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Part I - D2C Telehealth Services: Legal and Regulatory Considerations

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Corporate Practice of Medicine & Fee-Splitting Prohibitions

STATE CORPORATE PRACTICE OF MEDICINE (CPOM) RESTRICTIONS

- Prohibits non-physician owned entities from employing physicians or contracting for physician services in a manner that cedes control of the physician's clinical practice to a non-physician
- Some states require that only physicians and physician-owned entities (PCs, PLLCs) can provide health care services
 - Limited exceptions, such as for hospitals, certain non-profits, MCOs
- Rationale is that non-physicians, not subject to the same code of ethics as physicians, are motivated by profit, rather than the provision of the highest quality patient care, and therefore should not have any control over a physician's practice of medicine

STATE CORPORATE PRACTICE OF MEDICINE (CPOM) RESTRICTIONS

- At least 34 states maintain a CPOM prohibition in some form
 - Statutory prohibitions
 - Attorney General opinions
 - Case law
- Scope of state prohibitions vary; main themes include:
 - Business entities cannot employ physicians to provide medical care
 - Entities that provide medical services must be owned and operated by licensed physicians
 - Professional fees cannot be split between licensed professionals and non-licensed individuals or business entities
 - Management fees stated within management services agreements must be set at fair market value and not based on a percentage of revenue

STATE FEE-SPLITTING PROHIBITIONS

- Distinct but closely related to CPOM prohibition
- Prohibits physicians and practices from splitting fees/compensation for professional services with a person or entity who did not render the service
- Signifies improper economic influence by others on physician's practice
 - AMA, Code of Medical Ethics Opinion 11.3.4: Payment by or to a physician or health care institution solely for referral of a patient is fee splitting and is unethical
- Some states do not have a CPOM, but have a vigorously enforced fee-splitting prohibition (e.g., Florida)

STRICT CPOM STATE: CALIFORNIA

- California's CPOM prohibition is strict and actively enforced
- Statutory prohibition intended to prevent unlicensed persons from interfering with, or influencing, the physician's professional judgment
 - Cal. Business & Prof. Code, section 2052: "Any person who practices or attempts to practice, or who holds himself or herself out as practicing...[medicine] without having at the time of so doing a valid, unrevoked, or unsuspended certificate...is guilty of a public offense."
 - CBP, section 2400: "Corporations and other artificial entities shall have no professional rights, privileges, or powers."

STRICT CPOM STATE: CALIFORNIA

- California BOM has issued broad and fulsome CPOM guidance, which prohibits unlicensed entities from:
 - Owning a patient's medical records
 - Selecting, hiring/firing (as it relates to clinical competency or proficiency) of physicians, allied health staff and medical assistants
 - Setting the parameters under which the physician will enter into contractual relationships with third-party payers
 - Making decisions regarding coding and billing procedures for patient care services
 - Approving of the selection of medical equipment and medical supplies for the medical practice

(LESS) STRICT CPOM STATE: NORTH CAROLINA

- 1955 AG Opinion and Board of Medicine Position Statement
 - Prohibits private corporations from practicing medicine, including the employment of physicians (except for public and non-profit hospitals)
- Concerns about “straw ownership” in which a physician is sole shareholder of the corporation in name only to disguise real control/decision-making authority resides with a non-physician. Suspect indicia includes:
 - MD owner has no control over the practice and does not control revenue or enjoy profits of practice
 - MD owner cannot sell ownership without permission from de facto lay owner
 - Disengagement from business decision-making and advertising
 - Reliance on non-physician personnel to provide direct patient care without adequate supervision by the physician owner.

“FRIENDLY” PC/ MANAGEMENT SERVICES ORGANIZATION (MSO) MODEL

- For-profit entities can partner with physician-owned entities to meet CPOM requirements. Under the Friendly PC model,
 - Friendly PC is owned by a physician (per state law requirements) and employs or contracts with physicians to provide clinical services
 - Management services company manages day-to-day business operations of Friendly PC under Management Services Agreement
 - MSA compensation and funds flow generally must be carefully structured to meet CPOM guidance and state fee-splitting requirements
 - MSO and Friendly PC have “stock transfer/restriction agreement” that contemplates that PC/PLLC is owned by a “friendly physician” who can only be replaced by new physician identified by the MSO

MANAGEMENT SERVICES ORGANIZATION (MSO) / "FRIENDLY" PC MODEL



MANAGEMENT SERVICES ORGANIZATION (MSO) / "FRIENDLY" PC MODEL

Friendly PC

- Owns and operates the clinical practice
- Employs professional staff who are prohibited by local law from being employed by laymen
- Owns professional fees
- State may prohibit fees paid to MSO from percentage of revenue model

MSO

- Provides management, administrative and back office services
- Employs non-clinical staff
- Arranges for physical space, technical services (e.g., telehealth platform)
- Provides billing and collection services

** Key is to structure MSA to avoid fee-splitting and prohibition on control of clinical practice*

CONSEQUENCES OF VIOLATING CPOM PROHIBITIONS

- Direct enforcement of CPOM prohibitions vary by state
 - Disciplinary actions against licenses (e.g., suspension/loss of licensure)
 - Unauthorized practice of medicine/aiding and abetting (which may include criminal penalties)
- CPOM often used strategically between private parties to avoid enforcement of contractual obligations
 - Courts will often not enforce contracts as against public policy where the lay entity is controlling the practice or employing the physicians in violation of the CPOM
- Commercial Fraud Claims
 - Under recent case law (e.g., NY, NJ), state courts are willing to enforce insurers' right to withhold reimbursement from unlicensed medical providers when illegally controlled by lay entity in violation of CPOM

PROVIDING TELEMEDICINE ACROSS STATE LINES: FOREIGN REGISTRATION

- PCs/PLLCs or other corporate forms (in a non-CPOM state) doing business outside their home state typically must be registered with the secretary of state's office in the state where they seek to practice ("foreign" entity)
 - Process is state-specific
 - Entities not operating in CPOM states will be required to comply with CPOM restrictions, including creating PC/PLLC where required
- A few states do not permit foreign entities to provide health care services (e.g., California)
 - Creation and operation of an entity in those state will be required

Structuring the entities properly from the start is essential

FOREIGN REGISTRATION PROCESS: NORTH CAROLINA

- An entity already registered in another state or country must qualify to conduct business in North Carolina
 - Must file an application for a Certificate of Authority with the NC Secretary of State
- For entities purporting to provide clinical services, additional review/approval is needed by the applicable state licensing boards
 - NC Secretary of State automatically refers entity applications related to physician services to NC BOM for review
 - BOM ensures that the entity meets all PC/PLLC requirements prior to approval and submits documents back to the Secretary of State for registration



Establishing the Provider-Patient Relationship: Modality, Prescribing, and the Standard of Care

ESTABLISHING THE PROVIDER-PATIENT RELATIONSHIP

- AMA Code of Ethics Opinion 1.1.1
 - “A patient-physician relationship exists when a physician serves a patient’s medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).”
- In traditional bricks-and-mortar health care practice, the provider-patient relationship is established through an in-person visit
- How and when the patient-provider relationship is established within the context of telehealth is less clear
- States have taken a variety of approaches
 - Cannot treat, diagnose or prescribe unless valid relationship is formed
 - Failing to properly create valid relationship subjects provider to disciplinary action and creates potential liability for telehealth platform

ESTABLISHING THE PROVIDER-PATIENT RELATIONSHIP

- Some states, but not all, specifically address whether a particular telehealth encounter is sufficient to establish the provider-patient relationship in accordance with professional standards
- Other states have not expressly addressed the establishment of a provider-patient relationship within the context of telehealth but do address, and in many instances are revising, the *modalities* available to practitioners for the provision of a telehealth visit
 - Emerging trend has been to clarify, and in some cases, broaden, the applicable standard or modalities available to practitioners for the provision of a telehealth encounter, allowing greater flexibility and convenience for both patient and provider
- Many states defer to the physician to determine whether the standard of care is met, whether or not modality is address

ESTABLISHING THE PROVIDER-PATIENT RELATIONSHIP: KEY QUESTIONS

- What does the state require to establish a provider-patient relationship via telehealth?
 - Does the state require a previous face-to-face encounter or can the relationship be formed during a telehealth encounter?
 - What modalities are permitted (synchronous, asynchronous, or both)?
 - If asynchronous encounters are permitted, which type (store and forward with images, static or dynamic questionnaire)?
- What are state rules on prescribing via telehealth?
 - What modalities are required to prescribe?
 - What are the state rules governing prescriptions when a physician-patient relationship does not exist prior to the telehealth encounter?
 - Are there restrictions on certain types of drugs (opioids, ED drugs, etc.)?

WHAT IS A MODALITY?

- “Modality” describes the communication technology used to deliver telehealth services
 - “Synchronous” or “asynchronous” modalities
- State laws will often mandate particular modalities (and prohibit others) in order to:
 - Establish the standard of care and form a valid provider-patient relationship
 - Prescribe as part of a telehealth encounter
- A number of states do not address what modalities are required to create a provider-patient relationship and/or prescribe or what modalities are required after a provider-patient relationship is formed

Synchronous vs. Asynchronous Communication Modalities

Synchronous

- Communication in *real time*
- May also be described as “interactive” communication
- States that require synchronous interactions may specifically require both audio and video capabilities
- Other states will permit other synchronous interactions (e.g., audio-only/telephone only; instant messaging; audio with store and forward)

Asynchronous

- Any communication that is not in real time
- Often called “store and forward” because data is submitted by patients via telehealth portal, “stored” and “forwarded” to provider for review
- Other examples include non-real time messaging/chat function; static and dynamic questionnaires

PRESCRIBING VIA TELEHEALTH

- Federal Food, Drug and Cosmetic Act prohibits controlled substances to be prescribed via the internet without a prior face-to-face visit
 - Limited waivers related to the COVID-19 PHE, but are not permanent
- State laws vary with regard to requirements for use of technology for prescribing, including modality requirements
 - States may also require an in-person exam be administered prior to a prescription being written, others allow the use of telehealth to conduct the exam
 - Many states consider using only an internet/online questionnaire to establish a provider-patient relationship (needed to write a prescription) as inadequate
- State laws also widely vary with regard to restrictions or prohibitions of drugs prescribed via telehealth technology

PROVISION OF ANCILLARY SERVICES VIA TELEHEALTH

- Provision of ancillary services via telehealth add additional federal and state regulatory complexity
- Examples:
 - Laboratory services
 - Telehealth with affiliated DME items and services
 - Telehealth with affiliated pharmacy services
 - Remote Therapeutic Monitoring/Remote Patient Monitoring (RTM/RPM)

Data Privacy Considerations

EVERYONE WANTS THE DATA!

DATA IS AN IMPORTANT STRUCTURAL CONSIDERATION

- What entity or entities will have access to data?
- For what purposes will those entities have access to data?
- How will data flow between and among parties?
- How will data flow between and among entities?
- How will the various parties be characterized under HIPAA?
 - Covered Entity/Business Associate/sub-Business Associate
- *Everyone wants the data!*

THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT ("HIPAA")

- Federal law that protects the privacy and security of health information (a/k/a Protected Health Information or “PHI”)
- Created national privacy and security standards that protect PHI
 - Privacy Rule
 - Security Standards
 - Breach Notification Rule
- See generally 45 CFR Parts 160 and 164

WHAT ACTORS ARE COVERED BY HIPAA?

- Covered Entities
 - **Health care providers** that transmit any health information in electronic form in relation to a covered transaction
 - **Health plans**
 - **Health care clearinghouses**
- Business Associates
 - A person or entity that **performs certain services for or on behalf of** a Covered Entity that require access to or use of PHI
- See 45 CFR 160.102, 103

WHAT DATA IS PROTECTED BY HIPAA?

- Protected Health Information (“PHI”) (45 CFR 160.103)
 - **Created or received by a health care provider**, health plan, public health authority, & others
 - Relates to the **past, present, or future physical or mental health or condition of an individual** (or payment for health care)
 - **Identifies the individual** or reasonably could be used to identify the individual
 - Transmitted or maintained electronically or in any other form
 - Very few carve-outs (e.g., education records covered by federal law, employer records)

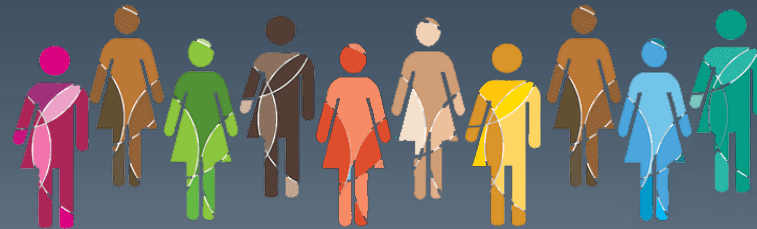
HOW CAN PHI BE USED AND DISCLOSED UNDER HIPAA?

- Certain disclosures are permissible without authorization or consent
 - Treatment
 - Payment
 - Health Care Operations (collectively, “TPO”)
 - As required by law, e.g., for public health disclosures, for certain law enforcement purposes
- Patients can authorize disclosure to themselves or to third parties

HOW CAN PHI BE USED AND DISCLOSED UNDER HIPAA?

- **No use and disclosure of PHI for marketing** without authorization – carve-outs to definition of “marketing” are *extremely* limited
- For **research purposes**, but only with authorization or waiver from a privacy board (e.g., an IRB)
- Health care providers **cannot sell** PHI
- PHI cannot be disclosed to manufacturers, distributors, or drug companies without a **permissible purpose or authorization**
- Covered Entities and Business Associates must maintain an **accounting of disclosures** and make available to patients upon request

K&L GATES



eCommerce
Platform

Customer
Data

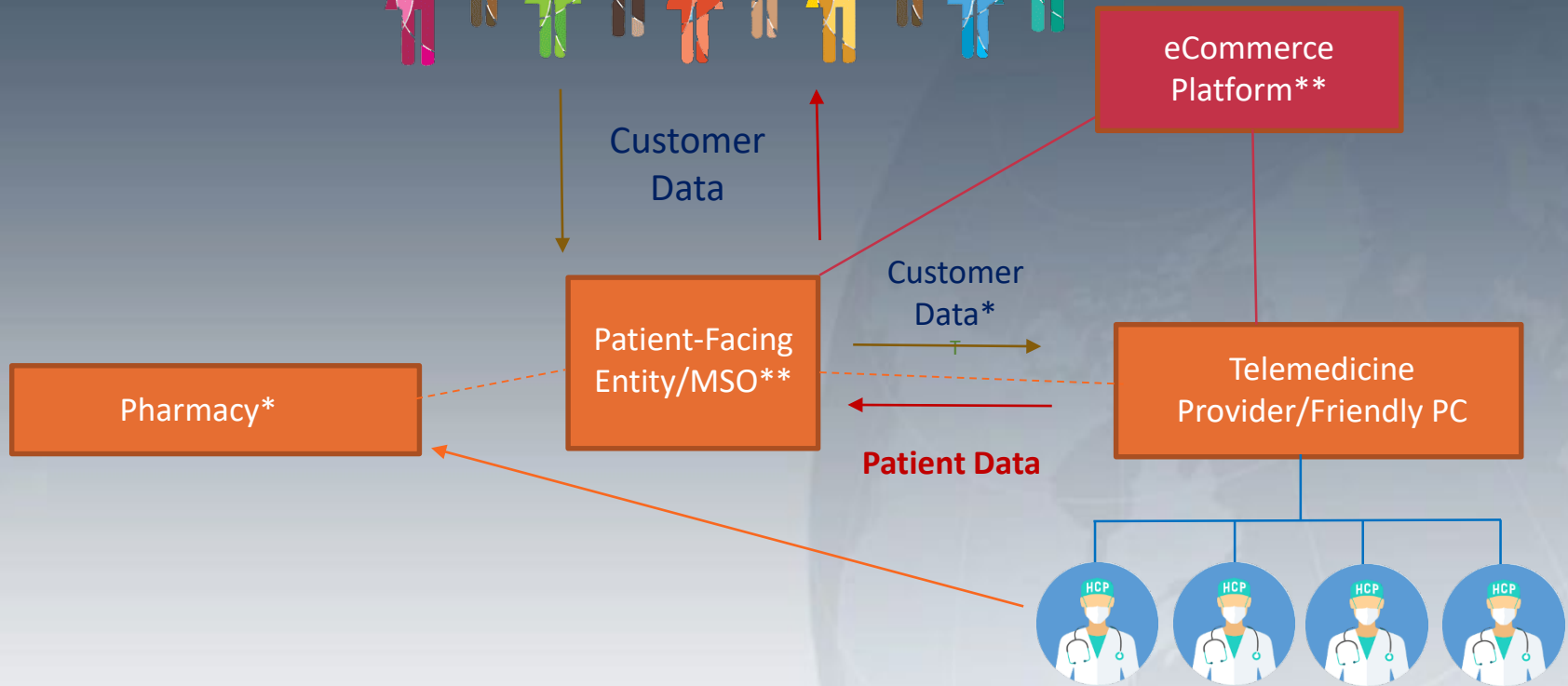
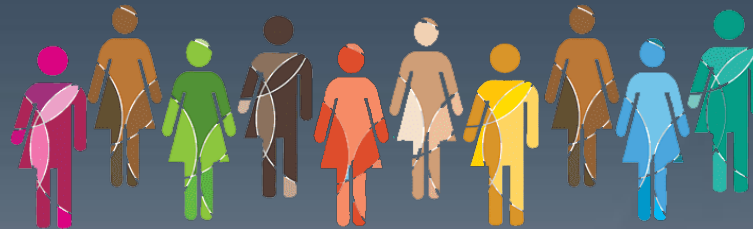
Pharmacy*

Telemedicine Provider



*Telemedicine Provider will transmit prescription to Pharmacy at Customer's request. Pharmacy dispenses drug.

K&L GATES

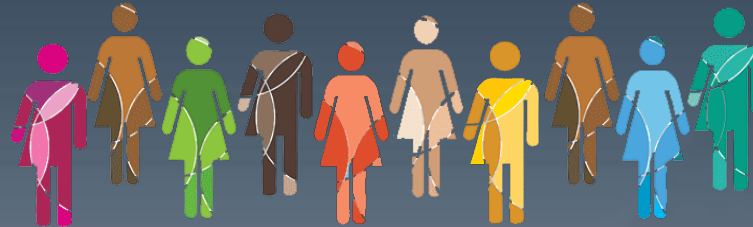


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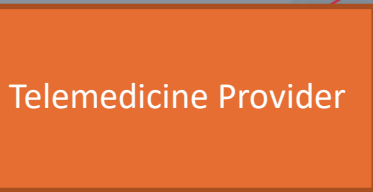
WHOSE DATA IS IT, ANYWAY?

K&L GATES

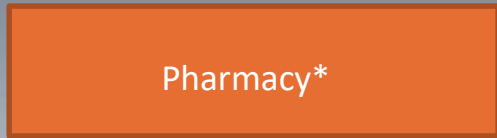
Customer Data is PHI



Customer Data

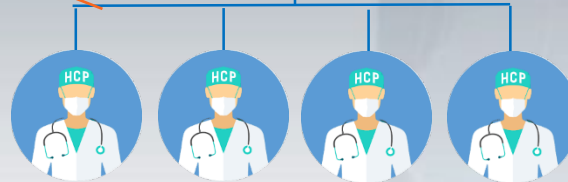


↑
eCommerce Platform is Business Associate of Telemedicine Provider



↑
Pharmacy is a Covered Entity

↙
Telemedicine Provider is Covered Entity



*Telemedicine Provider will transmit prescription to Pharmacy at Customer's request. Pharmacy dispenses drug.

WHOSE DATA IS IT, ANYWAY?

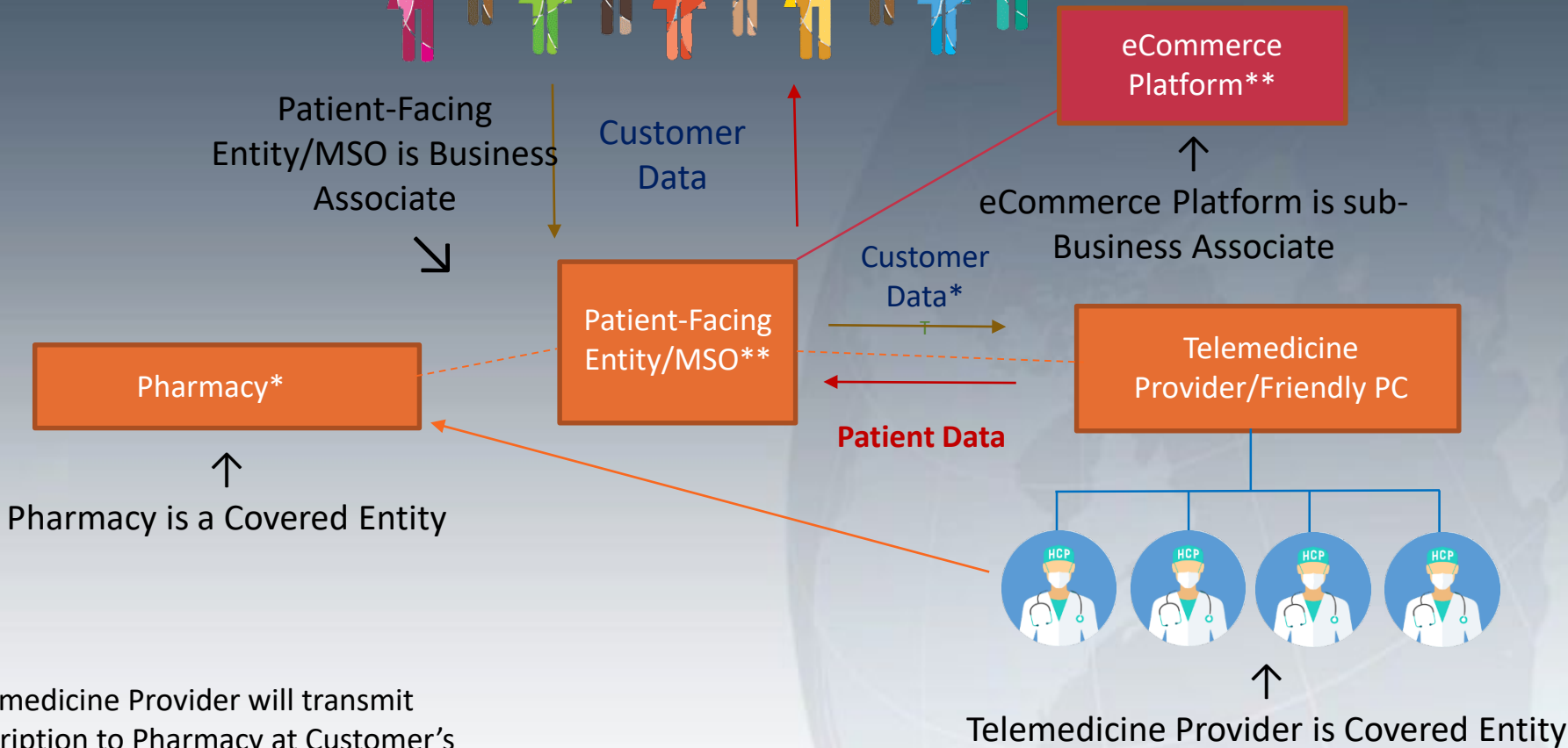
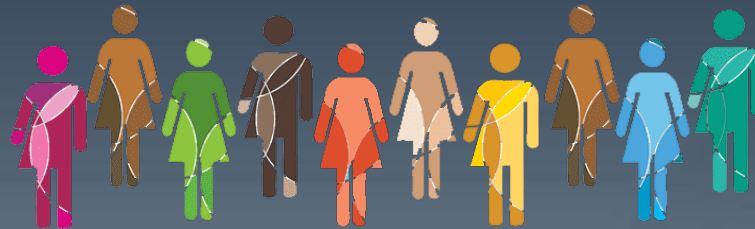
- **Telemedicine Provider** is HIPAA Covered Entity → **PHI** created, received, or maintained by the Telemedicine Provider **is the Telemedicine Provider's PHI**
 - Telemedicine Provider is an entity that is permitted to provide health care services in the relevant state
 - Telemedicine Provider delivers health care services consistent with relevant state laws
 - **Can access, use, and disclose PHI for TPO**
- **Pharmacy** is a HIPAA Covered Entity → PHI created, received, or maintained by the Pharmacy is the Pharmacy's PHI
 - Can access, use, and disclose PHI for TPO

WHOSE DATA IS IT, ANYWAY?

- **eCommerce Platform Provider is a Business Associate**
 - Serves as a Business Associates to the Telemedicine Provider
 - Telemedicine Provider and eCommerce Platform enter into a HIPAA compliant Business Associate Agreement (BAA)
 - Business Associates are **directly subject** to certain HIPAA requirements
 - **Can only access, use, or disclose PHI in its role as Business Associate → limited purposes**
 - Scope is defined by the services the BA performs for and on behalf of the Covered Entity

K&L GATES

Customer Data is PHI, collected by Business Associate for Telemedicine Provider



*Telemedicine Provider will transmit prescription to Pharmacy at Customer's request. Pharmacy dispenses drug.

WHOSE DATA IS IT, ANYWAY?

- **Telemedicine Provider** is HIPAA Covered Entity → **PHI** created, received, or maintained by the Telemedicine Provider **is the Telemedicine Provider's PHI**
 - Telemedicine Provider is an entity that is permitted to provide health care services in the relevant state
 - Telemedicine Provider delivers health care services through employed or 1099 health care providers, consistent with relevant state laws
 - **Can access, use, and disclose PHI for TPO**
- **Pharmacy** is a HIPAA Covered Entity → PHI created, received, or maintained by the Pharmacy is the Pharmacy's PHI
 - Can access, use, and disclose PHI for TPO

WHOSE DATA IS IT, ANYWAY?

- **eCommerce Platform Provider is a sub-Business Associate**
 - Serves as a sub-Business Associates to the Patient-facing/MSO Entity
 - Patient-facing/MSO Entity and eCommerce Platform enter into a HIPAA compliant Business Associate Agreement (BAA)
 - Business Associates are directly subject to certain HIPAA requirements
 - Can only access, use, or disclose PHI in its role as Business Associate → limited purposes
 - Scope is defined by the services the BA performs for and on behalf of the Covered Entity

WHOSE DATA IS IT, ANYWAY?

- **MSO/Patient-Facing Entity** → *Key Difference from other model*
 - Serves as a **Business Associates to the Telemedicine Provider**
 - Enters into a HIPAA compliant Business Associate Agreement (BAA)
 - Can only access, use, or disclose PHI in its role as Business Associate → **limited purposes**
 - Scope is defined by the services the BA performs for and on behalf of the Covered Entity
 - MSOs typically are engaged in a broad scope of services for and on behalf of the captive PC, e.g., billing and collections, HR, practice administration, quality assurance and improvement, peer review/credentialing, workforce training, education, & evaluation
 - Would require **patient authorization** for disclosures not tied to its role as a Business Associate

WHAT DOES ALL OF THIS MEAN?

- **Key Relationships Define Which Entities Can Access Data, For What Purposes**
 - In a CPOM state, where the entity that provides health care services must be a physician entity, ability of the MSO/Patient-Facing Entity to access data *without authorization* is limited
 - Can only access, use, or disclose PHI in its role as Business Associate → limited purposes
 - No Marketing without authorization
 - No Development/Innovation without authorization
 - No using or accessing PHI for its own purposes without authorization
- **What About Termination of the Relationship?**
 - BAA must return or destroy PHI upon termination of the CE/BA relationship

WHAT DOES ALL OF THIS MEAN?

- **Business Associates Cannot Access, Use, or Disclose PHI in Ways That Covered Entity Cannot**
- **Business Associate Must Comply with HIPAA's Privacy, Security, and Breach Notification Rules**
 - Must create, maintain, store, receive, and disclose PHI in compliance with Privacy Rule (e.g., disclosures for TPO, accounting of disclosures, use of valid HIPAA-compliant authorization, etc.)
 - Must maintain the confidentiality, integrity, & availability of ePHI
 - Must respond appropriately in the event of a breach of PHI

OTHER FEDERAL & STATE PRIVACY LAWS

- Other Federal and State laws may apply depending on the nature of the records
- Federal – *an example*
 - 42 C.F.R. Part 2 offers special protection for substance abuse and mental health records
- State – *some examples*
 - California Consumer Privacy Act (CCPA) protects health information and other personally identifiable information collected by certain businesses from California residents
 - Illinois Biometric Information Privacy Act (BIPA) and Genetic Information Privacy Act (GIPA) protect and restrict the use of certain sensitive biometric and genetic data collected by business from Illinois residents

FTC HEALTH BREACH NOTIFICATION RULE

16 C.F.R. Part 318

- Requires certain businesses to provide notifications following breaches of personal health record information
 - Applies to entities that maintain personal health records on behalf of consumers (or interacts with or offer services to an entity that does)
 - Covers personal health records that contain “individually identifiable health information” as defined under Section 1171(6) of the Social Security Act (i.e., identifiable health information created or received by a health care provider, health plan, employer or health care clearinghouse), as well as individually identifiable information provided by or on behalf of an individual directly to the entity
 - Does not apply to HIPAA covered entities and business associates

**DON'T FORGET ABOUT THE
INFORMATION BLOCKING RULE!**

Thank You for Joining Us!

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