)**
     - ❑ **Medical Device Reports (MDRs) (adverse event reports)**

TRADITIONAL MEDICAL DEVICE MARKET PATHWAYS



1. Unless otherwise exempt from certain requirements

CONSIDERATIONS FOR NON-DEVICE HEALTH SOFTWARE

- If health-related software is not a medical device, consider and address the following:
  - Is the software subject to FTC advertising laws? (Note: FTC regulates the advertising and sale of consumer products, including health and wellness software, mobile applications, etc.)
  - Is the software subject to state consumer protection laws (*e.g.*, most state laws allow consumers to sue for unfair or deceptive trade practices, false advertising, performance failures, etc.)?
  - Does the software present product liability / litigation risks if it fails to perform as intended or advertised?
  - Does the software maintain, transfer, or display protected health information (PHI) or other information subject to federal or state privacy laws?
  - Can the company document or demonstrate adequate quality and software development processes for the software?
  - Does the software raise fraud and abuse, anti-bribery, or disclosure law considerations (*e.g.*, free software; software provides valuable information to HCPs or referral sources)?
  - If the software is used for clinical research, is the software subject to good clinical practice (GCP) regulations or similar laws?
  - Is the software a form of labeling or advertising for a drug or medical device (*e.g.*, Prescription Drug Use Related Software (PDURS))?
  - Is the software a component or part of a “combination product” or digital therapeutic that is regulated as a drug / biologic?

KEY ELEMENTS OF PRODUCT DEVELOPMENT STRATEGY

Regulatory Evaluation

- Determine whether the activity is directly regulated by FDA or implicates FDA requirements
- If a product is involved, determine regulatory status of each component / accessory of finished product
- Consider whether any FDA or industry performance standards or related requirements apply to the product
- Are clinical trials required to establish safety and effectiveness or are you conducting clinical research?

Pathway Strategy

- Consider whether an IND, IDE, NDA, BLA, 510(k), or PMA will be required and related submission activities and milestones or whether your work product or activities will be included in an FDA marketing application
- Make sure strategy aligns with business timelines and product development activities
- Define roles and responsibilities among co-developers or partners
- Make sure your agreements and protocols appropriately define your role and assign responsibility for regulatory requirement requirements
- Ensure that you have proper indemnification provisions

Develop, Plan

- Develop life cycle management plan (*e.g.*, post-approval changes, label changes, etc.)
- Develop list of necessary agreements with third-party vendors or partners
- Product design, development, and protocols to reduce the risk of defects or “bugs” that may lead to user injury
- Develop labeling and instructions for use (human factors testing or other label comprehension testing might be needed)

POSTMARKET COMPLIANCE SYSTEMS

Postmarket Assessment

- Create processes for documenting and investigating product complaints
- Ensure that labeling and instructions clearly articulate the intended use
- Conduct legal, regulatory, or medical review of promotional materials, labeling, and advertising for apps
- Provide clear and conspicuous disclosure of warnings, contraindications, and disclaimers, especially where such language may limit the scope of express and implied warranties

Agreements / Policies

- Develop acceptance and certification criteria for third-party vendors, suppliers, and service providers
- Train developers, sales personnel, and vendors
- Develop reps and warranties regarding the standard of work, conformity to specifications and documentation, pharmacovigilance, support- and service-level agreements (particularly in Software-as-a-Service Agreements)
- Develop policies and training governing health economic support / help lines in order to mitigate risk, including False Claims Act risk

Compliance Monitoring

- Make sure you have appropriate audit rights for third parties and vendors (financial, support, data security, regulatory, as applicable) and appropriate limitation of liability, indemnification, and insurance provisions
- Monitor interactions between (1) reimbursement advisers and KOLs, medical societies, payors, government agencies, and other key stakeholders, and (2) reimbursement advisers and ultimate customers to guard against overly-aggressive reimbursement advisers

QUESTIONS?

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Digital Health Reimbursement

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Digital Health Reimbursement

- Reimbursement is currently considered to be one of the primary roadblocks to the adoption of digital health tools.

- This is an area where reimbursement practices and policies are not keeping pace with the advance of new technologies.

- Start thinking about reimbursement early.

Digital Health Reimbursement

- Know your customer
  - Knowing your customer will guide you toward who is going to pay for your product
- Direct-to-Consumer
- Physicians
- Hospitals/Ambulatory Surgery Centers
- Durable medical equipment and device suppliers
- Durable medical equipment and device manufacturers
- Other health technology companies

Digital Health Reimbursement

- Know your payor
- Cash/Self-Pay
- Third-party reimbursement
  - Medicare and other federal health care programs
  - Commercial insurance
  - Employers

Medicare and other federal health care programs

- Is your product in a category that Medicare covers?
- Are similar products on the market that are covered
- How are they covered?
  - Are the products separately reimbursed so that the Medicare pays for the products specifically?
  - Is payment for the product bundled into the payment for another product or procedure so that there is no separate payment?
- To be able to bill Medicare: You must be enrolled in the Medicare program!

Digital Health Reimbursement

Pathways to reimbursement

- Category I CPT Codes
- Category II- Healthcare Common Procedure Coding System (“HCPCS”) Codes
- Category III CPT Codes
  - A set of temporary codes for emerging technology, services, and procedures.
  - These codes are intended to be used to track the usage of these services, and the data collected may be used to substantiate widespread usage in the Food and Drug Administration (FDA) approval process. However, Category III codes are not given an automatic designation for services or procedure

Digital Health Reimbursement

- How do you get a new code or how do you get a code changed?
  - The American Medical Association develops CPT codes.
  - The Centers for Medicare & Medicaid Services develops new HCPCS codes.

Digital Health Reimbursement

- Obtaining a Category III code does not require FDA approval or clearance nor published peer-reviewed evidence for the drug or supply.
- The CPT editorial panel does require at least one of the following for the procedure/service and the integral drug/supply if required to approve a new Category III code:
  - a protocol for a study of procedures being performed
  - support from the specialties who would use the procedure
  - availability of U.S. peer-reviewed literature
  - descriptions of current U.S. trials outlining the efficacy of the procedure.

Digital Health Reimbursement

Medicare Coverage of Innovative Technology ("MCIT") Pathway for breakthrough devices

- Breakthrough devices are not automatically eligible for Medicare coverage upon FDA approval or clearance.
- If interested in the MCIT pathway, manufacturers simply need to notify CMS of their interest via an email box and specify the desired start date for coverage.
- CMS will coordinate with FDA and the manufacturer to ensure a smooth start to coverage once the breakthrough device is FDA market authorized.
- Manufacturers must still obtain the appropriate code(s) for the device.
- MCIT pathway will last for four years from the date of FDA market authorization.
- Coverage under the MCIT pathway could begin immediately upon the date of FDA market authorization (that is, the date the medical device receives Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request).

Reimbursement during clinical trials

- Commercial insurance companies may be willing to partner with you to cover your product.
- Medicare has a clinical trial policy.
  - Medicare covers the routine costs of **qualifying** clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.
  - Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs.
  - Other clinical trials, must meet qualifying criteria and apply to enroll the clinical trial with Medicare.

Thank you

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