FOLEY & LARDNER AT ATA NEXUS 2025

Exploring the Next Chapter in Virtual Care

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WELCOME AND OVERVIEW

Thank you for your interest in our presentation materials from the American Telemedicine Association (ATA) Nexus Deep Dive session, *The Business of Telehealth: The Biggest Legal Issues You Need to Understand*. This three-hour program, presented on May 3, 2025, offered attendees the opportunity to hear 11 different sessions on hot topics in telemedicine and digital health law, presented by 18 different speakers.

Deep Dive Sessions are a core component of ATA Nexus, where tremendous amounts of timely information are shared. This booklet offers our clients, industry colleagues, and friends a simple way to digitally access the presentation materials from the Foley lawyers. You will discover presentation slides along with additional resources and thought leadership on digital health.

Foley's national Telemedicine and Digital Health Industry Team has been referred to as "*the premier firm for telehealth counsel*," "*a market leader in telemedicine issues*" and "*the Dream Team*." Using a team-based approach of deep subject matter experts, we help established and emerging companies build innovative virtual care programs, create scalable and sustainable digital health companies, and reach patients in new markets around the block and around the world. We help create fully fledged telemedicine offerings, delivering end-to-end legal services by coupling precise strategic guidance with "*a stunningly high level of care and responsiveness*" to maintain that sense of urgency necessary to launch new initiatives and remain competitive in the marketplace. One firm; all your digital health needs.

Very truly yours,

Nathaniel Lacktman
Partner, Foley & Lardner LLP
Chair, Board of Directors of the American Telemedicine Association

About Foley's Telemedicine & Digital Health Industry Team

Foley's Telemedicine and Digital Health Industry Team helps organizations and entrepreneurs embrace emerging issues in virtual care, enabling them to provide innovative care for patients in new markets around the block and around the world. We are committed to helping clients fulfill their goals of harnessing new technology to reach patients anywhere and deliver care without borders or geographic limitations. We help clients create fully fledged telemedicine offerings, delivering end-to-end legal services by coupling precise strategic guidance with rapid turnarounds to maintain that sense of urgency necessary to launch new initiatives and remain competitive in the marketplace. One firm; all your digital health needs. For more information on Foley's Telemedicine & Digital Health Industry Team, please click here.

About Foley

Foley & Lardner LLP is a preeminent law firm that stands at the nexus of the Energy & Infrastructure, Health Care & Life Sciences, Innovative Technology, and Manufacturing Sectors. We look beyond the law to focus on the constantly evolving demands facing our clients and act as trusted business advisors to deliver creative, practical, and effective solutions. Our 1,100 lawyers across 26 offices worldwide partner on the full range of engagements from corporate counsel to intellectual property work and litigation support, providing our clients with a one-team solution to all their needs.
For nearly two centuries, Foley has maintained its commitment to the highest level of innovative legal services and to the stewardship of our people, firm, clients, and the communities we serve.

FOLEY PRESENTERS

The Business of Telehealth: The Biggest Legal Issues You Need to Understand

FOLEY & LARDNER LLP

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Data Privacy Considerations for Your Digital Strategy

Jennifer Hennessy

Jess Heimler

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Our Agenda

- The importance of understanding your regulatory scheme.
- Tracking technologies.
- HIPAA security risk analysis enforcement initiative.
- Patient access rights under HIPAA and state laws.

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HIPAA, State Laws, or Both?

- Most consumer data privacy laws either exempt HIPAA covered entities or at least exempt PHI regulated by HIPAA and medical information governed by state medical records laws.
  - The California Privacy Rights Act (CPRA) exempts medical information governed by the California Confidentiality of Medical Information Act (CMIA) and PHI collected by a HIPAA-regulated entity.
  - The Washington My Health My Data Act has similar data exemptions.
  - The Texas Data Privacy and Security Act exempts out HIPAA-regulated entities, as well as PHI and medical records.
- Therefore, make sure you understand what information is HIPAA PHI versus what is “personal information” regulated by state laws.

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Tracking Technologies

- Current regulatory landscape
  - FTC
    - FTC Act and FTC Health Breach Notification Rule
    - FTC, HHS and OCR 2021 Letter re: Use of Online Tracking Technologies
  - State laws
    - CPRA
    - Washington MHMD
  - HHS
    - American Hospital Association case: there may be some instances where the IP address of a visitor to an unauthenticated webpage is not PHI.
- Challenges with cookie consents
  - Opt-in vs. opt-out regime
  - Dark patterns
- Risk from plaintiffs' bar/litigation
  - Lucrative business - from nuisance claims up to class action potential.

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Key Takeaways on Tracking Technologies

- Identify which portions of your digital platforms are authenticated versus unauthenticated, treat them accordingly.
- Understand how you are regulated – what laws apply?
- Understand how you are using data.
  - What part of your platform is the data coming from?
  - What data pieces are being collected?
  - How is the data being used?
  - How is the data being sent?
  - Is this reflected in your privacy policy, terms of use, cookie consent, etc.?
- Understand the design of your cookie banner.

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HHS Security Risk Analysis Enforcement Initiative

- Since 2018, HHS has seen a 264% increase in reported large breaches involving ransomware.
- Security risk analysis: HIPAA Security Rule requires that HIPAA-regulated entities conduct "an **accurate and thorough assessment of the potential risks and vulnerabilities** to the confidentiality, integrity, and availability of" electronic PHI held by the entity and "implement security measures sufficient to **reduce risks and vulnerabilities** to a reasonable and appropriate level."
- HHS announced Security Risk Enforcement Initiative in October 2024 to focus select investigations on compliance with this requirement.
- Settlements have ranged from $10k-350k.

  "Failure to conduct a HIPAA Security Rule risk analysis leaves health care entities vulnerable to cyberattacks, such as ransomware. Knowing where your ePHI is held and the security measures in place to protect that information is essential for compliance with HIPAA. OCR created the Risk Analysis Initiative to increase the number of completed investigations and highlight the need for more attention and better compliance with this Security Rule requirement." - OCR Director, October 31, 2024

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HIPAA Right of Access

- Individuals have a broad right to inspect and obtain a copy of their PHI maintained in a Designated Record Set.
- HIPAA covered entities must:
  - Respond within **30 days**,
  - Provide individuals with all PHI included in a Designated Record Set,
  - Provide access to PHI in the form and format requested, and
  - Charge only specified fees.
- ***Heavily*** enforced by OCR – over 50 settlements to date.

  "A patient's right to timely access their own health information is well-established by the HIPAA Privacy Rule. Health care entities must be responsive to their patients' requests for their medical records. Patients should not have to file a complaint with OCR as a necessary step before receiving their records." - OCR Director, January 15, 2025

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Similar Rights Under State Laws

- California, for example:
  - Patients entitled to inspect records within **five working days** after provider's receipt of the request; any requested copies must be transmitted within **15 days** after provider's receipt of the request.
  - Under the CPRA, consumers have the right to obtain from a business, within **45 days** of receipt of the request:
    1. The categories of personal information, and specific pieces of personal information, the business has collected about that consumer;
    2. The categories of sources from which the personal information is collected;
    3. The business or commercial purpose for collecting, selling, or sharing personal information; and
    4. The categories of third parties to whom the business discloses personal information.

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DEA Telemedicine Prescribing: Special Registrations, Waivers, Buprenorphine, and What to Expect

Marika Miller

Nathan A. Beaver

DEA Registration & Telemedicine Prescribing Requirements Refresh

DEA Registration

Without Flexibilities:

- Practitioners must have a separate DEA registration in each state in which a telemedicine patient is located.

With Flexibilities:

- Practitioners only need a registration in one state – the state in which they are located.

Telemedicine Prescribing

General Rule

- No prescribing of controlled substances without at least one in-person evaluation.

Exception: "Practice of Telemedicine"

- Defined as communicating with a patient via a telecommunications system.
  - Includes two-way, real-time:
    - Audio-video
    - Audio-only*

** If the practitioner has the capability to use audio-video, but the patient is either unable to use video or does not consent to it.*

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"Practice of Telemedicine" Exceptions

There are seven specific cases where a practitioner can prescribe via telemedicine without an in-person exam:

1. **Hospital or Clinic**
   Patient is treated by and physically located in a hospital or clinic.
2. **With Another Practitioner**
   Patient is treated by and in the physical presence of another practitioner.
3. **Indian Health Services**
   Patient is treated by an employee of the Indian Health Services.
4. **Public Health Emergency**
   Treatment occurs during a PHE declared by HHS.
5. **Special Registration**
   Practitioner holds a special registration.

   Special registration proposed rule establishes this process
6. **VA Medical Emergency**
   Patient is treated for a medical emergency by a Veterans Health Administration employee.
7. **Other Regulations**
   Patient is treated under other circumstances permitted by HHS regulations.

   Current DEA telemedicine flexibilities and the buprenorphine final rule fall under this exception

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Special Registration Proposed Rule

Comment Period Closed March 18, 2025

To prescribe controlled substances via telemedicine using the Special Registration pathway, the following must occur:

Special Registration

Each practitioner and telemedicine platform must obtain a Special Registration

State Telemedicine Registration

Each practitioner and telemedicine platform must also obtain a State Telemedicine Registration in each state they prescribe or dispense

PDMP Check

Practitioners must check the PDMP of the state where they are located, the state where the patient is located, and any state that has a reciprocity agreement with these states

Telehealth Modality

Prescriptions must be issued via an audio-video visit

except

buprenorphine may be prescribed via an audio-only visit in certain circumstances

Schedule II

Practitioners must be located in the same state as the patient and prescribe less than 50% of Schedule II prescriptions via telemedicine

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Buprenorphine Final Rule

Implementation Delayed to December 31, 2025

Before prescribing via telemedicine and dispensing buprenorphine for OUD treatment, the following must occur:

PDMP Check

Check PDMP of state where the patient is located

Scope of PDMP Review

Prescription history for the past year or whatever is available

Initial Prescriptions

Issue up to a six-month supply if able to review PDMP data

or

Issue up to a 7-day supply if *not* able to review PDMP data

Follow-Up Prescriptions

Conduct an in-person visit

or

Meet one of the seven Ryan Haight Act exceptions to prescribe via telemedicine

Pharmacist Verification

Verify the identity of the patient using acceptable documentation

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The Future for DEA Telemedicine Prescribing

Our Predictions

Special Registration Proposed Rule

Likely to be shelved or revamped

- Burdensome requirements
- Unworkable Schedule II restrictions
- Current DEA will likely want to write their own rule

Buprenorphine Final Rule

Likely to be delayed further or to be rescinded

- Delayed twice already
- Second delay was to review 32 comments
- Current DEA will likely want to write their own rule

Current Telemedicine Prescribing Flexibilities

Likely to be extended another year

- No other viable alternative to continue prescribing via telemedicine to avoid interruptions in patient care and patient harm
- Pressure from stakeholders will be important

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50-State Telehealth Practice Laws

Jacqueline Acosta

Olivia Dresevic

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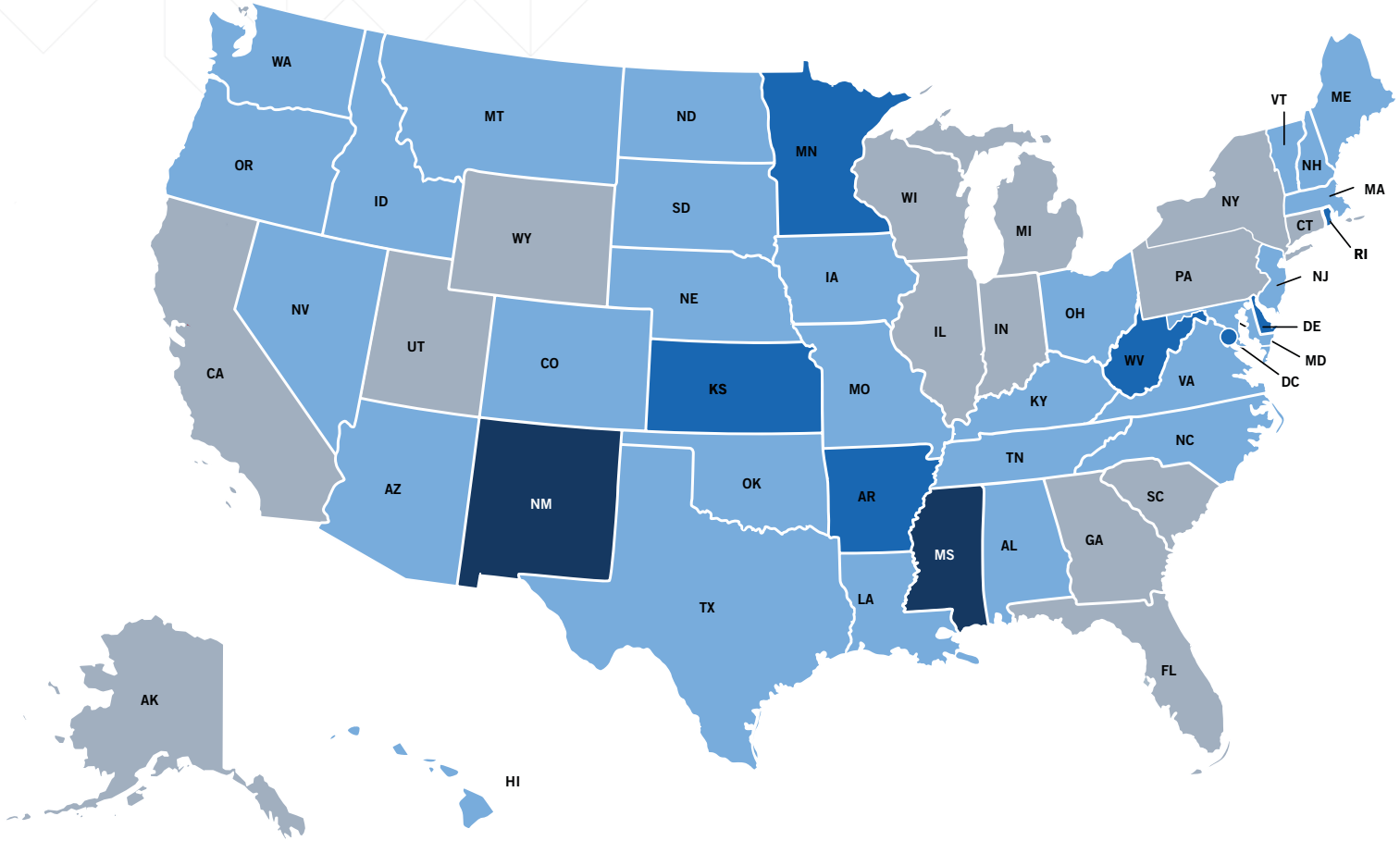
Minimum Required Modality to Create Doctor-Patient Relationship: 2025



- Silent
- Audio/Video
- Interactive Audio
- Asynch

Interpretive summary only; not legal advice; state laws are constantly evolving and state laws must be analyzed and applied to a specific clinical application. Medical board rules only; excludes Medicaid or other payor rules.

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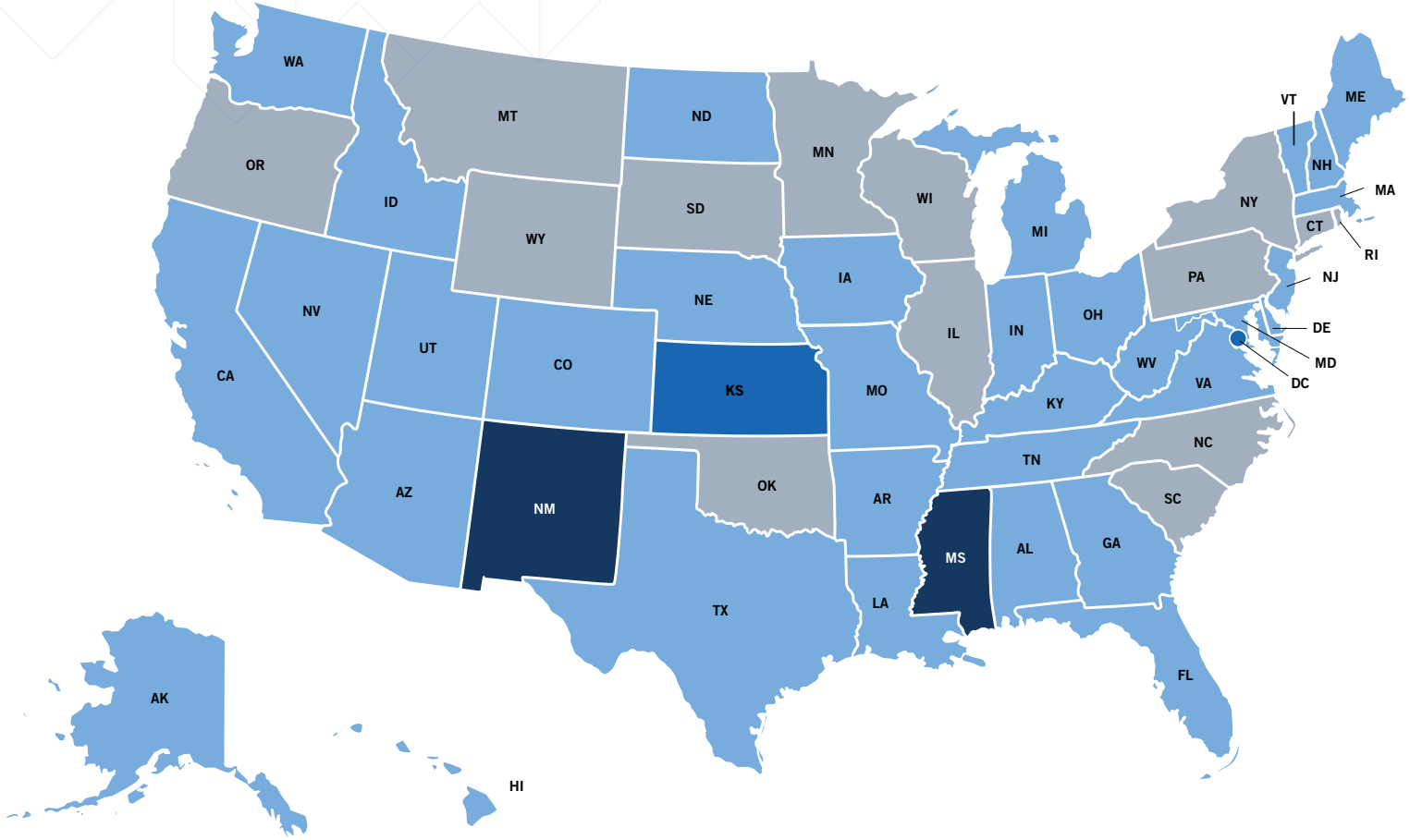
Minimum Required Modality for Prescribing Non-Controlled Substances: 2025



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- Interactive Audio
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Asynchronous Telemedicine by the Numbers: 2025

States with laws that **expressly ban asynchronous** telemedicine to be used to establish a valid doctor-patient relationship, instead requiring the use of either audio-video or “interactive audio with store & forward” as the modality.

9 states

States with laws that **expressly allow asynchronous** telemedicine to be used to establish a valid doctor-patient relationship.

28 states

States with **do not mandate or proscribe a** specific modality, instead choosing to more broadly define telemedicine to allow for new changes in technology and innovation (e.g., the use of secure electronic communications and information technologies between a patient at an originating site and a physician at a distant site).

14 states

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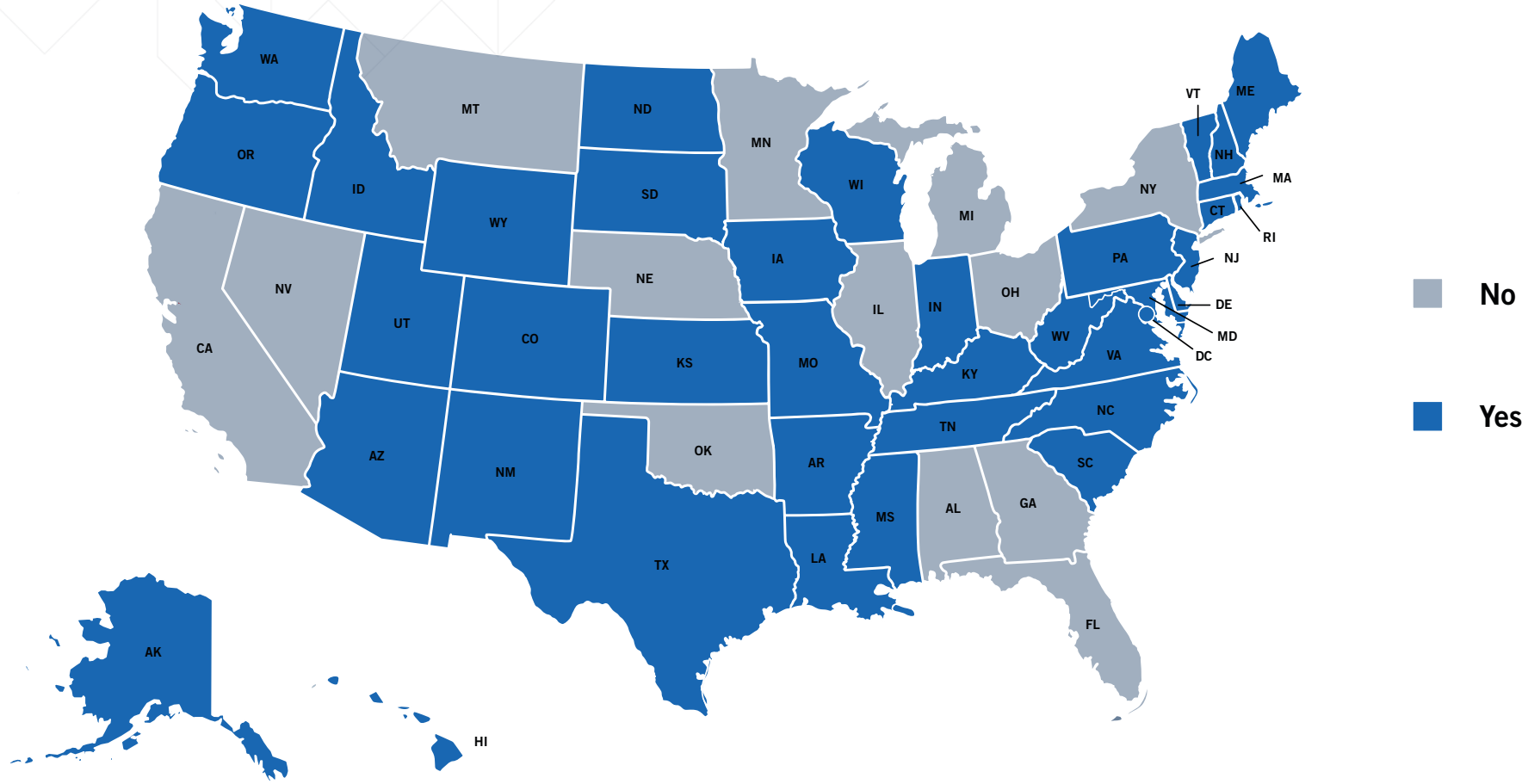
States With Questionnaire-Based "Internet Prescribing" Limitations: 2025



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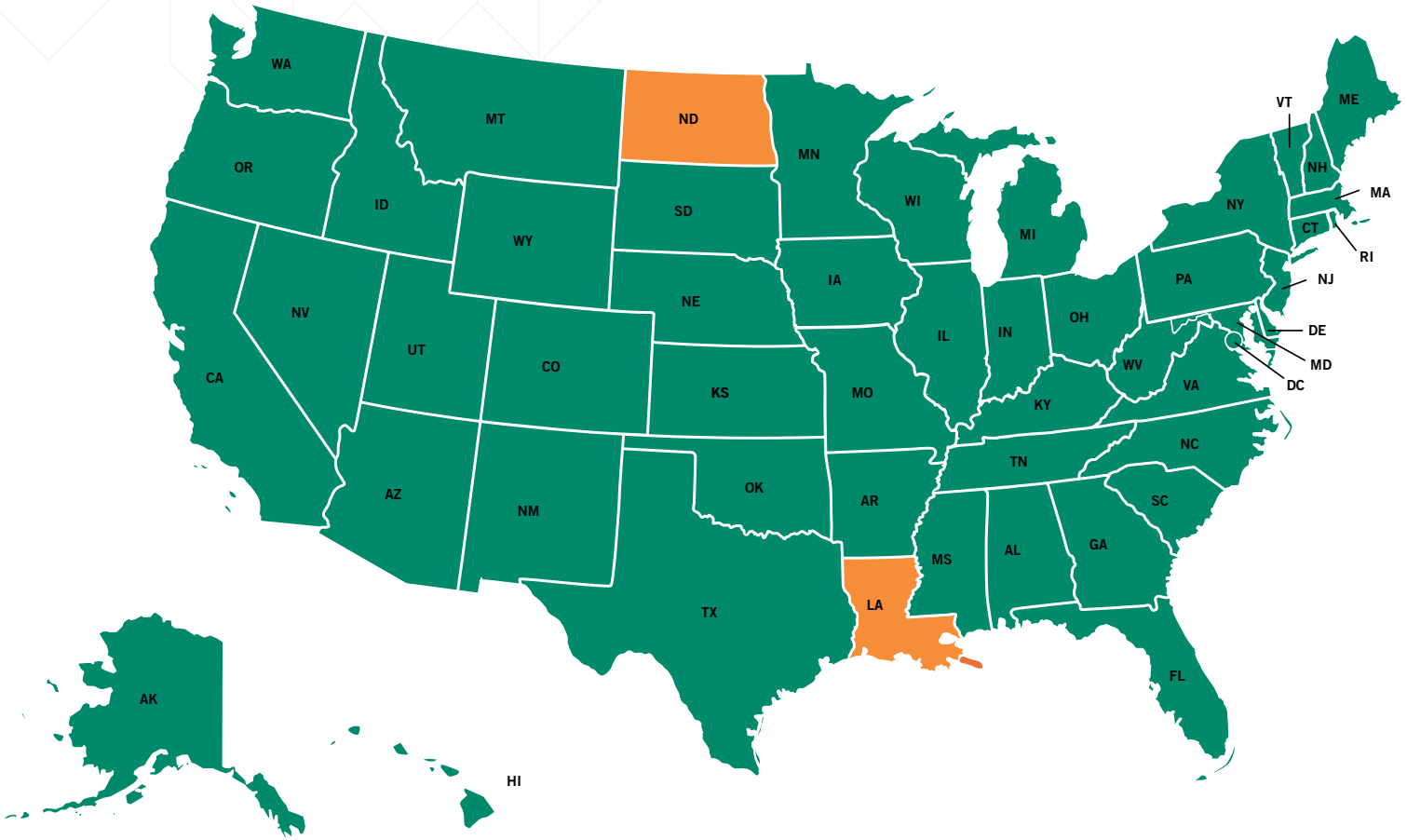
Telemedicine Prescribing of Weight Loss and Lifestyle Medications: 2025



- Not Expressly Prohibited
- Expressly Prohibited

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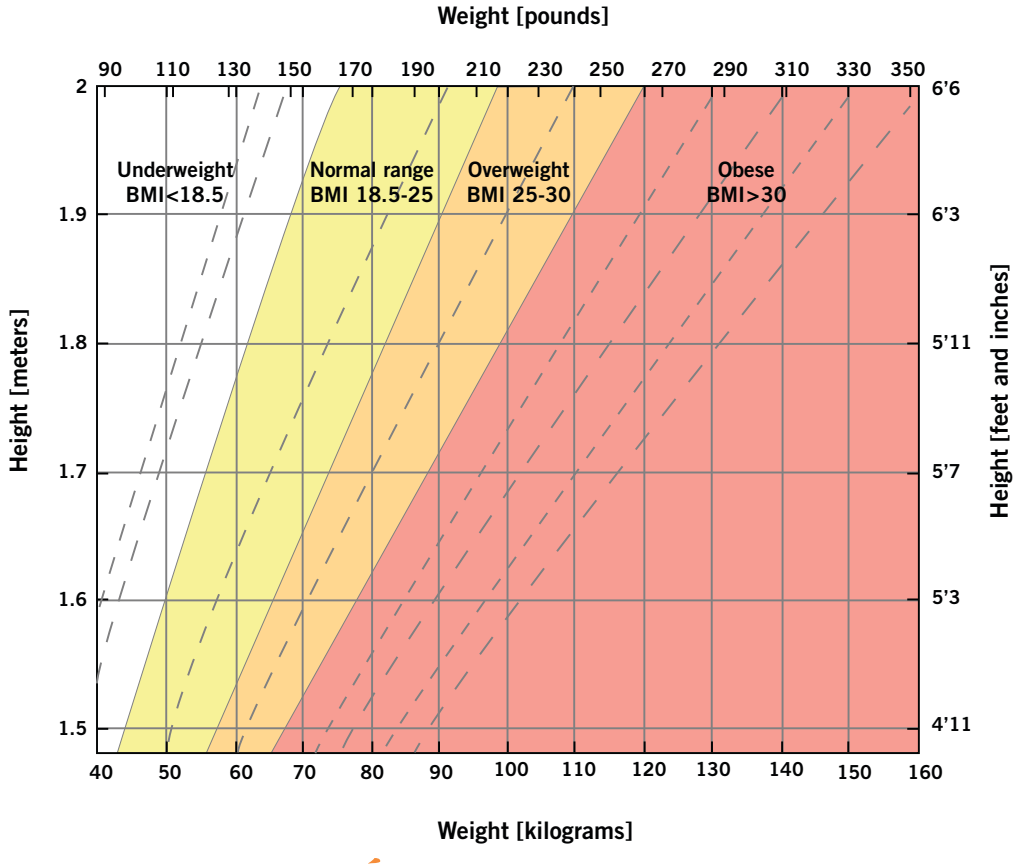
General Practice Standards – Weight Loss Medications: 2025

- **Florida.** BMI calculations, physical examination, history, and testing.
- **New Jersey.** History, physical examination, laboratory and/or diagnostic tests, co-morbidity assessment, psychiatric or psychological assessment.
- **Virginia.** Physical examination, lab work, ECG (in certain circumstances), recording of blood pressure, pulse, and other tests.



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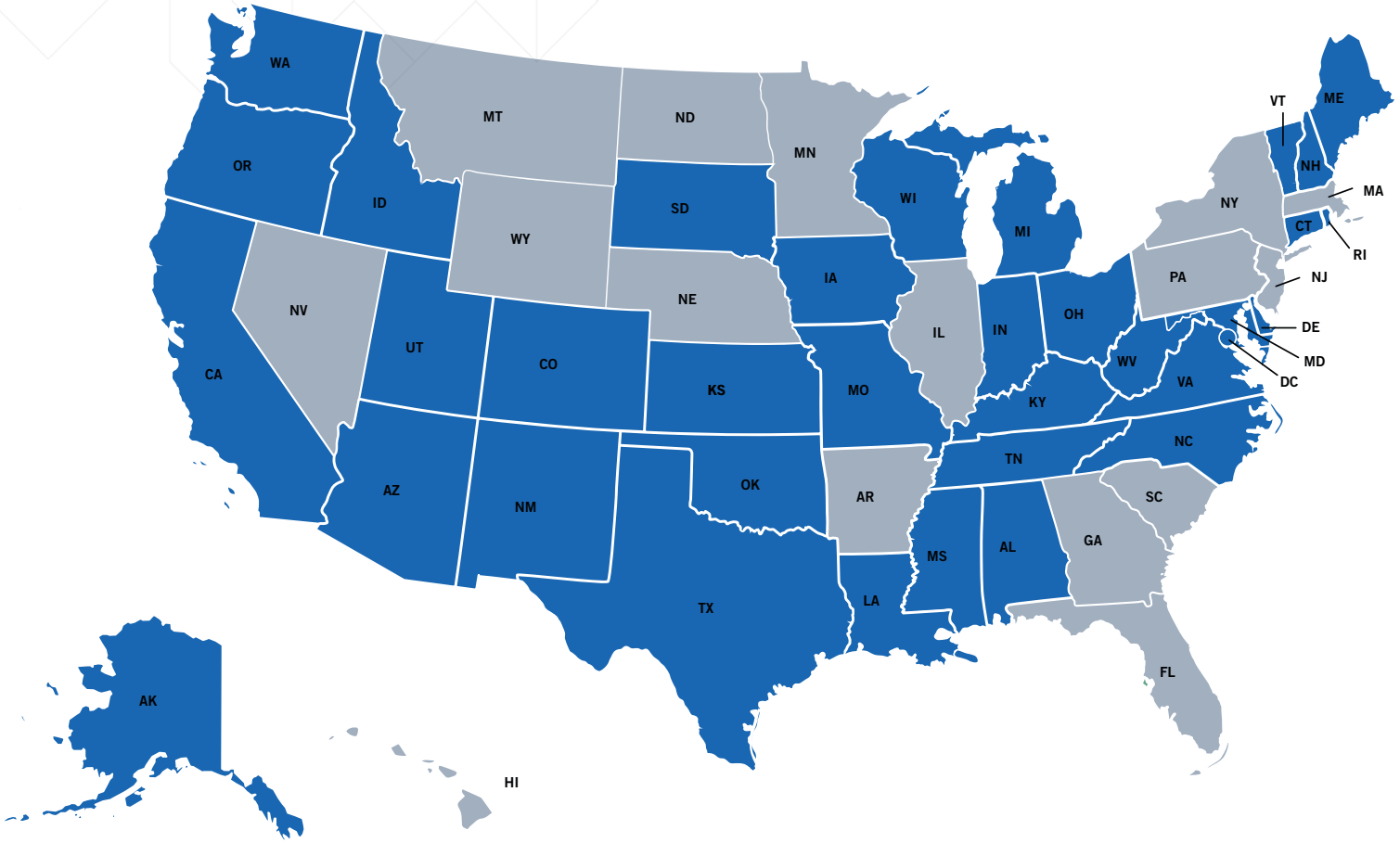
Telemedicine Patient Informed Consent Requirements: 2025



Express Telemedicine Informed Consent Requirements

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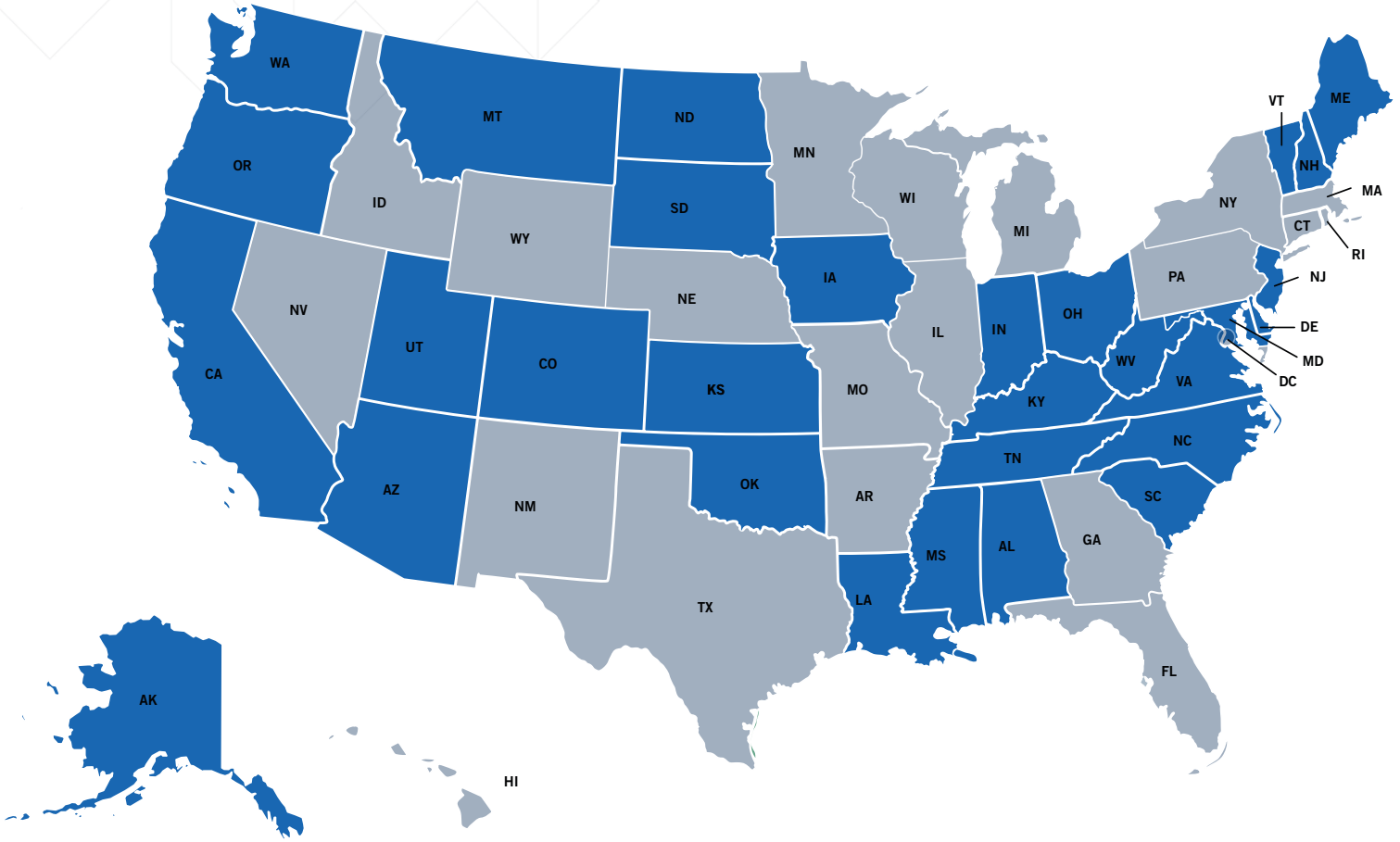
Telemedicine Patient ID Verification Requirements: 2025



Express Patient ID Verfication Requirements

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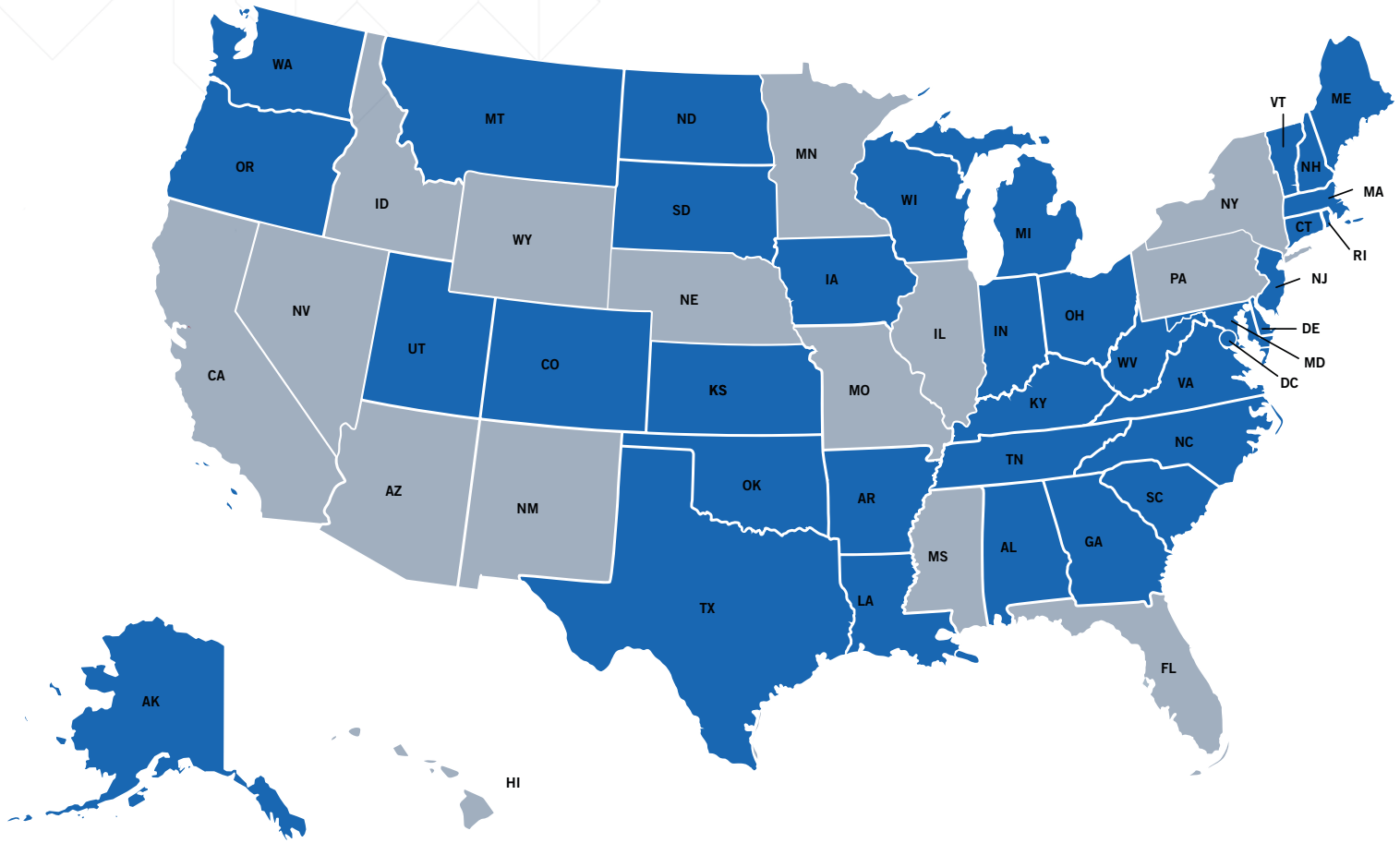
Telemedicine Special Notice/Disclosure Requirements: 2025



Special Notice/Disclosure Requirements

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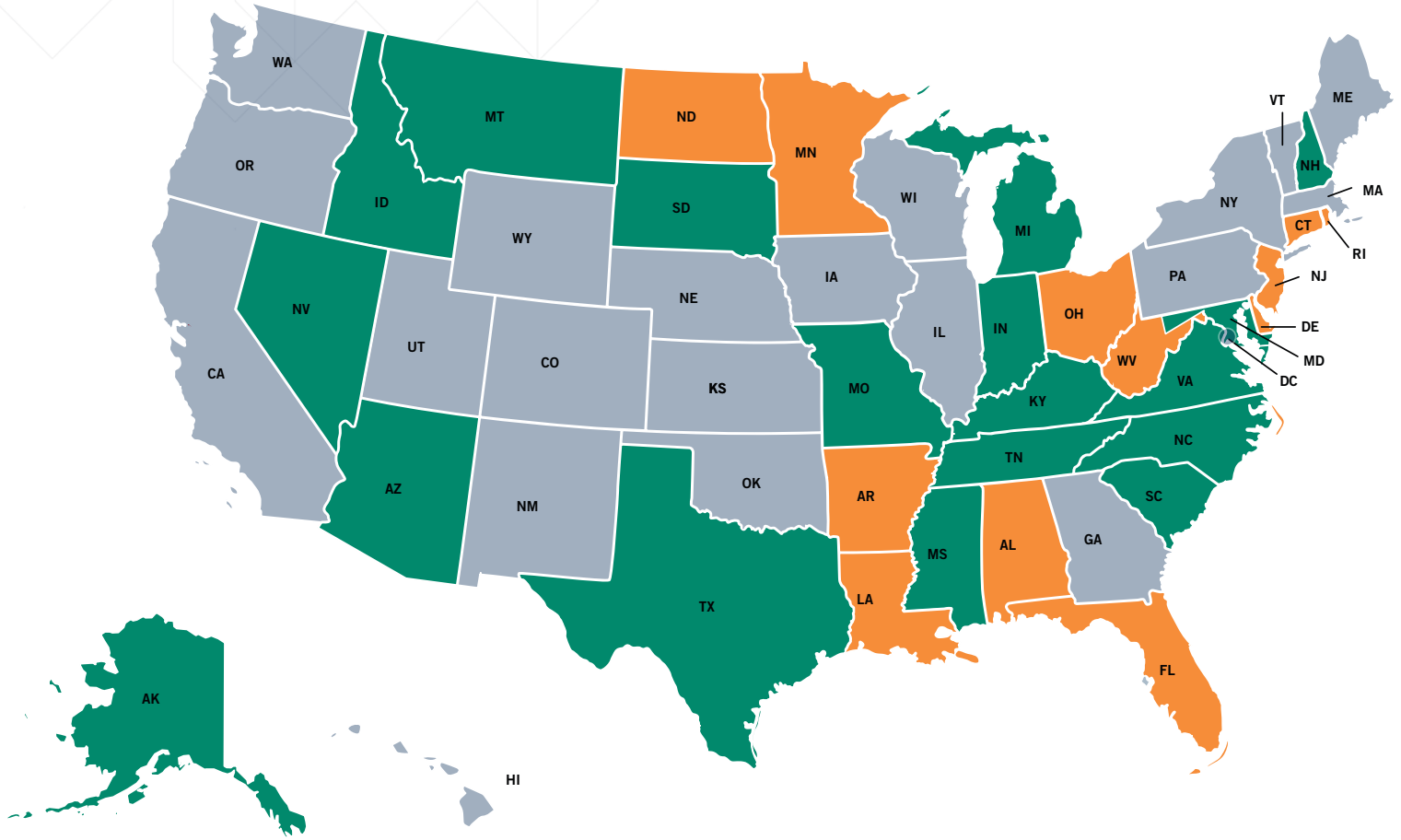
Telemedicine Prescribing and Controlled Substances: 2025



- Expressly Allowed (some limitations)
- Expressly Prohibited (unless prior in-person exam)
- Silent

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Health Care Transaction Review Laws

for Digital Health Companies

Hannah Zaitlin
Evan Hellman

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Background/History

- Many states have long established Attorney General review of non-profit hospital/health care transactions (e.g., Colorado, Georgia, Hawaii, Michigan, Ohio, Rhode Island, Tennessee, Texas, Virginia).
- More recent crop of state laws aimed at monitoring the impact of health care transactions on *competition, quality, access and cost*.
- MA 2013 > CT 2014 > WA 2020 > NV 2021 > OR 2022 > NY 2023 > MN 2023 > IL 2024 > CA 2024 > IN 2024 > PA? > MN?
- Efforts to target private equity and management service organizations, including pending legislation in California, Pennsylvania, and Minnesota.

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Transaction Notice/Approval Requirements – State Chart

State	Timeline	Notice and/or Approval
California	90 days pre-closing	Notice
Connecticut	30 days pre-closing	Notice
Illinois	30 days pre-closing	Notice
Indiana	90 days pre-closing	Notice
Massachusetts	60 days pre-closing *At least 30 days after commission issued report (if applicable)	Notice (and Approval *subject to commission's final market impact report, if required)
Minnesota	60 days pre-closing (* $80 mil+) 30 days pre-closing or within 10 business days of date parties first reasonably anticipate entering into transaction ($10-80 mil)	Notice
Nevada	30 days pre-closing	Notice
New York	30 days pre-closing & Post-closing e-mail notice to Department	Notice
Oregon	180 days pre-closing notice Oregon Health Authority must complete initial review within 30 days of submission.	Notice and Approval
Washington	60 days pre-closing	Notice and Approval (assumed unless within 60 days after notice is given, WA AG initiates further investigation).

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Practice Pointers

- Laws vary from state to state, including relevant definitions and materiality thresholds and filing requirements, and require fact sensitive analysis.
  - *Important if the transaction structure changes over the course of the deal – could impact notice or approval requirements. Type of entity involved in transaction matters.*
- Does NOT necessarily matter where entities are headquartered or domiciled.
- Revenue/assets *in* state versus *national* revenues may matter.
- Project revenue post-transaction *may* matter.
- Whether to file in a particular state may be driven more by a political/risk analysis then a technical legal conclusion.

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Avoiding Delays/Inefficiencies

- Start early. Notice and approvals are generally **pre-closing**. Different timelines will play a role in the transaction.
- Diligence the health care operations of both parties in a transaction (including affiliates).
  - The operations of all parties may be relevant to the material change analysis.
- Seek early clarity on deal structure (financing/equity raise, stock deal/merger, asset sale, new management company, changes in board control or management).
- This process should be collaborative. Both parties may have to provide information to adequately notify regulators (e.g., financial and geography of operations, headcount of providers).
- Consider local counsel/experts (application submissions, liaisons with state AG offices/health departments).

Applicability of Laws – Digital Health Platforms*

- **New York** – If $25MM+ gross in-state revenue is expected from transaction.
  - Filing required 30 days prior to closing.
  - Law applies specially to entities that provide management services.

- **Oregon** – One party had average revenue of $25 million or more in the preceding three fiscal years; other party had an average revenue of at least $10 million in the preceding three fiscal years.
  - Law applies to entities that are “closely related to an entity that provides health care.”
  - Filing required 180 days prior to closing; but pre-review process.

- **Minnesota** – Broad definition of “exercising control” over a health care entity.

  - *But, if digital platform is performing any payor contracting functions or ancillary health care services closer review as to applicability of these laws is needed.

Applicability of Laws – Health Providers

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- California
- Connecticut
- Illinois
- Indiana
- Massachusetts
- Nevada
- Washington

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Non-compete Agreements for Health Care Workers: An Overview

Larry Perlman, MD

David Sanders

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Choice of Law

- Delaware should not be the default.
- Focus on where the individual is located (for telehealth and brick-and-mortar).

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States Banning or Limiting Physician Non-Competes

- Arkansas
- Delaware
- Georgia
- Indiana
- Kentucky
- Massachusetts
- New Hampshire
- Rhode Island
- South Dakota
- Colorado
- New Mexico

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Most Recent Legislation

- **Arkansas** - On March 4, 2025, the governor signed a law amending the state's non-compete statute to ban physician non-compete agreements. The term "physician" includes any person authorized or licensed to practice medicine under the Arkansas Medical Practice Act and any person licensed to practice osteopathy under Arkansas law. The Act will take effect in the summer of 2025.

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Kentucky

- As of July 14, 2022, health care services agencies may not restrict employment through non-compete agreements.
- The law was amended on June 29, 2023, under the amendment, the statute only applies to “direct care staff that is contracted with or employed by the agency.”

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Colorado

- Physician non-compete agreements restricting a physician's right to practice is void as a matter of law.
- The statute provides exceptions, however, allowing physicians to:
  - Agree to damage provisions imposed if they leave the practice, and for the recovery of those damages reasonably related to the injury suffered; and
  - Disclose their new professional contact information to any existing patient with a rare disorder or a successor organization to whom the physician was providing consultation or treatment before termination of the agreement.

Colorado (cont.) – Example Language

- Carve-Outs. Notwithstanding the foregoing, nothing herein shall restrict Employee from the following activities disclosing Employee's continuing practice of medicine and new professional contact information to any patient with a rare disorder, as defined in accordance with criteria developed by the National Organization for Rare Disorders, Inc., or a successor organization, to whom Employee was providing Clinical Services or Remote Services before termination of the Employment Period and continuing to provide Clinical Services or Remote Services or at a new employer to any such patient.

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Colorado (cont.) – Example Language

- "With respect to Sections 9(a)(ii) and 9(a)(v), the Company's sole and exclusive remedy for any violation of the provisions in such Sections shall be the payment of damages (and not as a penalty) in an amount that is reasonably related to the injury suffered by the Company Group by reason of Employee's (A) termination of employment pursuant to or in violation of the terms of this Agreement; plus (B) violation of those Sections 9(a)(ii) and 9(a)(v)."

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States Banning J-1 Visa Physician Non-Competes

- Idaho
- Nevada
- J-1 Visas are non-immigrant study and work-related exchange programs.

NEXUS 2025

States that Strictly Construe Non-Competes for Health Care Workers

- Arizona
- Ohio

NEXUS 2025

Arizona

- Courts strictly construe physician non-compete restrictions against the enforcer.
- Arizona courts strongly favor the patient's right to choose a doctor freely.
  - The Arizona Supreme Court determined that "the doctor-patient relationship is special and entitled to unique protection." *Valley Med. Specialists v. Farber*, 982 P.2d 1277, 1283 (Ariz. 1999).
- Based on *Farber*, physician non-competes should be limited to **five to 10 miles** depending on population density and location of patients.
  - In *Farber*, the Court held that the covenant not to compete between the physician and Practice was unenforceable. It noted that the Practice's protectable interests were small compared to the patients' right to see the doctor of their choice. The Court also found that the three-year duration was unreasonable; the five-mile radius was unreasonable because with the three business locations the restriction covered more than 235 square miles; the restriction was overly broad because it was not limited to the physician's specialty.
  - Best practice is to review where patients are coming from before setting geographic scope.

NEXUS 2025

States Permitting Physician Non-Competes Under Specific Conditions

- Pennsylvania
- Connecticut
- Tennessee
- Texas
- West Virginia
- Florida
- North Carolina

NEXUS 2025

Most Recent Legislation

- **Pennsylvania** – the Fair Contracting for Health Care Practitioners Act, effective January 1, 2025, bans most non-compete agreements for physicians, osteopaths, certified registered nurse anesthetists, certified registered nurse practitioners, and physician assistants.
- Among other carve-outs, the Act does not ban non-compete agreements that are one year or less and apply to a health care practitioner who voluntarily terminated their employment.

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Connecticut

- Existing Law
  - Non-competes for physicians, APRNs, and PAs are only enforceable if the agreements are:
    - Necessary to protect a legitimate business interest;
    - Reasonably limited in time, geographic scope, and practice restrictions; and
    - Otherwise consistent with law and public policy.
  - Connecticut's statue also prohibits any restriction of more than one year or more than 15 miles from the physician’s primary practice site.
- Recent Amendments
  - Agreements are unenforceable if:
    - The physician does not receive a material increase in compensation at the time of the extension or renewal of the non-compete; and
    - The non-compete expires and is not renewed by the employer; or the employment or contractual relationship is terminated by the employer, unless such employment or contractual relationship is terminated by the employer for cause.
  - Under the amendment, a non-compete can only include one site where the 15-mile restriction can be in place.

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Tennessee

- Non-compete agreements for many health care workers are only enforceable where:
  - The agreement is signed in writing; and
  - The restriction is for a maximum of two years and the geographic restriction is:
    - Limited to a ten-mile radius of the physician's primary practice site;
    - Limited to the county of the physician's primary practice site; or
    - There is no geographic restriction, but the physician may not practice in the employer’s facilities.
- The statute specifically enumerates which types of health care workers these restrictions apply to. For example, they apply to chiropractors but not physical therapists.

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Texas

- Physician non-competes are only enforceable where the non-compete restriction:
  - Does not deny physician access to a list of patients whom the physician had seen or treated within one year of the end of the employment relationship;
  - Provides access to customary patient medial records for a reasonable fee;
  - Provides a buy-out provisions for a reasonable price or as agreed by the parties; and
  - Allows the physician to continue treating specific patients or those with acute illnesses after the employment has terminated.

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Texas (cont.) – Example Language

- Carve-Outs. Notwithstanding the foregoing, nothing herein shall restrict Employee from the following, so long as Employee is licensed as a physician by the Texas Medical Board: (1) continuing to care for and treat patients with acute illnesses; and (2) accessing (A) a list of patients that Employee saw or treated in the 12 months prior to the expiration of the Employment Period and (B) a patient's medical records for a reasonable fee, provided that such patient provides his or her consent to the release of such records to Employee.
- Notwithstanding anything herein to the contrary, Employee has the option to be released from the covenants contained in Sections 9(a)(i) and 9(a)(iv) upon Employee's payment of a reasonable price to the Company (the "*Option*"). If the Parties are unable to agree upon a reasonable price, at the time Employee intends to exercise the Option, the price shall be determined by a mutually agreed upon arbitrator or, in the case of an inability to agree, an arbitrator of the court whose decision shall be binding on the Parties.
- **Practice Tip**: Practitioners generally use one year of base salary for buyout provision.

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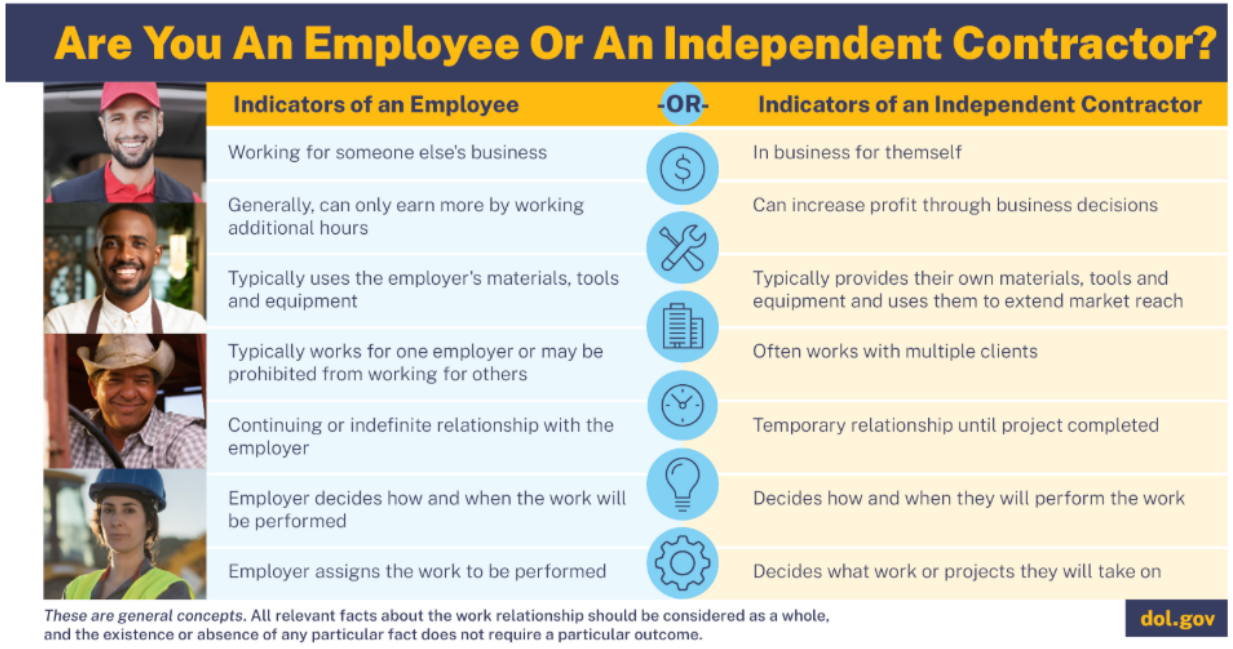
Independent Contractors

- Be careful that restrictive covenants do not undermine 1099 status

Misclassification of Employees as Independent Contractors Under the Fair Labor Standards Act



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States With General Employment-Based Non-Compete Bans

- California
- Minnesota
- North Dakota
- Oklahoma

- Montana: it’s complicated

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States with General Employment-Based Non-Compete Income Thresholds as of 2025: Some States Change Annually or Less Periodically

- Colorado ($127,091)
- Illinois ($75,000)
- Maine ($62,600)
- Maryland ($22.50 hourly or $46,800 annually)
- Massachusetts (FLSA non-exempt)
- Nevada (paid solely on an hourly wage basis, exclusive of tips or gratuities)
- New Hampshire ($14.50 per hour or tipped minimum wage)
- Oregon ($116,427)
- Rhode Island ($39,125 or FLSA non-exempt)
- Virginia ($76,081.20)
- Washington ($123,394.17 and for independent contractors $308,485.43)
- Washington D.C. ($158,364 and for medical specialists $263,939)

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2025

The State of Digital Therapeutics: The Legal Environment in 2025 & Beyond

Thomas (T.J.) Ferrante

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The State of Digital Therapeutics: The Legal Environment in 2025 & Beyond

Bringing DTx Products to Market

- FDA Pathways
- Rx vs. Non-Rx
- Manufacturer Compliance

Promotion & Distribution

- Prescription Gateway
- State Distribution Laws
- Digital Pharmacy
- Marketing & Advertising Laws

Payment & Reimbursement

- Benefit Categories
- Managed Care / Employer Plans
- DMHT / RTM

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Digital Health Product Advertising and Promotion Rules of the Road

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Agenda

- FDA & FTC Authority
- Fundamental FDA Advertising and Promotion Requirements
- Fundamental FTC Advertising and Promotion Requirements

NEXUS 2025

Memorandum of Understanding

- FDA shares jurisdiction with FTC over the marketing of dietary supplements, foods, drugs, medical devices, and other health-related products.
- FDA and FTC have agreed to an MOU detailing how the agencies will work together to oversee advertising and other promotional communications for products subject both to FDA oversight and to FTC enforcement. See Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18, 539 (Sept. 16, 1971).

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FDA & FTC Jurisdiction

- FDA has primary responsibility over claims that appear on labeling, while FTC has primary responsibility for claims made in advertising.
- The FD&C Act Section 201(k) defines “label” as “a display of written, printed, or graphic matter upon the immediate container of any article.” However, the container label is only a subset of the broader legal concept of “labeling,” which is defined as “all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) **accompanying** such article” (emphasis added). *See* 21 U.S.C. § 321(m).
- The FDA and courts have interpreted "accompanying" broadly and not restricted to information that is physically with a product. One court concluded that labeling "supplements or explains" a drug, and includes "advertising or descriptive matter" where "no physical attachment one to the other is necessary." *See Kordel v. United States*, 335 U.S. 345, 348-50, 69 S.Ct. 106, 93 L.Ed. 52 (1948).
- FDA has interpreted its regulatory authority over a drug’s “labeling” to include most of a manufacturer’s communications that mention or allude to the drug product. This regulatory concept of “promotional labeling,” therefore, encompasses most of a drug’s written and printed promotional materials and even oral statements about the drug made by company representatives.

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Jurisdiction Summary

- Prescription Drugs and Biologics
  - Labeling FDA
  - Advertising FDA
- Restricted Devices
  - Labeling FDA
  - Advertising FDA
- OTC Drugs
  - Labeling FDA
  - Advertising Federal Trade Commission
- Unrestricted Devices
  - Labeling FDA
  - Advertising Federal Trade Commission
- Dietary Supplements
  - Labeling FDA
  - Advertising Federal Trade Commission
- Cosmetics
  - Labeling FDA
  - Advertising Federal Trade Commission

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Basic FDA Requirements for Rx DTC Drug Ads

- All basic FDA requirements apply to both DTC and HCP promotion: materials should not be false or misleading; must contain fair balance and must disclose material facts; and claims must be supported by appropriate evidence and be consistent with the use of the drug as described in its PI.
- Product claim ads must provide a “fair balance” of information about drug risks as compared with information about drug benefits. This means that the content and presentation of a drug’s most important risks must be reasonably similar to the content and presentation of its benefits.

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Major Statement (Broadcast) / Brief Summary (Print Ads)

- Broadcast (TV or radio) ads for prescription drugs must include a “major statement,” which refers to the presentation of the drug’s most important risks. This presentation must be spoken. It also can be included in the video part of TV advertisements.
- Any print advertisements for prescription drugs (with the narrow exception of exempt reminder ads), must present a true statement of information in a brief summary.
- The brief summary generally includes:
  - Who should not take the drug.
  - When the drug should not be taken.
  - Possible serious side effects of the drug and, if known, what can be done to lower the chance of having them.
  - Frequently occurring, but not necessarily serious, side effects.

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FDA Jurisdiction Over Telemedicine Companies

- Whether or not telehealth companies are subject to FDA jurisdiction when marketing and promoting prescription drugs has been under debate for many years.
- Some have claimed these FD&C Act legal requirements, although clearly applicable to drug manufacturers, packers, and distributors, do not apply to telehealth companies and associated medical providers because the telehealth company and their associated providers are not addressed in the FD&C Act and not included in the definition of “firm” under applicable FDA Guidance documents.
- Under this argument, telehealth companies and their associated providers are not subject to these drug advertising laws in their DTC marketing campaigns.

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FDA Jurisdiction Over Telemedicine Companies Cont.

- Former FDA Commissioner Robert Califf observed how a number of online advertisements by telehealth companies fail to give the complete risk-benefit story (something drug manufacturers must do), as he noted how the FDA lacks the legal authority to regulate the advertising activities of such telehealth companies.
- On February 20, 2025, U.S. Senators Dick Durbin (D-IL) and Roger Marshall, M.D. (R-KS) introduced bipartisan legislation, the Protecting Patients from Deceptive Drug Ads Act (the Act), which closes perceived "legal loopholes" in social media advertisements by telehealth companies. The Act would require the U.S. Food & Drug Administration (FDA) to target false and misleading prescription drug promotions by social media influencers and telehealth companies.

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FTC – Truth in Advertising

- When consumers see or hear an advertisement, whether it's on the internet, radio or television, or anywhere else, federal law says that ad must be truthful, not misleading, and, when appropriate, backed by scientific evidence.
- The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

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FTC – Regulation of Drugs Ads

- No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug. *See* 15 U.S.C § 55.
- **STANDARDS:**
  - Before disseminating an advertisement, the advertiser must substantiate all claims – express and implied – that the ad conveys to reasonable consumers. Substantiation Policy Statement, appended to Thompson Medical Co., 104 F.T.C. 648 (1984).
  - To be considered reasonable, the interpretation does not have to be the only one. When a seller's representation conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable for the misleading interpretation.
  - Health and safety claims require a high level of substantiation – "competent and reliable scientific evidence".
  - Often that means two well controlled clinical studies.

NEXUS 2025

FTC – Deceptive Ads

- The FTC works to stop deceptive ads, which can be particularly problematic in the context of endorsements, use of influencer, and reviews.
- An ad is deceptive if a contains a representation or omission of fact that is likely to mislead a consumer and the representation or omission is material to a consumer's purchasing decision.
- An "endorsement" means any advertising, marketing, or promotional message for a product that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.
- Verbal statements, tags in social media posts, demonstrations, depictions of the name, signature, likeness or other identifying personal characteristics of an individual, and the name or seal of an organization can be endorsements.
- The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the "endorser" and could be or appear to be an individual, group, or institution.

NEXUS 2025

FTC – Endorsements

- When endorsing a product through social media, the message should make it obvious that the endorser has a relationship with the brand, e.g., a personal, family, or employment relationship or any kind of financial relationship.
- If there's a connection between an endorser and the marketer that a significant minority of consumers wouldn't expect and it would affect how they evaluate the endorsement, that connection should be disclosed clearly and conspicuously.
- "clear and conspicuous" means that a disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers. If a communication's representation necessitating a disclosure is made through visual means, the disclosure should be made in at least the communication's visual portion; if the representation is made through audible means, the disclosure should be made in at least the communication's audible portion; and if the representation is made through both visual and audible means, the disclosure should be made in the communication's visual and audible portions.
- Knowing about the connection is important information for anyone evaluating the endorsement.

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FTC – Endorsements (Examples)

- An influencer who is paid to endorse a vitamin product in their social media posts discloses their connection to the product’s manufacturer only on the profile pages of their social media accounts. The disclosure is not clear and conspicuous because people seeing their paid posts could easily miss the disclosure.
- In an advertisement for a pain remedy, an announcer unfamiliar to consumers except as a spokesperson for the advertising drug company praises the drug's ability to deliver fast and lasting pain relief. The spokesperson does not purport to speak from personal experience, nor on the basis of their own opinions, but rather in the place of and on behalf of the drug company. The announcer’s statements would not be considered an endorsement.

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