Compliance Issues for PAs

Idaho Ass'n of Physician Associates

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(4.25)

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Some Applicable Laws

- Medical Practices Act, IC 54-1801 et seq.
  - Licensure
  - Scope of practice
  - Grounds for Discipline
- Rules for Licensure of Physician Assistants, IDAPA 24.33.02
- Rules for Professional Discipline, IDAPA 24.33.03
- Medical Consent Act, IC 39-4501 et seq.
- Health Insurance Portability and Accountability Act ("HIPAA"), 45 CFR part 164
- Fraud and Abuse Laws
- Anti-Discrimination Statutes
- Idaho Virtual Care Act, IC 54-5701 et seq.
- Idaho Patient Act, IC 48-301 et seq.
- Others

Grounds for Professional Discipline

- Providing care or performing any service outside the licensee or permittee's scope of practice, including providing care without supervision if such is required by Idaho Code or rule.
- Providing health care which fails to meet the standard of health care provided by other qualified physician assistants in the same community.
- Dividing fees or gifts or agreeing to split or divide fees or gifts received for professional services with any person, institution or corporation in exchange for referral.
- Giving or receiving or aiding or abetting the giving or receiving of rebates, either directly or indirectly.
- Failing to safeguard the confidentiality of medical records or other medical info pertaining to identifiable patients, except as required or authorized by law.
- Abandoning a patient.

(IC 54-1814; IDAPA 24.33.03.150)

Grounds for Professional Discipline

- Aiding or abetting any person to practice medicine who is not authorized to practice medicine.
- Delegating professional responsibilities to:
  - An unlicensed person when the licensee knows or has reason to know that such person is not qualified by training, experience, or license to carry them out; or
  - A person licensed by this state to engage in activities which may involve the practice of medicine when the delegating licensee knows or has reason to know that the delegated activities are outside the licensed person's scope of practice.
- Engaging in a pattern of unprofessional or disruptive behavior or interaction in a health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient. Such behavior does not have to have caused actual patient harm to be considered unprofessional or disruptive.

(IC 54-1814)

Grounds for Professional Discipline

- Failing to obey any and all state laws and rules related to the licensee's practice or profession.
- Committing or being convicted of a felony or other drug or alcohol related criminal charges.
- Violating any state or federal law or regulation relating to controlled substances.
- Advertising the practice of medicine in any unethical or unprofessional manner.
- Directly promoting the sale of drugs, devices, appliances or goods to a patient that are unnecessary and not medically indicated.
- Prescribing, selling, administering, or giving any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug to him/herself or to a spouse, child or stepchild.
- Commission of any act of sexual contact, misconduct, exploitation or intercourse with a patient or former patient or related to the licensee's practice. Consent is no defense.
- Failing to maintain adequate records. Adequate patient records means legible records that contain, at a minimum, subjective info, an evaluation and report of objective findings, assessment or diagnosis, and the plan of care.

(IC 54-1814; IDAPA 24.33.03)

Scope of Practice

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Collaboration

- A PA shall collaborate with, consult with, or refer to the appropriate member of the facility health care team as indicated by:
  - Condition of the patient;
  - Education, experience, and competence of the PA; and
  - Community standard of care.

(IC 54-1807A(2))

- Degree and nature of collaboration shall be determined by the facility or practice that employs the PA:
  - Facility or practices with credentialing system: As set forth in facility bylaws or procedures; or
  - Other situations: In a written collaborative practice agreement ("CPA").

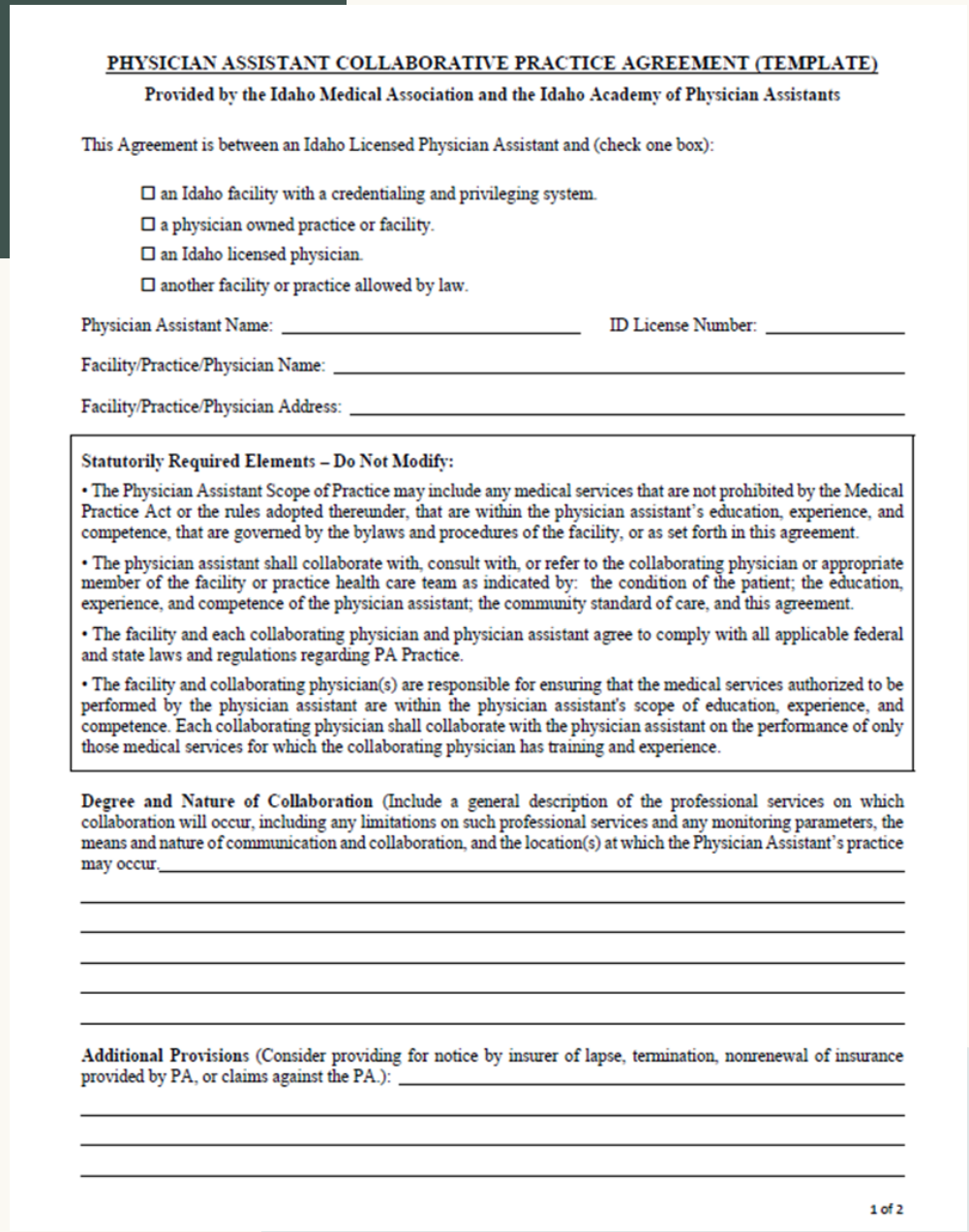
(IC 54-1807A(2))

Collaborative Practice Agreement

Must contain:

- Parties to the agreement w/ at least one collaborating physician.
- Authorized scope of practice for each licensed PA.
- Require that PA collaborate with, consult with, or refer to appropriate physician as indicated by:
  - condition of the patient;
  - education, experience, competence of PA; and
  - community standard of care.
- If necessary, any monitoring parameters.

(IDAPA 24.33.02.028.02)



PHYSICIAN ASSISTANT COLLABORATIVE PRACTICE AGREEMENT (TEMPLATE)

Provided by the Idaho Medical Association and the Idaho Academy of Physician Assistants

This Agreement is between an Idaho Licensed Physician Assistant and (check one box):

- ☐ an Idaho facility with a credentialing and privileging system.
- ☐ a physician owned practice or facility.
- ☐ an Idaho licensed physician.
- ☐ another facility or practice allowed by law.

Physician Assistant Name: _____ ID License Number: _____

Facility/Practice/Physician Name: _____

Facility/Practice/Physician Address: _____

Statutorily Required Elements – Do Not Modify:

- The Physician Assistant Scope of Practice may include any medical services that are not prohibited by the Medical Practice Act or the rules adopted thereunder, that are within the physician assistant's education, experience, and competence, that are governed by the bylaws and procedures of the facility, or as set forth in this agreement.
- The physician assistant shall collaborate with, consult with, or refer to the collaborating physician or appropriate member of the facility or practice health care team as indicated by: the condition of the patient; the education, experience, and competence of the physician assistant; the community standard of care, and this agreement.
- The facility and each collaborating physician and physician assistant agree to comply with all applicable federal and state laws and regulations regarding PA Practice.
- The facility and collaborating physician(s) are responsible for ensuring that the medical services authorized to be performed by the physician assistant are within the physician assistant's scope of education, experience, and competence. Each collaborating physician shall collaborate with the physician assistant on the performance of only those medical services for which the collaborating physician has training and experience.

Degree and Nature of Collaboration (Include a general description of the professional services on which collaboration will occur, including any limitations on such professional services and any monitoring parameters, the means and nature of communication and collaboration, and the location(s) at which the Physician Assistant's practice may occur._____

Additional Provisions (Consider providing for notice by insurer of lapse, termination, nonrenewal of insurance provided by PA, or claims against the PA.): _____

1 of 2

PA Scope of Practice

- "The scope of practice of PAs include only those duties and responsibilities identified in a collaborative practice agreement or the facility bylaws or procedures of any facility with credentialing and privileging systems."

(IDAPA 24.33.02.028.01)

- Facility, practice and collaborating physician must ensure that that PA's services are:
  - Within PA's education, experience and competence;
  - Policies or CPA established by employing facility or practice; and
  - Collaborating physician's training and experience.

(See IC 54-1807A(2), (4))

- Exception: care of ill or injured person at scene of an emergency or disaster outside place of employment.

(IDAPA 24.33.02.028.04)

PA Scope of Practice

Grounds for Board discipline include:

- Providing health care which fails to meet the standard of health care provided by other qualified physician assistants in the same community or similar communities, taking into account his training, experience and the degree of expertise to which he holds himself out to the public.

(IC 54-1814(7))

- Providing care or performing any service outside the PA's scope of practice as set forth in Idaho Code, including providing care or performing a service without supervision, if such is required by Idaho Code or Board rule.

(IDAPA 24.33.03.150.03(j))

- Advertising or representing himself either directly or indirectly as a physician.

(IDAPA 24.33.02.028.03)

Collaborating Physician

- Collaborating physician must:
  - Collaborate on only those services for which the physician has training and experience.
  - Ensure that PA's services are within the PA's scope of education, experience and competence.

(IC 54-1807A(2), (4))

- Collaborating physician:
  - No limit on number of PAs with whom a physician may collaborate.
  - Not required to notify Board of collaborating physician or identify an alternate.
  - Not required to conduct on-site review at least monthly, review certain number of records of PA, and have regularly scheduled conferences with PA.
- PA may provide services even if collaborating physician is not available so long as permitted by bylaws, policies or CPA.

PA Employment or Ownership of Practice

- If employed—
  - By entity with physicians, must have either bylaws or procedures for credentialing or a collaborative practice agreement.
  - By entity without physicians, must have a collaborative practice agreement.
- One or more PAs may independently own a practice if:
  - Licensed as PA in any state for at least 2 years.
  - Each PA has a collaborative practice agreement with a physician licensed in Idaho.

(IC 54-1807A(2)-(3))

- Idaho Board of Medicine has disavowed the corporate practice of medicine so non-physicians may own practices and employ physicians or physician assistants.

Professional Liability

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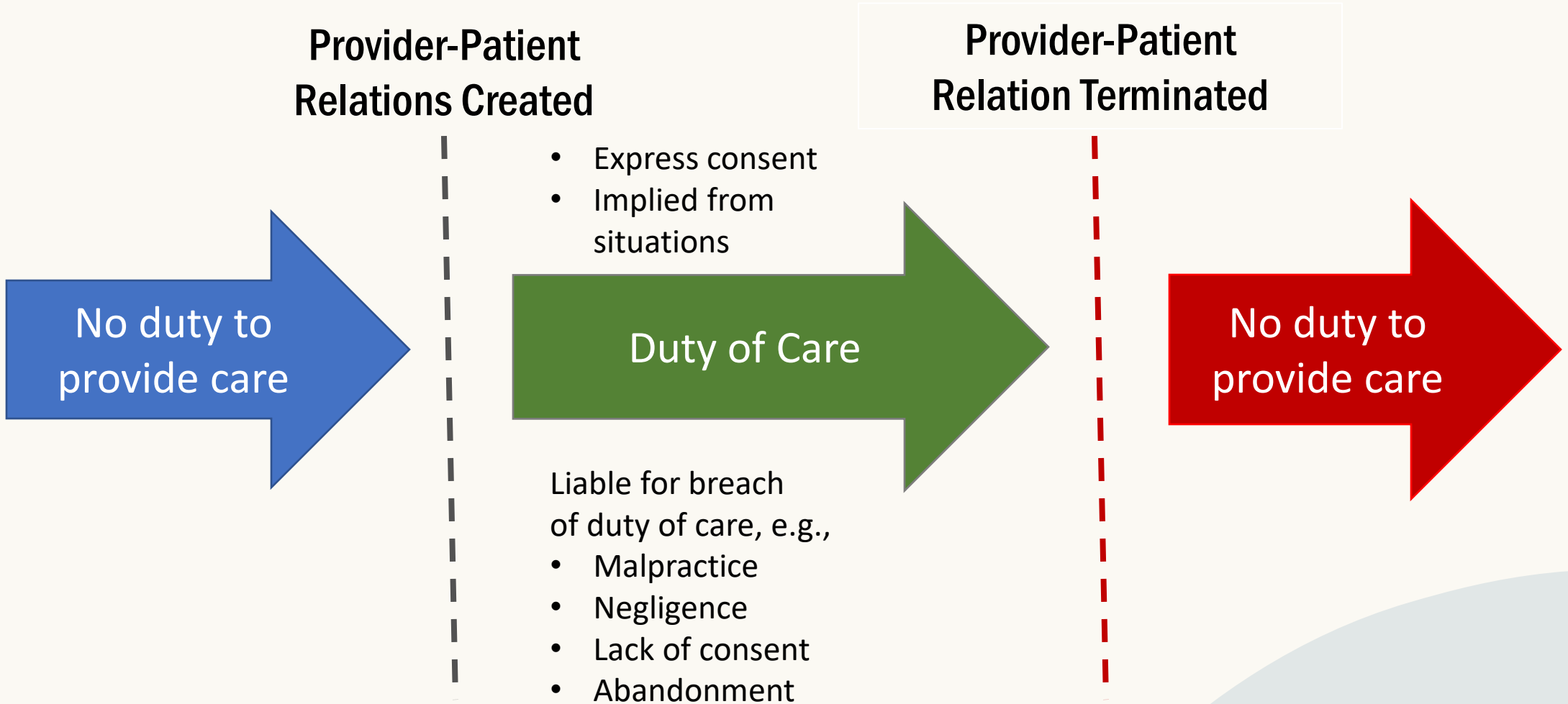
Legal Duty to Provide Care



Professional Negligence

Plaintiff ("P") must prove:

1. Duty.
2. Breach of the duty, e.g., practicing outside scope of practice, training, or designated service agreement.
3. Causation, i.e., D's negligence caused the damage.
4. Damages, i.e., P suffered some damage recognized by the law.

- *Make sure you have malpractice insurance!*

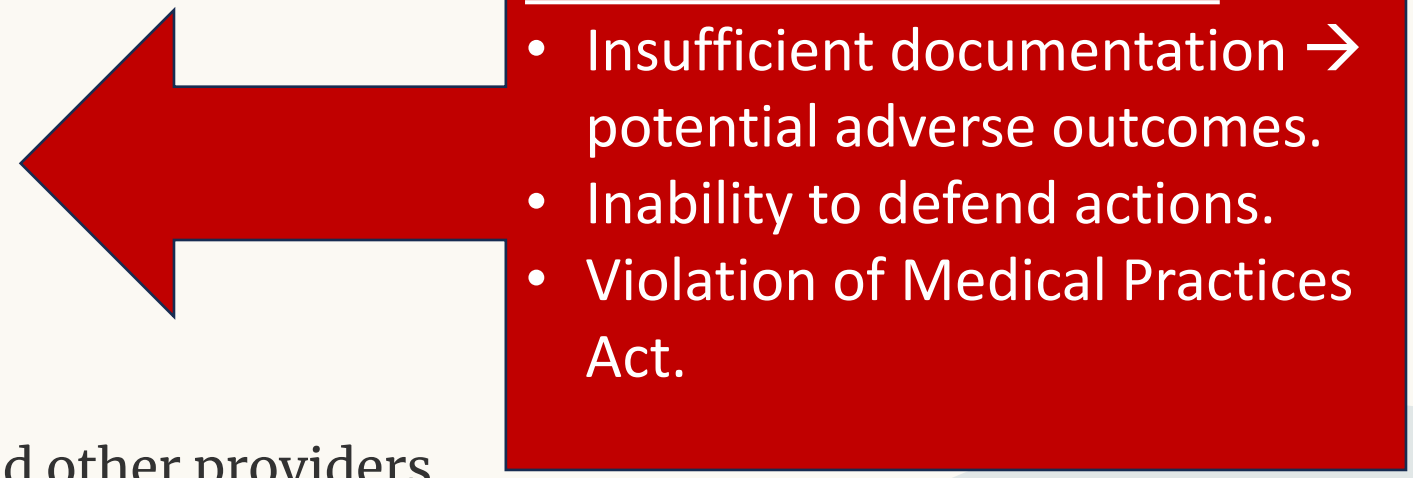
In malpractice case, these must be established by expert testimony concerning the community standard of care. (IC 6-1012, 6-1013)

Keys to Avoid Malpractice

- Stay within the scope of your licensure, training, and collaborative practice agreement.
  - Realize your limits.
- Communicate and relate to your patient.
  - Listen and learn.
  - Informed consent.
  - Ensure the patient understands.
    - Expectations – reality = frustration → lawsuits.
  - Be courteous.
    - People don't usually sue their friends.
- Communicate and collaborate with other providers.
  - Ask for help.

Keys to Avoid Malpractice

- Do your homework.
  - Read the chart.
  - Check with specialists.
- Check twice before administering or performing.
- Follow up.
  - Appointments, tests, etc.
- Document, document, document.
  - Informed consent
  - Accurate medical history
  - Detailed medical notes
  - Collaboration with physicians and other providers
  - Patient's noncompliance
- Don't hide a mistake.



Idaho Apology Law

- **Expressions of apology, condolence and sympathy:** "[A]ll statements … expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence, including any accompanying explanation, … which relate to the care provided to the patient, or … the discomfort, pain, suffering, injury, or death of the patient as the result of the unanticipated outcome of medical care shall be inadmissible as evidence…."
  - *"I'm sorry that you are going through this…"*
  - Be careful how you phrase it!
- **Admission of Fault:** "A statement of fault which is otherwise admissible and is part of or in addition to [an apology] identified [above] shall be admissible."
  - *"It is our fault; we made a mistake…"*

(IC 9-207)

Maintain Malpractice Insurance

- PAs must have malpractice insurance, either through employer or facility or individually. (IC 54-1807A(2))
  - Occurrence based
    - Policy covers you if acts/omissions occurred during policy term.
  - Claims-made based
    - Policy covers you if (1) acts/omissions occurred and (2) claims made during policy term.
  - Tail coverage
    - Extends claims-made policy to cover claims made after the originally policy terminated.
  - Policies may or may not cover certain types of claims, e.g., fines, penalties, administrative actions, etc.

Informed Consent

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Consent

- Must have valid consent for treatment.
- If patient lacks capacity to consent:
  - Check for advance directive, or
  - Obtain consent from authorized representative.
- If it is an emergency and no time to obtain consent, provide necessary care.
- Must provide sufficient info to ensure that the consent is informed.

No informed consent =

- Treat patient who lacks capacity to consent (e.g., patient medicated, intoxicated, minor, etc.).
- Ignore patient's decisions or objections.
- Treatment that exceeds scope of consent.
- Fail to inform patient of sufficient info reasonably necessary to enable patient to make an informed decision.
- Fail to effectively communicate with patient (e.g., limited English proficiency, disability, etc.).

Consent:
Adults and Emancipated Minors

- "Any person … who comprehends the need for, the nature of, and the significant risks ordinarily inherent in any contemplated health care services is competent to consent thereto on his or her own behalf."
- "Any health care provider may provide such health care services in reliance upon such a consent."

(IC 39-4503)

Test for whether a patient is competent to consent for themselves or others.

Consent: Surrogates for Adults and Emancipated Minors

"Consent for the furnishing of health care services to any person who is not then capable of giving such consent ... may be given or refused in the order of priority set forth hereafter; provided however, that [1] the surrogate decision-maker shall have sufficient comprehension as required to consent to his or her own health care services ...; and [2] provided further that the surrogate decision-maker shall not have authority to consent to or refuse health care services contrary to such person's advance care planning document or wishes expressed by such person while the person was capable of consenting...:

1. Court appointed guardian.
2. Person named in living will and durable power of attorney.
3. Spouse.
4. Adult child.
5. Parent.
6. Delegation of parental authority per IC 15-5-104.
7. Relative.
8. Any other competent person representing himself to be responsible for health care.

(IC 39-4504(1))

Consent: Unemancipated Minors

- "[A]n individual shall not furnish a health care service or solicit to furnish a health care service to a minor child without obtaining the prior consent of the minor child's parent."
  - "Parent" = biological or adoptive parent or an individual who has been granted exclusive right and authority over the welfare of a child under state law.
- Exceptions:
  - Blanket consent.
  - Medical emergency that could result in serious injury to child.
  - Maybe EMTALA situations.
- Violation: parent may sue for damages, costs and fees.

(IC 32-1015)

Parental consent act likely preempts contrary Idaho laws that would otherwise allow minor to consent to their own care, e.g.,

- Contraceptives
- Care for STDs and certain other communicable diseases
- Mental health care
- Others?

Informed Consent

- General rule: consent must be informed to be effective.
  - "Consent, or refusal to consent, for the furnishing of health care services shall be valid in all respects if the person giving or refusing the consent is sufficiently aware of pertinent facts respecting the need for, the nature of, and the significant risks ordinarily attendant upon such a person receiving such services, as to permit the giving or withholding of such consent to be a reasonably informed decision." (IC 39-4506)
- Parental consent law: do not need informed consent of parent if have "blanket consent." (IC 32-1015(4))
  - But not sure exactly what this means.
  - Be careful about relying on "blanket consent" for risky, controversial or costly care.

Form of Consent

- "It is not essential to the validity of any consent … that the consent be in writing or any other specific form of expression."

(IC 39-4507)

- Under Idaho law, consent may be:
  - Implied
  - Oral
  - Written

  } The more significant the treatment, the greater the need to document informed consent.

- Other laws or payer standards may require documented consent.

Informed Consent ≠ Consent Form

Informed Consent = Communication	Consent form = Documentation
• Practitioner communicates info relevant to treatment • Patient understands the material facts. • Patient makes informed decision to consent or refuse treatment. • ***Ensure patient understands!*** • ***Beware barriers, e.g., language, impairment, etc.***	• Supplements oral or other info given by the practitioner. • Documents that the communication process took place, e.g., that practitioner communicated relevant info, patient understood info, and patient made voluntary, informed decision.

“Against Medical Advice”

- Provider should give sufficient info to allow patient to make informed refusal.
- Document in chart:
  - Patient’s competency.
  - Explanation of risks and benefits.
  - Practitioner’s attempt to obtain patient’s informed consent.
  - Patient’s signature confirming voluntary decision.
  - Witnesses.
- Attempt to obtain patient’s signed refusal.

Advance Directives

- "Advance directive", "advance care planning document", "health care directive" = document that represents a competent patient's person's authentic expression of wishes re health care, e.g.,
  - Living Will
  - Durable Power of Attorney
  - Physician's Order for Scope of Treatment ("POST")
    - Order from practitioner
    - Does not automatically suspend during surgery
  - Do Not Resuscitate ("DNR")
    - Order from practitioner
  - Mental Health Care Directives

(IC 39-4502)

- "Any authentic expression of a patient's wishes ought to be honored."

(IC 39-4509(3))

Patient Abandonment

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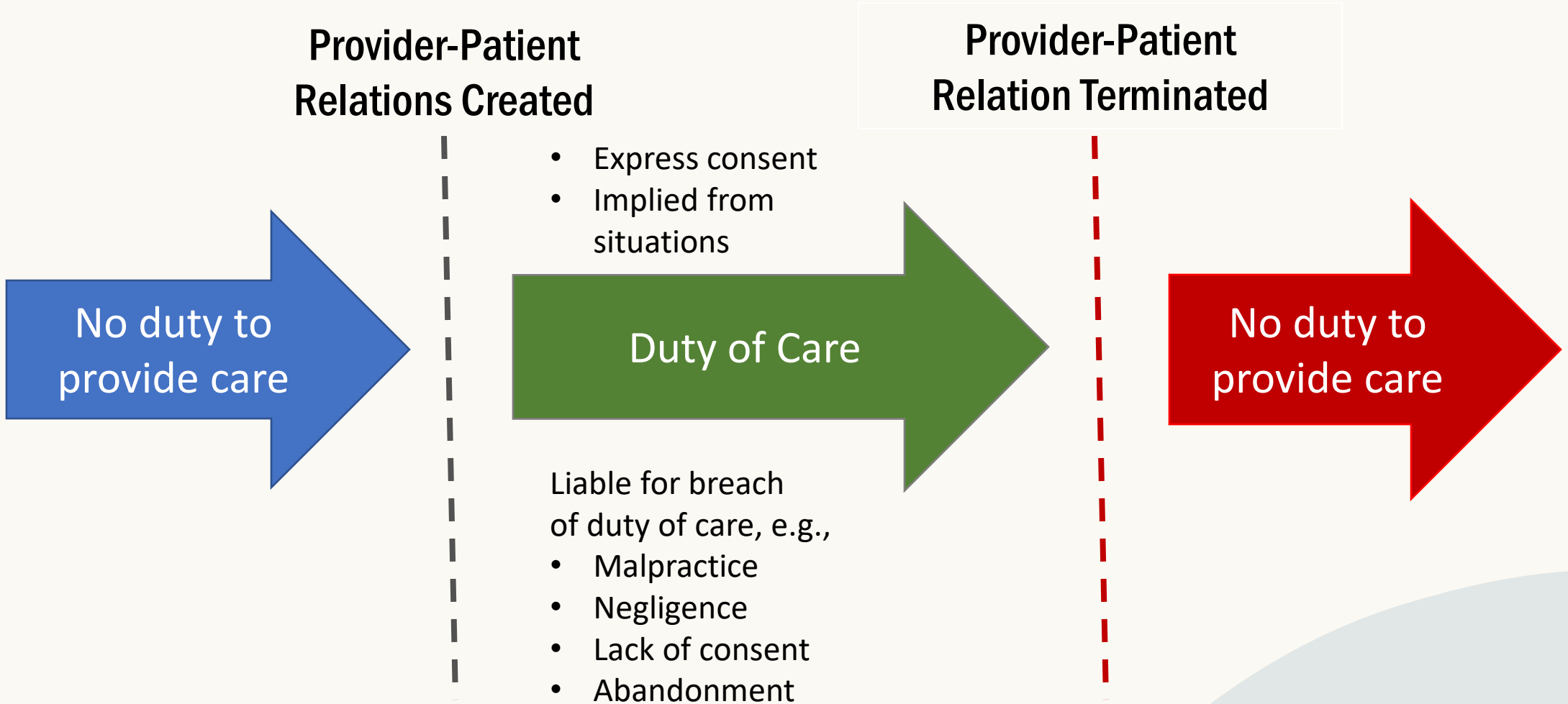
Legal Duty to Provide Care



Patient Abandonment

- Abandonment =
  - Ignoring or failing to follow up with patient.
  - Leaving town without securing coverage for your patients.
  - Terminating relationship without giving patient sufficient:
    - Notice that you are ending relationship
    - Time to find a new practitioner
    - Care until the patient can transfer to a new practitioner
    - Other?
- Penalties
  - Lawsuit by patient for damages
  - Action against license

(See IC 54-1814(15); IDAPA 22.01.03.037.02)

Avoiding Patient Abandonment

- Can terminate relationship for any legitimate reason or no reason, but not bad reason.
- Legitimate reasons
  - Failure or refusal to pay bills
  - Breakdown in relationship or communications
  - Disruptive conduct
  - Noncompliance with treatment
  - Missed appointments
  - Etc., etc., etc.
- Bad reasons
  - Discrimination

Avoiding Patient Abandonment

- Factors to consider before ending patient relationship
  - Patient's current health needs
  - Availability of alternative care
  - Basis for termination (e.g., legitimacy compared to patient's health care needs)
  - Whether patient is in protected class
  - Documentation supporting termination
  - Alternative actions
    - Warnings
    - Patient care conference
    - Behavior contract

Avoiding Patient Abandonment

- If termination necessary and appropriate:
  - Notify patient in writing and perhaps orally.
  - Give sufficient time to transfer care.
    - Depends on patient's condition.
    - 30 days seems to be fairly standard but not absolute rule.
  - Facilitate transfer of care and records.
  - Provide necessary care in the interim.

(See https://www.hollandhart.com/firing-patients-avoiding-patient-abandonment).

- Make sure you have documentation to support decision, e.g.,
  - Justification.
  - No harm to patient.
  - Adequate notice and time to transfer care without injury.

Patient Confidentiality

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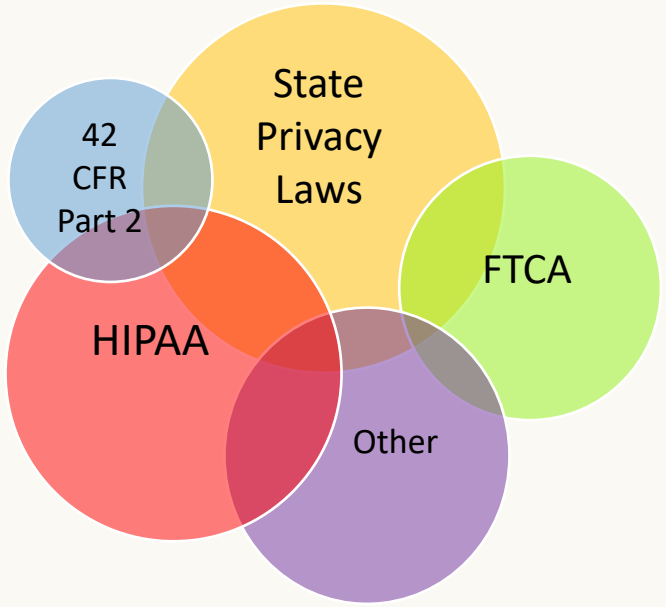
Privacy Laws

Privacy Protection

Comply with the law that provides the most privacy protection, e.g.,

- Substance Use Disorder Records (42 CFR part 2)
- Health Insurance Portability and Accountability Act ("HIPAA") (45 CFR part 164)
- Other state of federal privacy rules



HIPAA Civil Penalties

Conduct	Penalty
Did not know and should not have known of violation	• $141* to $71,162* per violation • Up to $2,134,831* per type per year • No penalty if correct w/in 30 days • OCR may waive or reduce penalty
Violation due to reasonable cause	• $1,424* to $71,162* per violation • Up to $2,134,831* per type per year • No penalty if correct w/in 30 days • OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	• $14,232* to $71,162* per violation • Up to $2,134,831* per type per year • Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	• $71,162 to $2,134,831* per violation • Up to $2,134,831* per type per year • Penalty is mandatory

(45 CFR 102.3, 160.404; 85 FR 2879)

HIPAA Criminal Penalties

Applies if individuals obtain or disclose PHI from covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of the law	$50,000 fine 1 year in prison
Committed under false pretenses	100,000 fine 5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	$250,000 fine 10 years in prison

(42 USC 1320d-6(a))

Enforcement

- Must self-report breaches of unsecured protected health info
  - To affected individuals.
  - To HHS.
  - To media if breach involves > 500 persons.
- In future, individuals may recover portion of penalties or settlement.
  - On 4/6/22, HHS issued notice soliciting input. (87 FR 19833)
- Must sanction employees who violate HIPAA.
- Possible lawsuits by affected individuals or others.
- State attorney general can bring lawsuit.
  - $25,000 fine per violation + fees and costs

HIPAA Privacy Rules: Use and Disclosure of PHI

- May not use or disclose individually identifiable protected health info ("PHI") unless—
  - For treatment, payment or health care operations.
  - Disclosure is required by law.
  - Disclosure necessary to avert serious and imminent threat of harm.
  - For certain public health or legal proceedings if certain conditions are satisfied.
    - Contact privacy officer.
  - For use in facility directory if person asks for patient by name.
    - May only disclose name, location and general condition.
  - To family members and others involved in care if patient does not object and you determine it is reasonable under the circumstances; or
  - Have patient's or personal representative's HIPAA-compliant authorization.
- Must limit use or disclosure to minimum necessary.

(45 CFR 164.501-.514)

HIPAA Reproductive Rights Rule

Effective 6/25/24:

- Limits disclosure of PHI re reproductive health for civil, criminal or administrative action if reproductive health is legal.

(45 CFR 164.502(a)(5)(iii))

- Must obtain attestation before using or disclosing reproductive health PHI for:
  - Health oversight activities.
  - Judicial or administrative proceedings.
  - Law enforcement purposes.
  - Coroners or medical examiners.

(45 CFR 164.509)

- By 2/16/26, modify notice of privacy practices.

(45 CFR 164.520)

HIPAA Privacy Rule: Patient Rights

Patients have right to:

- Notice of Privacy Practices.
- Request restrictions on use or disclosure for treatment, payment or healthcare operations.
  - Generally, not required to agree, so don't do so!
  - If patient pays for episode of care, they can direct you not to disclose info to third-party payer for payment purposes.
- Access or copy PHI in designated record set.
  - Must respond within 30 days.
  - May charge reasonable cost-based fee.
- Request amendment of records in designated record set.
  - Must respond within 60 days.
  - May deny if record is correct, but patient has right to have statement attached to record.
- Obtain accounting of certain disclosures of protected health info.

(45 CFR 164.520-.528)

Idaho Parent's Access to Minor's Records

- "No health care provider or governmental entity shall deny a minor child's parent access to health information that is … in such health care provider's … control."
  - "Health info" = info or data, collected or recorded in any form or medium, and personal facts about events or relationships that relates to:
    (i) Past, present, or future physical, mental, or behavioral health or condition of individual or member of individual's family;
    (ii) Provision of health care services to an individual; or
    (iii) Payment for the provision of health care services to an individual.
- Violation: parent may sue for damages, costs and fees.

(IC 32-1015)

✓ *Likely applies to records created or info relating to treatment before 7/1/24.*

Idaho Parent's Access to Minor's Records

IDAHO LAW EXCEPTIONS

May deny parent access if:

- "Minor is emancipated.

(*See* IC 32-1015(5))

- "Parent's access to the requested health info is prohibited by a court order"; or
- "The parent is a subject of an investigation related to a crime committed against the child, and a law enforcement officer requests that the information not be released to the parent."

(IC 32-1015(6))

MAYBE FEDERAL EXCEPTIONS

- HIPAA
  - Disclosure could endanger the person.
  - PHI not in designated record set.
  - Info provided under promise of confidentiality.
  - Psychotherapy notes.

(45 CFR 164.502(g) and .524)

- Title X records re family planning services

(42 CFR 59.10)

  - *But see Deandra v. Becerra* (5th Circ. 2024)

- Substance use disorder records from federally assisted program

(42 CFR part 2)

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Non-Custodial Parent Access

- "Notwithstanding any other provisions of law, access to records and information pertaining to a minor child including, but not limited to, medical, dental, health, and school or educational records, shall not be denied to a parent because the parent is not the child's custodial parent.
- "[I]nformation concerning the minor child's address shall be deleted from such records to a parent, if the custodial parent has advised the records custodian in writing to do so."

(IC 32-717A)

HIPAA Privacy Rule: Administrative Requirements

- Designate HIPAA privacy and security officers in writing.
- Implement written policies and reasonable safeguards to protect PHI and implement HIPAA requirements.
  - "Incidental disclosures" are not a violation if implemented reasonable safeguards.
- Train workforce and document training.
- Execute written agreements with business associates who perform functions with PHI.
- Respond to complaints.
- Mitigate violations.
- Sanction members of your workforce.

(45 CFR 164.502(e), .504(e), and .530)

HIPAA Security Rule

- Must conduct a risk analysis re electronic PHI ("e-PHI").
- Must implement specific administrative, technical and physical safeguards to protect e-PHI:
  - Confidentiality
  - Availability
  - Integrity

(45 CFR 164.301-.318)

- Proposed rule would significantly expand obligations under security rule.

Communicating by E-mail or Text

- HIPAA Privacy Rule allows patient to request communications by alternative means or at alternative locations.
  - Including unencrypted e-mail.

(45 CFR 164.522(b))

- Omnibus Rule commentary states that covered entity or business associate may communicate with patient via unsecured e-mail so long as they warn patient of risks and patient elects to communicate via unsecured e-mail to text.

(78 FR 5634)

- Does not apply to disclosures between your employees or providers.

HIPAA Breach Notification Rule

- If there is a breach of unsecured PHI in violation of the privacy rule, must self-report breach unless you can demonstrate that there is a low probability that the data has been compromised by evaluating:
  - nature and extent of PHI involved;
  - unauthorized person who used or received the PHI;
  - whether PHI was actually acquired or viewed; and
  - extent to which the risk to the PHI has been mitigated.

(45 CFR 164.402)

- Failure to report breach likely constitutes "willful neglect," which would trigger mandatory penalties.

HIPAA Breach Notification Rule

- If there is breach of unsecured PHI,
  - Covered entity must provide written notice to:
    - Each individual whose unsecured PHI has been or reasonably believed to have been accessed, acquired, used, or disclosed.
      - Notice must contain required elements.
      - Must send notice within 60 days of discovery.
    - HHS.
      - ≥ 500 persons: within 60 days of discovery.
      - < 500 persons: within 60 days after the end of the calendar year.
    - Local media, if breach involves > 500 persons in a state.
  - Business associate must notify covered entity.

(45 CFR 164.400 et seq.)

Telehealth

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Idaho Virtual Care Act

- Provider rendering "virtual care" must comply with:
  - Laws and rules, and
  - Community standard of care that applies to in-person treatment.

(IC 54-5704)

- "Virtual care" = "technology-enabled health care services in which the patient and provider are not in the same location" such as "telemedicine, telehealth, m-health, e-consults, e-visits, video visits, remote patient monitoring, and similar technologies."
- Virtual care is considered to be rendered at the physical location of the patient.

(IC 54-5703)

- Providers rendering care in Idaho are subject to Idaho law and may be sanctioned as Idaho providers.

(IC 54-5713)

Idaho Virtual Care Act: Provider-Patent Relationship

- Must first establish provider-patient relationship.
  - May establish by virtual care technology
- Exceptions:
  - Patient has provider-patient relationship with another provider in the group.
  - Provider is covering calls for provider with established relationship.
  - Provider writing initial hospital admission orders.
  - Provider is writing prescription for--
    - a patient of another prescriber for whom the prescriber is taking call;
    - a patient examined by an APP or practitioner with whom the prescriber has a supervisory or collaborative relationship;
    - A new patient prior to the patient's first appointment;
  - Emergency where life or health of the patient is in imminent danger.

(IC 54-5705 and 54-1733)

Idaho Virtual Care Act: Evaluation and Treatment

Providers rendering virtual care must:

- Obtain and document patient's relevant clinical history and current symptoms to diagnose and identify underlying conditions and contraindications.
  - Static online questionnaire is not sufficient.
- Comply with relevant state and federal laws for prescription of controlled substances, including Ryan Haight Act, 21 U.S.C. 829 and 21 CFR 1306.09.
- Obtain proper informed consent.
- Be available for follow-up care or provide info.
- Refer when medically indicated, including emergencies.
- Create and maintain medical records as with in-person treatment.

(IC 54-5706)

Telehealth

As a general rule, telehealth provider must comply with both

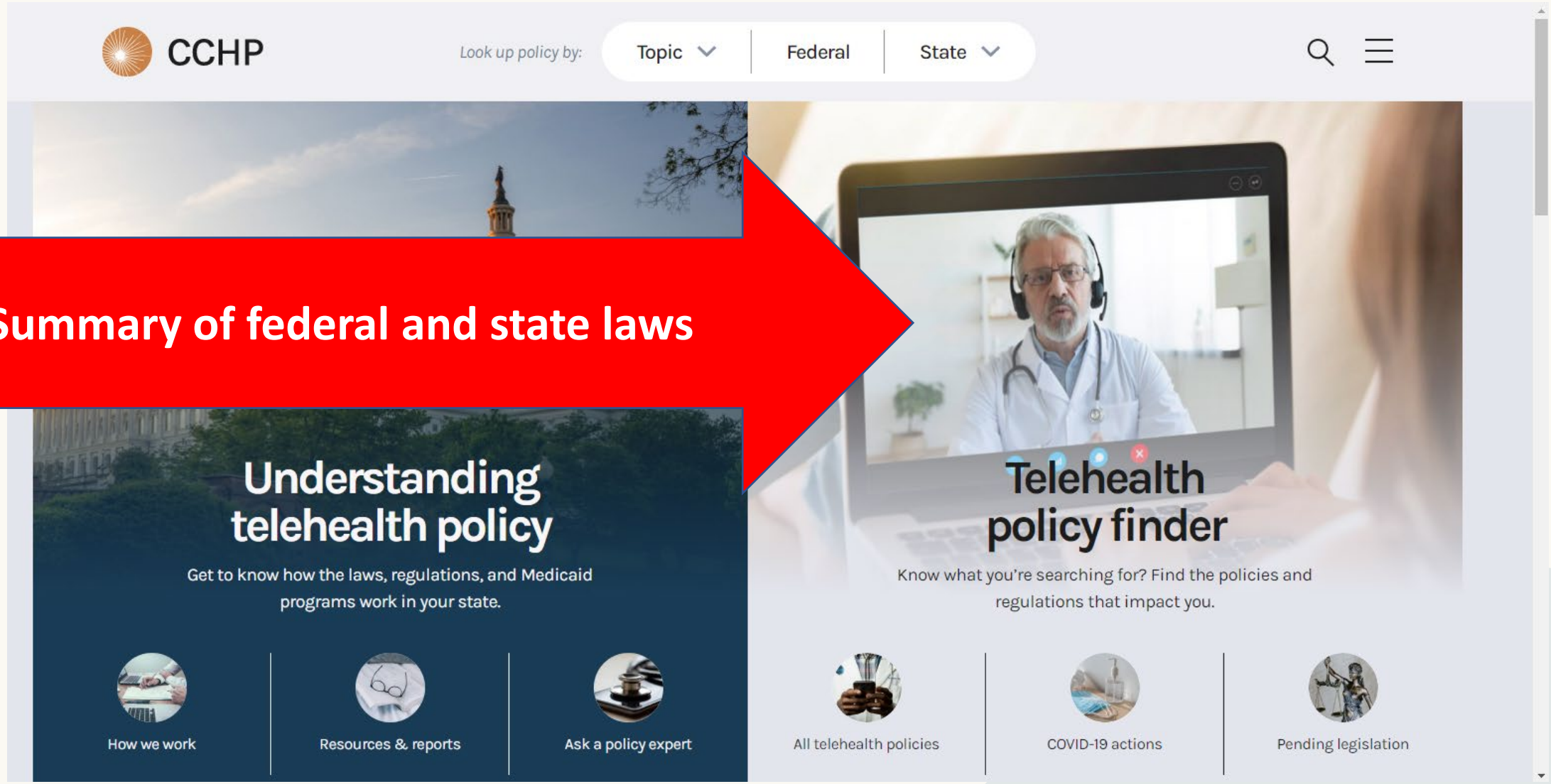
- Law of state in which telehealth provider is located,

and

- Law of state in which patient is located.
  - States want to protect patients.
  - Likely sufficient contacts to establish jurisdiction over telehealth provider

- Licensure
- Permissible telehealth methods
- Provider-patient relationship
- Scope of practice
- Standard of care
- Informed consent
- Remote prescribing
- Credentialing telehealth providers
- Reimbursement and payment parity
- Malpractice liability and insurance
- Corporate practice of medicine
- Others?

Center for Connected Health Policy, https://www.cchpca.org/



Non-Discrimination Rules

Anti-Discrimination Laws

LAWS

- Civil Rights Act Title VI
- Americans with Disability Act
- Age Discrimination Act
- Affordable Care Act § 1557
  - HHS issued new rules on 5/6/24.
  - Effective 7/5/24

  (45 CFR part 92; 89 FR 37522)
- Rehabilitation Act § 504
  - HHS issued new rules on 5/9/24.
  - Effective 7/8/24

  (45 CFR part 84; 89 FR 40066)
- State discrimination laws

Not sure how Trump Administration will enforce these rules.

RISKS

- Persons with disabilities
- Persons with limited English proficiency
- Sex discrimination
- Physical access
- Websites
- Facilities and equipment
- Service animals
  - Dogs and mini-horses
  - Not emotional support animals

Anti-Discrimination Laws

DISABILITIES

- Must provide reasonable accommodation to ensure effective communication and accessibility.
  - Auxiliary aids
  - Modifications
- Includes person with patient.
- May not charge patient.
- May not rely on person accompanying patient.

LIMITED ENGLISH

- Must provide meaningful access
  - Interpreter
  - Translate key documents
- Includes person with patient.
- May not charge patient.
- May not require patient to bring own interpreter.
- May not rely on person accompanying patient.

Fraud and Abuse Laws

False Claims Act ("FCA")

- Cannot knowingly submit a false claim for payment to the federal govt, e.g.,
  - Not provided as claimed
  - Substandard care
  - Failure to comply with applicable regulations
- Must report and repay an overpayment within the later of 60 days or date cost report is due.

(31 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.200)

<u>Penalties</u>

- Repayment plus interest
- Civil penalty of $13,946* to $27,894* per claim
- Admin penalty $24,947* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.210; 45 CFR 102.3; 89 FR 9766)

- Potential *qui tam* lawsuits
  - ✓ *But see U.S. ex rel. Zafirov v. Florida Med. Associates LLC* (M. Dist. Fla. 9/30/24), holding qui tam lawsuits as unconstitutional.

Idaho False Claims Act

Cannot knowingly:

- Submit claim that is incorrect.
- Make false statement in any document to state.
- Submit a claim for medically unnecessary service.
- Fail repeatedly or substantially to comply with DHW rules.
- Breach provider agreement, e.g., fail to maintain appropriate records to support claim.
- Fail to repay amounts improperly received.

(IC 56-209h(6))

Penalties

- Exclusion from state health programs, e.g., Medicaid.
- Civil penalty of up to $1000 per violation.
- Referral to Medicaid fraud unit.

(IC 56-209h)

Anti-Kickback Statute

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services payable by govt program unless transaction fits within a regulatory safe harbor.
  (42 USC 1320a-7b(b); 42 CFR 1003.300(d))
- "One purpose" test.
  (*US v. Greber* (1985))

Penalties

- Felony: 10 years in prison + $100,000 criminal fine
- $124,732* civil penalty + 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)

- Automatic FCA violation

(42 USC 1320a-7a(a)(7))

- Minimum $100,000 settlement with OIG.

(OIG Self-Disclosure Protocol (2021), https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf)

Eliminating Kickbacks in Recovery Act ("EKRA")

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery home or clinical treatment facility unless arrangement fits within statutory or regulatory exception.

(18 USC 220(a))

Penalties

- $200,000 criminal fine
- 10 years in prison

(18 USC 220(a))

Idaho Anti-Kickback Statute

Service provider (including providers of healthcare services) cannot:

- Pay another person, or other person cannot accept payment, for a referral.
- Provide services knowing the claimant was referred in exchange for payment.
- Engage in regular practice of waiving, rebating, giving or paying claimant's deductible for health insurance.

(IC 41-348)

Penalties

- $5000 fine by Department of Insurance

(IC 41-347)

- May be used to void contract.

Civil Monetary Penalties Law ("CMPL"): Beneficiary Inducements

- Prohibits offering remuneration to a Medicare/Medicaid beneficiary if know or should know that it is likely to influence such beneficiary to order or receive services from a particular provider or supplier.

(42 USC 1320a-7a(5); 42 CFR 1003.1000(a))

Penalties

- $24,947* per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

- Likely also an AKS violation

Exclusion Statute

- Excluded person cannot order or prescribe items payable by federal healthcare program.
- Cannot submit claim for item ordered or furnished by an excluded person.
- Excluded owners cannot retain ownership interest in entity that participates in Medicare.
- Cannot hire or contract with excluded entity to provide items payable by federal programs.

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200(a)(3), (b)(3)-(6))

Penalties

- $24,947* per item or service ordered.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid

(42 USC 1320a-7a(a)(8); 42 CFR 1003.210; 45 CFR 102.3; OIG Bulletin, *Effect of Exclusion*)

Idaho Patient Act

Holland & Hart

To initiate "Extraordinary Collection Action" w/out Penalty

- w/in 45/90 days after services or discharge, submit charges to patient or payers identified by patient.
- w/in 60/240 days after services or discharge, submit "consolidated summary of services" to patient.
  - Exception: single billing entity that provides final statement and info re billing entity.
- Submit "final notice" to patient.
- Wait at least 60* days after final notice or CSS is received to send bill to third-party to collect or charge interest, fees or ancillary charges.
  - Presumed "received" 3 days after first class mail.
  - Patient may agree to email or other means.
- Wait at least 90* days after final notice or CSS and resolution of reviews, disputes and payer appeals .

(IC 48-304)

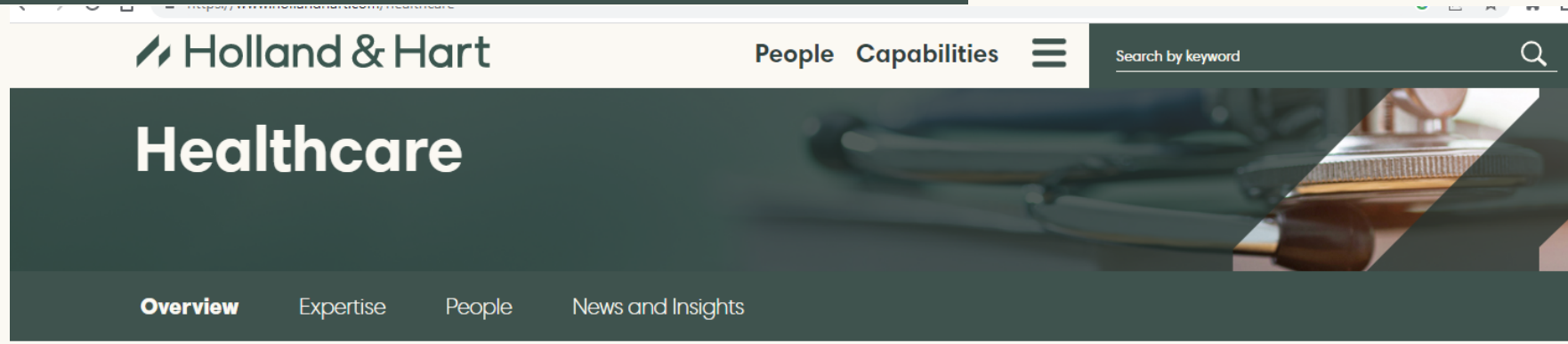
* Deadlines refer to date "received" by patient. Adjust by 3 days if mail by first class mail.

Additional Resources

HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE

Free content:

- Recorded webinars
- Client alerts
- White papers
- Other



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IDAHO PATIENT ACT TIMELINE

Mergers and Acquisitions | Real Estate

gal advice.

and highly regulated. In an ultra-
l issues so they can focus on

tback Statute, HIPAA,
ıg; mergers, acquisitions, and joint
; government investigations and
ax; employee benefits; and
our healthcare clients face that we

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