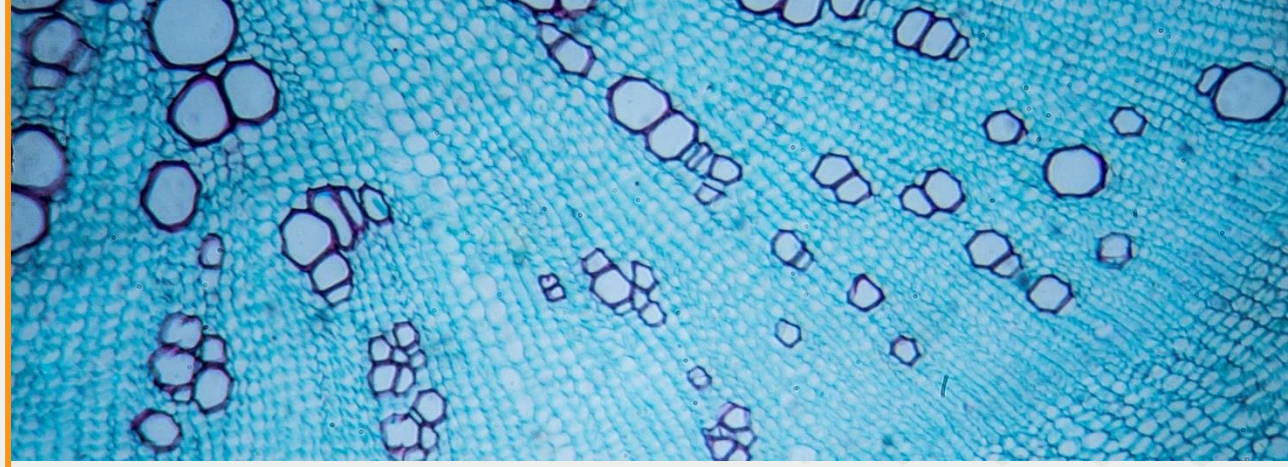
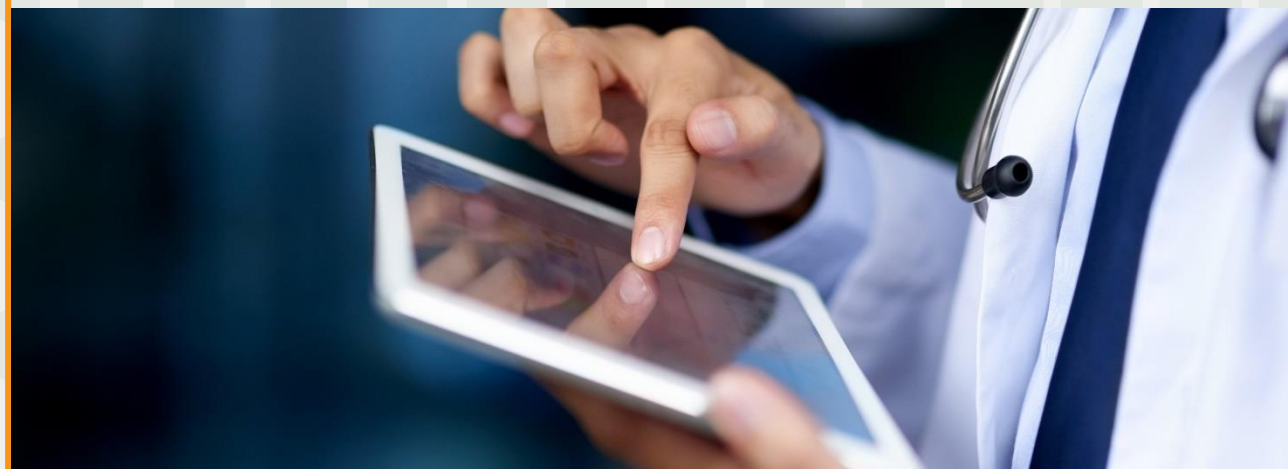
GOODWIN

Disrupt + Innovate + Transform: A Healthcare Series

Key Regulatory Issues for Digital Health Companies





Speakers

Roger A. Cohen, Esq.

Partner, Healthcare & Life Sciences
rcohen@goodwinlaw.com

Anne Brendel

Associate, Healthcare & Life Sciences
Abrendel@goodwinlaw.com

Steven Tjoe

Associate, FDA & Life Sciences
stjoe@goodwinlaw.com

GOODWIN

FDA Regulatory Issues

Evaluating Whether a Product is “Intended For Use” as a Device

- “Intended use” refers to the objective intent of the persons responsible for labeling the devices (21 C.F.R. § 801.4)
  - The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article
  - May be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.
  - If a manufacturer has knowledge that a product is being used for purposes outside its labeling, then the manufacturer must provide adequate labeling for the other purposes
- FDA has long taken the position that the regulations allow it to draw inferences of intended use from a broad range of evidence
  - September 2015 Proposed Rule: FDA will not consider a firm’s knowledge of off-label use as evidence of a new intended use
  - January 9, 2017 Final Rule: Partially amended definition of “intended use” with “totality of the evidence” standard
  - March 16, 2018: Indefinite stay of revision (after previously having been delayed twice)
  - September 23, 2020 Proposed Rule: Intent may additionally be determined by the design or composition of the article & objective intent of an unapproved new use for an approved or cleared device is not based solely on a firm’s knowledge that such device is being prescribed or used off label by health care providers

What is a “Device”?

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any **component**, **part**, or **accessory**, which is —
  - In the United States Pharmacopeia or National Formulary,
  - Intended for use in the **diagnosis** of disease or other conditions, or in the **cure**, **mitigation**, **treatment** or **prevention** of disease, or
  - Intended to affect the **structure** or any **function** of the body, **and** which
    - Does **not** achieve its **primary intended purposes** through **chemical action within or on the body**, **and**
    - Is **not dependent upon being metabolized for the achievement of its primary intended purposes**
- The term “device” does not include software functions excluded pursuant to the 21st Century Cures Act (December 13, 2016), which amended FDCA section 520(o)
  - For products with multiple functions, the exempted software function will not be regulated, except that FDA can assess the impact of the exempted software function on the safety & effectiveness of the device

Device Exclusions Under the 21st Century Cures Act

- SW functions for **administrative support** of a healthcare facility
- SW function to serve as **electronic patient records**, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart so long as
  - They were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;
  - They are part of health IT that is certified under PHS Act 3001(c)(5);
    - FDA does not intend to enforce the certification requirement under PHS Act 3001(c)(5) (by the Office of the National Coordinator for Health Information Technology Health IT Certification Program) if meet other 2 requirements
  - Such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
- SW function for **transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results**, findings by a healthcare professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, **unless** such function is intended to **interpret or analyze** clinical laboratory test or other device data, results, and findings

Device Exclusions Under the 21st Century Cures Act

- **General Health and Wellness Software:** SW functions intended for "**maintaining or encouraging a healthy lifestyle** and is **unrelated** to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition"
- **Clinical Decision Support (CDS):** SW functions that meet all the following four criteria –
  1. **Not** intended to acquire, process, or analyze a **medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system**;
  2. Intended for the purpose of displaying, analyzing, or printing **medical information about a patient or other medical information** (such as peer-reviewed clinical studies and clinical practice guidelines);
  3. Intended for the purpose of **supporting or providing recommendations** to a **health care professional** about prevention, diagnosis, or treatment of a disease or condition; and
  4. Intended for the purpose of enabling such health care professional to **independently review the basis** for such recommendations that such software presents so that it is **not the intent that such health care professional rely primarily on any of such recommendations** to make a clinical diagnosis or treatment decision regarding an individual patient.

Limitations

- Electronic patient records, SW that transfers data, and clinical decision support software **will not be excluded** from the device definition if:
  - FDA finds that the SW function would be **reasonably likely to have serious adverse health consequences** and certain substantive and procedural criteria are met
- None of the above will be excluded from device definition if
  - SW meets the criteria for **Class III** device:
    - General and special controls insufficient to provide reasonable assurance of safety and effectiveness, and
    - Life supporting or life sustaining,
    - Of substantial importance in preventing impairment of human health, or
    - Presents a potential unreasonable risk of illness or injury

FDA Enforcement Discretion Policies: Software Functions and Mobile Medical Applications

- FDA intends to apply its **regulatory oversight** to those SW functions that are devices and whose **functionality could pose a risk to patient safety** if the mobile app were to not function as intended
  - SW functions that are an extension of one or more devices by connecting to such device(s) for purposes of **controlling the device(s) or for use in active patient monitoring or analyzing** medical device data
  - SW functions that **transform the mobile platform** into a regulated device by using **attachments, display screens, or sensors**
  - SW functions that become a regulated device by performing **patient-specific analysis** and providing **patient-specific diagnosis or treatment recommendations**
- SW functions for which FDA intends to exercise **enforcement discretion**
  - Help patients self-manage their disease or conditions without providing specific treatment suggestions
    - E.g., Help patients with PTSD maintain their behavioral coping skills by provide a Skill of the Day behavioral technique
  - Use video and video games to motivate patients to do their physical therapy exercises at home

FDA Enforcement Discretion Policies: Low Risk General Wellness Devices

- **Enforcement discretion** for certain low risk wellness products that relate to a disease or condition**:**
  - If the intended use of a product –
    - Relates to the role of a healthy lifestyle with **helping to reduce the risk of** or **may help living well** with certain **chronic diseases or conditions**, and
    - It is **well understood and generally accepted** that **healthy lifestyle choices may play an important role in health outcomes** for the disease or condition
  - FDA does not intend to examine whether low risk general wellness products in this category are devices, or if they are devices, whether they comply with premarket & post-market regulatory requirements for devices, including, but not limited to registration & listing, premarket notification requirements, labeling, cGMP, and medical device reporting (MDR)

FDA Enforcement Discretion Policies: HCP, Patient and Caregiver Decision Support Devices

- CDS intended for use by patients and caregivers (non HCP) = device
- FDA intends to exercise enforcement discretion for CDS intended for use by patients and caregivers where the CDS functions inform clinical management for **non-serious health care situations or conditions**
  - Should provide information to the patients about the inputs and basis of the recommendations made by the software
  - Recommendations should concern the type of decision a patient or caregiver would routinely make without the input of a HCP
  - Data used by the CDS function and the basis for recommendations would be of a kind that patients or caregivers understand
- Additionally, FDA intends to exercise enforcement discretion for CDS intended for use by HCPs where the product does not enable independent review of the recommendation where the CDS functions inform clinical management for **non-serious health care situations or conditions**.
- Example: Lower risk CDS for use by patients:
  - SW that reminds a patient how or when to take a prescribed drug, consistent with the drug's labeling and the patient's prescription.

FDA Regulation of Devices: Classification

- Determines the regulations applicable to the device, such as whether a premarket notification (510(k)) or a premarket approval (PMA) is required
- Device class defined by risk & knowledge about the device and degree of control necessary to reasonably assure safety and effectiveness

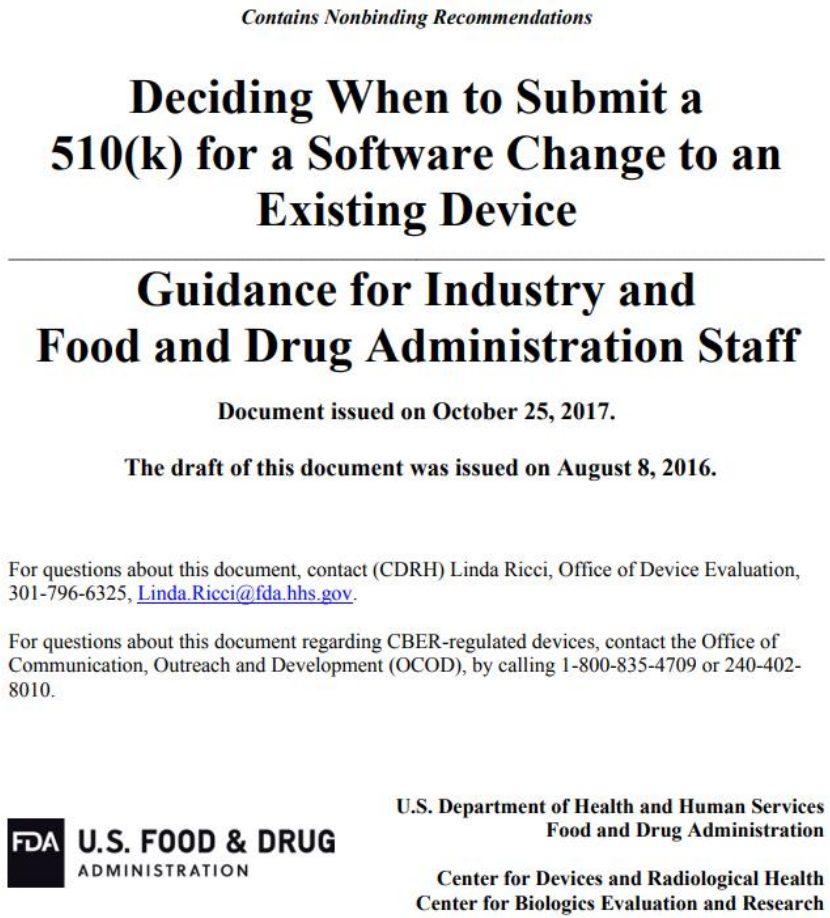
- **Class I (Low Risk)**
  - General controls
  - Generally not subject to premarket notification (510(k)) requirements
- **Class II (Moderate Risk)**
  - General controls & special controls
  - Generally subject to 510(k) requirements; may be exempt when premarket review is not necessary to provide reasonable assurance of safety and effectiveness
- **Class III (High Risk)**
  - General controls
  - PMA approval necessary if subject to current PMA requirement
  - Subject to preapproval cGMP inspection

FDA Regulation of Devices: FDA Requirements

- **General Controls**
  - Misbranding and adulteration requirements
  - Registration & listing
  - Labeling
  - cGMP (with exceptions)
  - Records and Reports
- **Special Controls**
  - Performance standards
  - Post-market surveillance
  - Patient registries
  - Special labeling
  - Premarket notification data requirements
  - User education and training

Regulations (Title 21, Code of Federal Regulations)	
Part 11	Electronic Records; Electronic Signatures
Part 50	Protection of Human Subjects
Part 54	Financial Disclosure by Clinical Investigators
Part 56	Institutional Review Boards
Part 801	Labeling
Part 803	Medical Device Reporting
Part 807	Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
Part 810	Medical Device Recall Authority
Part 812	Investigational Device Exemptions
Part 814	Premarket Approval of Medical Devices
Part 820	Quality System Regulation
Part 860	Medical Device Classification Procedures
Parts 862-892	Device Classification Regulations
Part 895	Banned Devices

FDA Regulation: Changes to FDA Cleared Digital Health Devices



Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

For questions about this document, contact (CDRH) Linda Ricci, Office of Device Evaluation, 301-796-6325, Linda.Ricci@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

- **21 CFR § 807.81(a)(3)**:
  - A new 510(k) is required for significant changes or modifications in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that required a 510(k):
    - A change or modification that could **significantly affect the safety or effectiveness** of the device
    - A **major change or modification in the intended use** of the device
- **FDA AI/ML-Based SaMD Action Plan (January 2021)**
  - Predetermined Change Control Plans
  - Real-World Performance
  - Algorithm Transparency

GOODWIN

Corporate Practice of Medicine

Corporate Practice of Medicine

- Restrictions on the “corporate practice of medicine” (“CPOM”) in many states prohibit corporations and other business entities from practicing medicine or employing a physician to practice medicine on the corporation’s behalf
- A majority of states have some form of CPOM prohibition, however scope of the prohibition, if any, varies by state
  - Most states have CPOM exceptions that allow physicians to practice medicine through partnerships, professional service corporations, and / or limited liability companies, but usually only if owned exclusively by physicians
- Corporate practice limitations frequently apply to other licensed professions, like dentistry, optometry, psychology, etc.

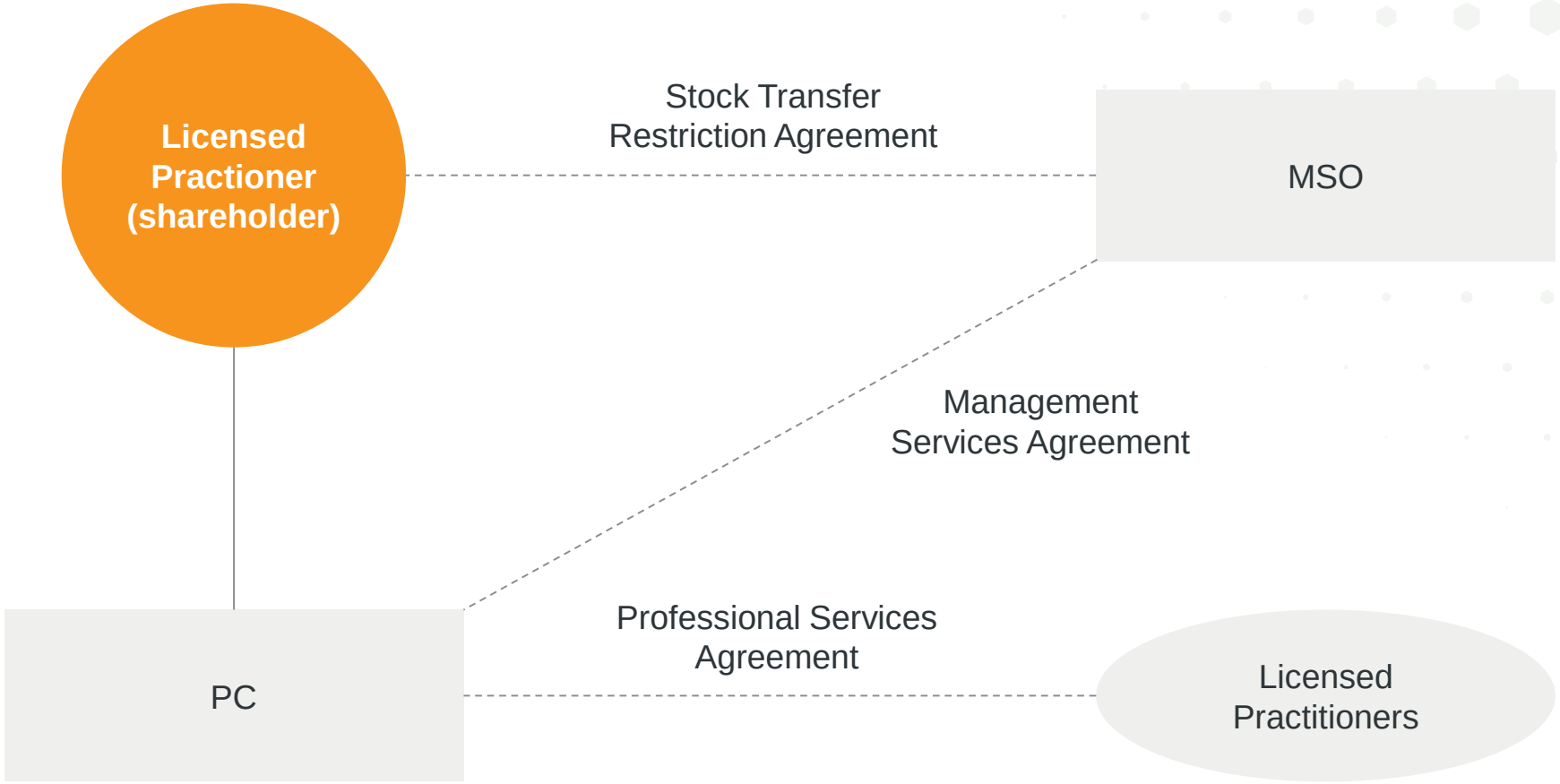
Fee Splitting

- Ancillary to CPOM laws, most states also prohibit “fee splitting” by physicians and certain other professionals, i.e., the sharing of a physician’s professionally earned fees with non-physicians
  - **Example:** Fee for marketing services of 10% of professional fees for referred cases is illegal fee splitting. *E&B Marketing Enterprises, Inc. v. Ryan* (Ill. App. 1991)
  - **Example:** Payment of 20% of gross revenue from dental practice as partial consideration for the occupancy and use of a fully-equipped dental facility under a long-term lease violated public policy. *Sachs v. Saloshin* (N.Y. App. Div. 1988)
- As with CPOM, fee-splitting prohibitions vary from state to state
  - Some state laws tie the fee-splitting prohibition to referrals; others contain a blanket prohibition.
  - Some states prohibit sharing fees with other physicians.
  - Any agreement that provides for a payment based on a physician’s revenues must be analyzed under state fee splitting rules and, if Medicare or other federal healthcare program patients are involved, under anti-kickback laws as well

Friendly PC Model

- A “friendly PC” is an entity owned by licensed physicians and affiliated with a practice management company (MSO)
- The friendly PC is generally organized as a professional corporation, but may take any corporate form that is authorized by state law to engage in the practice of medicine (e.g., PLLC)
- Friendly PC contracts with MSO for management services
- Stock Transfer Agreement requires transfer of friendly PC shares to designee of MSO upon certain events such as termination of management services agreement and prohibits certain actions by shareholder such as sale of shares and amending bylaws

Friendly PC Model (contd.)



GOODWIN

Friendly PC Model (contd.)

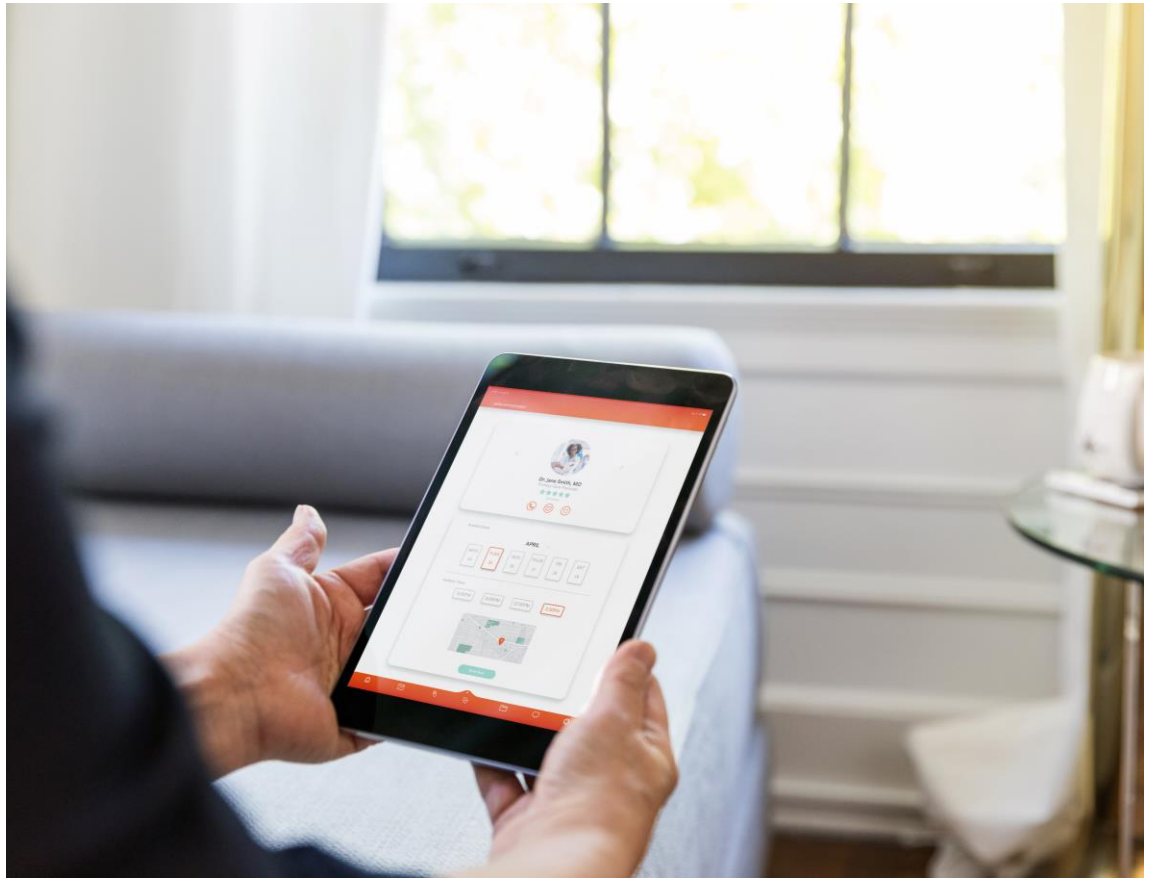
- Limitations on MSO relationship with PC (in states that prohibit corporate practice)
  - PC must maintain control of clinical matters
  - Some CPOM states prohibit purchase of medical equipment or supplies by the MSO because these may be clinical decisions (e.g., North Carolina)
  - De facto control of PC by MSO generally prohibited
  - Generally compensation of MSO for services must be consistent with fair market value
    - Some states prohibit compensation of MSO based on percentage of PC collections
  - Specific limitations vary by state

Telehealth

What Does it Mean to “Practice Medicine”?

- Typical definition of “practice of medicine”:
  - “Any person shall be regarded as practicing medicine, within the meaning of this chapter, who treats, or professes to diagnose, treat, operates on or prescribes for any physical ailment or any physical injury to or deformity of another.” Tenn. Code Ann. § 63-6-204(a)(1)

Telemedicine and Professional Licensure Laws



- Generally, a physician must be licensed in the state where the patient is located, subject to COVID-19 waivers
  - e.g., “No person shall practice medicine in any of its departments within this state unless and until such person has obtained a license from the board created by § 63-6-101.” Tenn. Code Ann. § 63-6-201(1)
- Exceptions to general licensure requirement:
  - Consultation Exception
  - Special or Temporary Telemedicine License
  - Licensure by Endorsement
  - Physician Interstate Medical Licensure Compact

GOODWIN

Requirements Related to Prescribing Drugs

Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. No. 110-425)

- Prohibits online pharmacies from dispensing controlled substances without a valid prescription from a physician who has examined the purchaser in person

DEA's Public Emergency Exception for Telemedicine Prescribing of Controlled Substances

- DEA-registered practitioners may issue prescriptions for controlled substances to patients without first conducting an in-person medical evaluation, subject to certain conditions

Requirements Related to Prescribing Drugs (contd.)

Other Prescription Drugs

- A number of states require that a physician physically examine a patient before prescribing drugs for the patient
- Every state prohibits “unprofessional conduct”
- Numerous state medical boards have issued policies prohibiting prescriptions “based solely on an on-line questionnaire or consultation.”

Nurse Practitioners & Physician Assistants

Nurse Practitioners (NPs)	Physician Assistants (PAs)
Scope of practice varies by state	Scope of practice varies by state
Prescriptive authority	Prescriptive authority
Collaboration Agreement or written protocols typically required	Written guidelines or protocols are often required
Number of NPs a physician can supervise may be limited (e.g., New York limits to 4 NPs)	Number of PAs a physician can supervise may be limited (e.g., Pennsylvania limits to 4 PAs)
Chart review may be required	Chart review or co-signature may be required
Physician must be available for consultation and/or supervision	Physician supervision requirements may vary

Telemedicine: Medicare Coverage (Traditional Limitations)

5 conditions of coverage must be met to qualify for Medicare reimbursement of a telehealth service:

- Beneficiary must be at an originating site in a qualifying rural area (outside of Metropolitan Statistical Area or in a Health Professional Shortage Area in a rural census tract)
- Originating site must be one of eight categories:
  - Physician Office, Hospital, Critical Access Hospital, Rural Health Clinic, FQHC, Hospital-based or CAH-based Renal Dialysis Center, SNF, Community Mental Health Center
- Services are provided by one of ten types of eligible distant site practitioners
  - MD, NP, PA, Nurse-midwife, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Clinical Psychologist, Clinical Social Worker, Registered Dietitian or Nutrition Professional
- Communication via interactive audio and video telecommunications system that permits real-time communication

Telemedicine: Medicare Coverage (COVID-19 Era)

- CMS Expanded Telehealth Coverage
  - 200+ telehealth services added to Medicare fee-schedule
  - Provider types expanded to include physical therapists, occupational therapists, speech language pathologists, and clinical psychologists
- CMS Reduces Barriers to Telehealth
  - Qualifying originating sites expanded to all locations
  - Technology requirements reduced (for both new an established patients)
    - Audio-only permitted
    - Store and forward technology permitted

Telemedicine: Medicaid Coverage

- States have the option to determine whether (or not) to cover telemedicine, including:
  - What types of telemedicine to cover;
  - Where in the state it can be covered;
  - How it is provided and covered;
  - What types of telemedicine may be provided by certain practitioners; and
  - How much to reimburse for telemedicine services, as long as such payments do not exceed federal limits
- 48 states and Washington, DC reimburse for some form of live video in Medicaid fee-for-service
- 15 states provide reimbursement for store-and-forward
- 6 states have some form of rural or geographic restriction

Fraud & Abuse

Anti-Kickback Statute

- Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal healthcare program business
- Prohibits referrals **from anyone** and **for any type of goods and services**
- Applies to companies providing **marketing services** that generate services/items reimbursable by federal healthcare programs
- Includes **all federal healthcare programs** (TRICARE, FEHB, etc.) not just Medicare and Medicaid
- There must be an **intent** to induce referrals
- Voluntary safe harbors

- Criminal Penalties:
  - Fines up to $100,000 per violation
  - Up to a ten year prison term per violation
- Civil Penalties:
  - False Claims Act liability
  - Civil monetary penalties of up to $50,000 per violation
  - Program exclusion
  - Penalty of up to three times the amount of the kickback

Anti-Kickback Safe Harbors

- Safe Harbors are voluntary — if your arrangement does not fit squarely within safe harbor, not fatal
- Exceptions include:
  - Space rental
  - Equipment rental
  - Personal services arrangements
  - E-prescribing and EHR items
- Additional safe harbors
  - Discounts
  - Referral services
  - Group purchasing organizations
  - Investment interests
  - Value-based arrangements

Advisory Opinion 19-04: Zocdoc

- Proposed Arrangement
  - Zocdoc, a technology company, would provide federal healthcare program beneficiaries with the following:
    - Online Directory
      - Access to its online healthcare directory for searching and booking medical appointments, where healthcare professionals would pay per-click or per-booking fees to be listed in the directory
    - Banner Advertisements
      - Sponsored advertisements on its online healthcare directory and third-party websites, where healthcare professionals would pay per-impression or per-click fees for such sponsored advertisements.

Advisory Opinion 19-04: Zocdoc (contd.)

- Online Directory Approval
  - OIG approved a fee structure where the Zocdoc charged a fee per-booking for new patients that varied by specialty, geographic location of the provider, and in some instances, other factors affecting fair market value because (1) booking fees were set in advance and (2) aggregate listing fees would not exceed fair market value
  - OIG determined that the fees would not vary directly based on the volume or value of Federal health care program business generated by the Marketplace because the per booking fees would apply: (i) only when a user who identifies himself or herself as a new patient books an appointment; (ii) regardless of the user's insurance status; and (iii) except in limited circumstances, regardless of whether the user cancels the appointment.
- Banner Advertisement Approval
  - OIG approved the advertising arrangement because (1) it did not have the same concerns as white coat advertising arrangements because the company is not a healthcare provider/supplier and is not affiliated with a healthcare provider/supplier and (2) the marketing was generalized (not product/services specific) and passive (beneficiary initiated)

False Claims Act

- **Imposes liability for:**
  - knowing submission of a false claim to federal government
  - knowingly causing the submission of a false claim for payment to federal government
  - Knowingly concealing, avoiding, or decreasing an obligation to pay or transmit money to the federal government
- "Knowingly" includes recklessness and deliberate ignorance
- Statute provides for "treble damages" (3 times the amount of damages to government) plus penalties of ~$12,000 - ~$23,000 for each false claim
- Whistleblowers authorized to bring actions on behalf of the government and share in up to 30% of recovery
- eClinicalWork settled FCA case for $150 million related to alleged false certifications that it met meaningful use standards for EHRs and paid kickbacks to healthcare providers

HIPAA

What Is HIPAA?

- HIPAA is an abbreviation for the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)
- Sets standards related to the privacy and security of **protected health information**
- Applies to **covered entities** and **business associates**

What Is PHI?

- Protected Health Information ("**PHI**") is **individually identifiable health information** that is in **any form —**
  - Paper
  - Oral
  - Electronic
- PHI **excludes** employment records held by an employer in its role as an employer (**e.g., physician's note submitted by employee documenting reason for absence from office**)
- Examples
  - Medical records
  - Shipping records
  - Billing records
  - Reimbursement records

HIPAA Rules Apply to…

- The HIPAA Privacy rules apply (although sometimes in different ways) to all "**Covered Entities**":
  - Health plans
  - Healthcare clearinghouses
  - Healthcare **providers** who **transmit any health information in electronic from** in connection with one of the **transactions** covered by HIPAA
    - Covered transactions are:
      - Submitting claims to insurers for products and services
- **Business Associates** are outside entities that perform services on behalf of a Covered Entity and **create**, **receive**, **maintain** or **transmit** PHI in connection with the services
  - Examples: billing companies, accounting firms, attorneys, SaaS services providers
- A "subcontractor" of a Business Associate who creates, receives, maintains, or transmits PHI on behalf of a Business Associate is also a Business Associate itself

HIPAA Compliance for Covered Entities

- No use or disclosure of PHI without patient authorization except for treatment, payment, and healthcare operations, pursuant to limited exceptions
- Administrative, physical, and technical safeguards
- Privacy officer and security officer
- Risk assessment
- Privacy and security policies and procedures
- HIPAA training (on hire and periodically after)
- Notice of privacy practices
- Business Associate agreements with business associates
- Breach notification to individuals and regulators

HIPAA Compliance for Business Associates

- No use or disclosure of PHI except to provide services to covered entity, for management and administration of the business associate, and as required by law
  - No de-identification of PHI or data aggregation unless expressly permitted in BAA
- Administrative, physical, and technical safeguards
- Security officer
- Risk assessment
- Privacy and security policies and procedures
- HIPAA training (on hire and periodically after)
- Business Associate agreements with subcontractor business associates
- Notification to covered entity of security incidents and breaches (but BAA may require notice to individuals)

Use of PHI by BA for Machine Learning

- Use of PHI for machine learning generally not permitted unless patients authorize use of PHI for such purpose
- Can use de-identified information for machine learning
- Business associate must have express authorization under business associate agreement to de-identify PHI
- Generally, business associate using de-identified PHI for machine learning should also have an IP license to use the de-identified information for machine learning

Privacy Rule: Authorization Requirements

- A written authorization is needed from subject of PHI for disclosures that are not for treatment, payment, and healthcare operations or allowed under another HIPAA exception
- To be valid, an authorization must contain:
  - Description of information to be disclosed
  - Name of person / class of persons authorized to make disclosure and to whom CE can make disclosure
  - Description of purpose of disclosure
  - Expiration date or event
  - Signature
  - Right to revoke authorization and limitations
  - Ability / inability to condition treatment, payment, or enrollment on authorization
  - Potential for re-disclosure
- Use or disclosure of PHI must be consistent with the terms of the authorization
- An authorization can be revoked by written notice

Business Associate Agreement Requirements

- General Rules
  - Need specific HIPAA-dictated language in a contract with all business associates
  - Business Associate Agreement must be written
  - Must include language that specifically says that the BA will ensure that individual's HIPAA rights are followed

Business Associate Agreement Provisions

- What are the standard provisions found in a BAA?
  - Obligations of the Business Associate
  - Permitted Uses and Disclosures of the Business Associate
  - Breach Notification to the Covered Entity
  - Sample BAA from OCR (http://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html)
- What are some important negotiating points in BAAs?
  - Breach notification
    - Who bears costs
    - Timeline for notification
  - Indemnification
  - De-identification and data aggregation
  - Use of PHI for management and administration

Privacy Rule: Use of PHI for Marketing and Sale of PHI

- “Marketing” means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service
- Marketing involving remuneration to covered entity from third party and sale of PHI require authorization stating the disclosure will result in remuneration to covered entity
- Marketing Does not Include
  - Refill reminders
  - Communications for case management or care coordination for the individual, or to direct or recommend alternative care
  - A covered entity describing its health-related product or services to its patients/members without an authorization

Privacy Rule: De-Identification

- Health information that does not identify an individual and for which there is no reasonable basis to believe an individual may be identified is not PHI
- This determination may be made by either:
  - Obtaining analysis from an expert concluding that there is a very small risk that an individual may be identified by the information
  - De-identifying the information by removing any “individually identifiable” information:

Name	Account Numbers
Geographic Subdivisions (other than State)	Certificate / License Numbers
Dates Elements (other than year)	Vehicle Identifiers
Telephone / Fax Numbers	Device Identifiers
Email Addresses	URLs
SSNs	IP Addresses
Medical Record Numbers	Biometric Identifiers
Health Plan Beneficiary Numbers	Photo IDs

Texting PHI

- Texting PHI via SMS text generally prohibited because SMS texting is not secure
- But, patients can authorize communication via SMS text
- Generally, even with authorization, PHI in SMS text should be limited
- Best practice to advise patients that SMS texting is not secure when obtaining authorization

Thank You

About Us

At Goodwin, we use law to achieve unprecedented results for our clients

13
OFFICES

Boston | Cambridge | Frankfurt | Hong Kong | London | Los Angeles | Luxembourg
New York | Paris | San Francisco | Santa Monica | Silicon Valley | Washington DC

Our **1,400 lawyers** across the United States, Europe, and Asia excel at complex transactions, high-stakes litigations and world-class advisory services in the financial, life sciences, private equity, real estate, and technology industries. We partner with our clients to practice law with integrity, ingenuity, agility and ambition.

To learn more, visit us at goodwinlaw.com and follow us on Twitter and LinkedIn

GOODWIN

Notices

US Disclaimer

This publication, which may be considered advertising under the ethical rules of certain jurisdictions, is provided with the understanding that it does not constitute the rendering of legal advice or other professional advice by Goodwin Procter LLP or its attorneys. Prior results do not guarantee a similar outcome.

UK Disclaimer

 Goodwin Procter LLP is a limited liability partnership which operates in the United States and has a principal law office located at 100 Northern Avenue, Boston, MA 02210. Goodwin Procter (UK) LLP is a separate limited liability partnership registered in England and Wales with registered number OC362294. Its registered office is at 25 Old Broad Street, Tower 42, London, EC42N 1HQ. A list of the names of the members of Goodwin Procter (UK) LLP is available for inspection at the registered office. Goodwin Procter (UK) LLP is authorized and regulated by the Solicitors Regulation Authority. This informational piece may be considered advertising under the ethical rules of certain jurisdictions. Prior results do not guarantee similar outcome.

GOODWIN