

COMPLIANCE UPDATE FOR IDAHO MEDICAL GROUPS

IMGMA
Conference

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(9-23)



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OVERVIEW

- Idaho post-COVID laws
- Medical consent amendments
- Telehealth changes
- Abortion laws
- Ban on gender-affirming care
- Fraud and abuse issues, including group compensation
- HIPAA and patient privacy
- Information Blocking Rule

IDAHO LAWS IN RESPONSE TO COVID-19



COVID-19 VACCINATIONS

- Business entities cannot:
 - Refuse service or admission because person has not received COVID-19 vaccination.
 - Require employees to obtain COVID-19 vaccination unless required by federal law.
 - **Does not apply to entities that receive Medicare/Medicaid funding.**
- Govt entities cannot require COVID-19 vaccination unless required by federal law.
- Entities may not offer different compensation or benefits based on COVID-19 vaccination except one-time incentive and time off.

(IC 73-503)

ESSENTIAL CAREGIVERS

- “It is the intent of the legislature to guarantee and protect the right of Idahoans to be visited by essential caregivers of their choosing when staying in a health care or assistance facility.”
(IC 39-9802)
- *Essential caregiver* = “a person or persons designated by a patient or resident to visit the patient or resident in person at a facility.”
- *Facility* = “an institution providing health care services, a health care setting, or a setting in which to receive assistance, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, nursing facilities, skilled nursing centers, residential treatment centers, rehabilitation and other therapeutic health settings, or assisted living facilities.”
(IC 39-9801)

ESSENTIAL CAREGIVERS: RIGHT TO VISIT

- “A patient or resident has the right to in-person visitation from an essential caregiver while receiving assistance or health care services at a facility, even if other visitors are being excluded by the facility. However...
 - “the essential caregiver must follow safety and other protocols imposed by the facility, and
 - “a facility may place reasonable restrictions as to where and when the essential caregiver may visit and the number of essential caregivers who may visit at the same time.”

(IC 39-9803(1))

ESSENTIAL CAREGIVERS: REASONABLE RESTRICTIONS

- “[A] restriction is reasonable if the restriction:
 - (a) Is necessary to prevent the disruption of assistance or health care services to the patient or resident; and
 - (b) Does not interfere with the patient's or resident's general right to visitation by essential caregivers.”

(IC 39-9803(1))

ESSENTIAL CAREGIVERS

“A facility that provides ... health care services or assistance must:

(a) When practicable, notify a potential patient or resident of the right to designate essential caregivers prior to admission to the facility;

(b) Provide each patient or resident an opportunity to designate essential caregivers; and

(c) Accommodate a patient's or resident's request to have essential caregivers visit within the limits prescribed by this section. If the patient or resident is a minor or incapacitated, visitation requests must be approved by a person with legal authority to make decisions on behalf of the patient or resident, such as a parent, guardian, or conservator.”

(IC 39-9803(2))

IDAHO MEDICAL CONSENT ACT



CONSENT FOR TREATMENT

“PERSONS WHO MAY CONSENT TO THEIR OWN CARE. 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 ~~if the consenting person appears to the health care provider securing the consent to possess such requisite comprehension at the time of giving the consent.~~”

(IC 39-4503, effective 7/1/23)

CONSENT: SURROGATE DECISIONMAKERS

“PERSONS WHO MAY GIVE CONSENT TO CARE FOR OTHERS. Consent for ... health care services to any person who is not then capable of giving such consent ... or who is a minor may be given or refused in the [following] order of priority...

- (a) The court appointed guardian of such person;
- (b) The person named in another person’s advance care planning document...“
- (c) If married, the spouse of such person;
- (d) An adult child of such person;
- (e) A parent of such person;
- (f) The person named in a delegation of parental authority..
- (g) Any relative of such person;
- (h) Any other competent individual representing himself or herself to be responsible for the health care of such person...”

(IC 39-4504)

CONSENT: SURROGATE DECISIONMAKERS

“If the person presents a medical emergency or there is a substantial likelihood of his or her life or health being seriously endangered by withholding or delay in the rendering of such other health care services to such person and the person has not communicated and is unable to communicate his or her wishes, the attending health care provider may, in his or her discretion, authorize or provide such health care services, as he or she deems appropriate...”

(IC 39-4504)

CONSENT FOR TREATMENT: MINORS

- General rule: minors may not consent for their own health care.
- Exceptions:
 - Minor is emancipated, e.g., married, armed forces, or living on own, but not pregnancy. (See IC 18-609A)
 - Contraceptives if sufficiently mature. (IC 18-603)
 - Family planning services under Title X program. (42 USC 300(a); *contra Deandra v. Becerra*, No. 2:2020cv00092 (N.D. Tex. 2022))
 - Age 16: drug treatment or rehab. (IC 37-3102)
 - Age 14: testing or tx for communicable diseases. (IC 39-3801)
 - Age 14: admission to mental health center approved by DHW rules to care for mentally ill. (IC 66-318)
 - Age 17: unpaid blood donations. (IC 39-3701)
 - Maybe mature minors?

CONSENT FOR TREATMENT: SUFFICIENCY

- “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 [1] need for, [2] the nature of, and the [3] 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. Any such consent shall be deemed valid and so informed if the health care provider to whom it is given or by whom it is secured has made such disclosures and given such advice respecting pertinent facts and considerations as would ordinarily be made and given under the same or similar circumstances ~~by a like health care provider of good standing practicing in the same community...~~”

(IC 39-4506)

CONSENT FORM ≠ INFORMED CONSENT

Informed Consent = Communication

- Practitioner communicates info relevant to treatment
- Patient understands the material facts, e.g., benefits, risks, and likely consequence of the proposed treatment and alternatives.
- Patient makes informed decision to consent or refuse treatment.

Consent form = Documentation

- 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.

ADVANCE CARE PLANNING DOCUMENT

- “Advance care planning document” (ACPD) replaces living will and durable power of attorney.
- ACPD, "advance directive," "directive," or "health care directive" means a document that:
 - “(a) Substantially meets the requirements of section 39-4510(1), Idaho Code;
 - (b) Is a POST form; or
 - (c) Is another document that represents a competent person’s authentic expression of such person’s wishes concerning health care services.”

(IC 39-4501)

ADVANCE CARE PLANNING DOCUMENT

- Any competent person aged eighteen (18) years or older may execute an ACPD
- To be considered a valid ACPD,* a document must include:
 - (a) The person's name, date of birth, telephone number, and mailing address;
 - (b) The signature of the person for whom the ACPD is created or the authorized agent of such person; and
 - (c) The date on which the document was signed.
- May but not required to contain additional info.
(IC 39-4510)

* *But see IC 39-4502(1) and -4509(3)*

ADVANCE CARE PLANNING DOCUMENT

- ACPD is effective upon execution until suspended, revoked or replaced.
 - Maker may revoke or suspend ACPD by any action that manifests maker's intent to suspend or revoke the ACPD.
 - Maker is responsible for notifying healthcare provider.
 - No civil or criminal liability for failure to act on revocation or suspension unless have actual knowledge.
- Persons are immune from criminal or civil liability for good faith actions pursuant to facially valid ACPD.

(IC 39-4511A - 4513)

PHYSICIANS ORDER FOR SCOPE OF TREATMENT (POST)

- Signed by
 - Licensed independent practitioner (“LIP”, i.e., physician, PA, or APRN), and
 - Patient or patient’s surrogate decision-maker.
- Licensed independent practitioner not required to periodically review POST form with patient.
- Providers should inquire whether patient has POST form and comply with POST form.
- May disregard POST if revoked, as ordered by a LIP, or to avoid oral or physical confrontation.

(IC 39-4512A -4513)

ADVANCE DIRECTIVES

- “The laws of this state shall recognize the right of a competent person to have his or her wishes for health care services ... carried out....”
- APCDs and POSTs are not the only effective means of communicating a patient’s wishes.
- “Any authentic expression of a person’s wishes with respect to health care services should be honored.”

(IC 39-4509)

WITHDRAWAL OF CARE

- May not withdraw or withhold healthcare necessary to sustain life or provide appropriate comfort for patient if requested by patient or surrogate unless it is “nonbeneficial medical treatment”.

(IC 39-4514)

- "Nonbeneficial medical treatment" means treatment:
 - (a) For a patient whose death, according to the reasonable medical judgment of a licensed independent practitioner, is imminent within hours or a few days regardless of whether the treatment is provided; or
 - (b) That, according to the reasonable medical judgment of a licensed independent practitioner, will not benefit the patient's condition.”

(IC 39-4502)

TELEHEALTH



TELEHEALTH

- COVID-19 waivers and relaxed standards have generally ended or will end.
 - Payer requirements, including Medicare and Medicaid.
 - Licensure requirements.
 - Ryan Haight Online Pharmacy Consumer Protection Act
- If engage in telehealth outside Idaho, beware:
 - State laws where patient is located, including licensure, scope of practice, prescribing, corporate practice of medicine, etc.
 - Federal laws concerning prescribing controlled substances.
 - Standard of care.
 - Malpractice insurance.
 - HIPAA privacy and security concerns.
 - DOJ guidance concerning discrimination.

FEDERATION OF STATE MEDICAL BOARD COMPARISON OF STATE LICENSURE LAWS

https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf

	State License Required	Reimbursement Policies				Private Payer Law	Other Rules/Regulations (citation only)
		Medicaid					
		Live Video	Store-and-Forward	Remote Patient Monitoring	Audio-only		
AL	√	√		√		Ala. Admin. Code § 540-x-16 ALBME Special Purpose License (Abolished 5/26/22) AL Medicaid Management Information System Provider Manual, Primary Care Physician	
AK	√*1	√	√	√	√	"Telehealth Statutes, Regulations & Policy" Alaska Dept. of Health and Social Services SB 74 of 2016, Chapter 25 SLA 16 "Board Issued Guidelines: Telemedicine", AMB, Nov. 2014 Alaska Courtesy License AK HB 265 (2022) re: out-of-state referrals	
AZ-M	√+2	√	√	√	√^3	Ariz. Rev. Stat. § 32-1421 "Issue Brief: Telemedicine" Arizona State Senate, Nov. 2014 AZ HB 2454 (2021)	
AZ-O	√+	√	√	√	√^	Ariz. Rev. Stat. § 32-1821 Ariz. Rev. Stat. § 32-1854 "Issue Brief: Telemedicine" Arizona State Senate, Nov. 2014 AZ HB 2454 (2021)	
AR	√	√		√	√	AR Code § 17-95-206 AR Stat. 10-3-1702(10) "When Does Telemedicine or Internet- Based Patient Healthcare Violate Regulation 2.8?" AR State Med. Board Newsletter Fall 2012	

¹ Alaska allows individuals with suspected or diagnosed life-threatening conditions, to be treated by an out-of-state physician as long as they have a referral from their Alaska-licensed physician, among other requirements.

² √+ denotes that a state requires physicians to register if they choose to practice medicine across state lines.

³ √^ denotes that a state has payment parity.

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)

VIRTUAL CARE ACT: LICENSURE

- Must have Idaho license to render virtual care in Idaho.
- Exceptions: practitioner licensed and in good standing in other jurisdiction:
 - Has established relationship with patient who is in Idaho temporarily for work, education, vacation, etc.
 - Has established relationship with patient and needs to provide short-term follow-up care.
 - Is employed by or contracted with Idaho facility or hospital to provide care services for which the provider has been privileged or credentialed.
 - Renders care in a disaster.
 - Provides care in preparation for scheduled in-person visit.
 - Consults with or refers patient to Idaho provider.
 - Mental health providers per IC 54-5714 (discussed below)

(IC 54-5713)

VIRTUAL CARE ACT: PROVIDER-PATIENT RELATION

- 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)



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FRIDAY, AUG. 21, 2015, 3:30 P.M.

Doctor fights for her career after Idaho telemedicine sanction

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Dr. Ann DeJong has had to sell her house in Wisconsin and is \$200,000 in debt. Now her medical career is in jeopardy, all because she was sanctioned by Idaho for prescribing a common antibiotic over the phone.

At the time, Idaho law required a face-to-face exam for a prescription. This year, lawmakers changed that to allow for consultations through telemedicine. DeJong was working for such a company, Consult-a-Doctor, when she prescribed the medication; it subsequently pulled out of Idaho. DeJong says if Idaho doesn't modify its order by October, she'll lose her board certification in family practice, and thus her job and livelihood. "It would keep me from practicing anywhere," said DeJong, who was licensed to practice medicine in eight states including Idaho when she took that call from an Idaho patient through Consult-a-Doctor in 2012.

Idaho House Minority Leader John Rusche, D-Lewiston, a retired physician who sponsored this year's telemedicine legislation, said, "I think the action on the part of the Board of Medicine is excessive. ... It seems to me that this was a statement or an attempt by the members of the Board of Medicine to take on the whole issue of tele-health and telemedicine, and the vehicle that they had was this individual."



Dr. Ann DeJong

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)

VIRTUAL CARE ACT: MENTAL HEALTH

- Mental and healthcare providers rendering virtual health in Idaho do not need to be licensed in Idaho if:
 - They are licensed or registered in another U.S. state, district, or territory to practice mental or behavioral health care.
 - Not subject to any past or pending disciplinary proceedings.
 - Comply with all Idaho laws and regulations.
 - Maintain liability insurance to extent required by Idaho law.
 - Register biennially with relevant Idaho licensing board to provide telehealth services. Registration is not licensure and does not allow in-person treatment.
 - Idaho community standard of care applies.
 - Subject to Idaho jurisdiction and penalties.
- (IC 54-5714)

IDAHO ABORTION LAWS



IDAHO ABORTION LAW: CRIMINAL PENALTIES

- Prohibits—
 - Abortion of a clinically diagnoseable pregnancy.
 - Not ectopic or molar pregnancy.
 - Not termination of nonviable fetus.
 - Assisting an abortion.
- Exceptions:
 - Necessary to save life of mother.
 - Rape or incest if performed during first trimester and receive copy of police report.
- Penalties:
 - 2 to 5 years in prison
 - Loss of license

(IC 18-622)

IDAHO ABORTION LAW: EMTALA EXCEPTION

- Preliminary injunction prohibits enforcement of Idaho's total abortion ban to the extent EMTALA applies, *i.e.*,
 1. Pregnant woman comes to hospital or hospital-based urgent care center seeking emergency care.
 2. Woman or child has an emergency medical condition.
 3. Abortion is necessary to stabilize the emergency medical condition.
 4. Pregnant woman is not or has not been admitted as inpatient or begun outpatient course of treatment.

(DCt Order; 42 USC 1395dd; 42 CFR 489.24; CMS, State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases (Rev. 7/19/19)

- Case is still pending.

IDAHO ABORTION LAW: ASSISTING AN ABORTION

- In March 2023, AG Labrador wrote a letter in which he concluded, “[a]n Idaho health care professional who refers a woman across state lines to an abortion provider or who prescribes abortion pills for the woman across state lines has given support or aid to the woman in performing or attempting to perform an abortion and has thus violated the statute.” (<https://www.courthousenews.com/wp-content/uploads/2023/04/labrador-idaho-opinion-letter.pdf>).
- In July 2023, the federal district court entered preliminary injunction blocking the AG from enforcing that interpretation. (*Planned Parenthood v. Labrador*, Case No. 1:23-cv-00142(BLW), Memorandum Decision at p.55, available here).
- Case is still pending.

IDAHO ABORTION LAW: CIVIL PENALTIES

- Certain family members may sue physician who performs abortion after fetal heartbeat is or could be detected.
- Exceptions:
 - Medical emergency, i.e., necessary to avert death or substantial impairment of major bodily function of mother.
 - Rape or incest if receive copy of police report.
- Damages:
 - Statutory damages of at least \$20,000
 - Costs and fees

(IC 18-8807)

IDAHO ABORTION TRAFFICKING LAW

- Prohibits recruiting, harboring or transporting a pregnant minor within Idaho to obtain an abortion (including an abortion out-of-state) with the intent to conceal the abortion from the parent or guardian.
- Affirmative defenses:
 - Parental or guardian consent
 - Not the fact that the abortion provider is in another state.
- Penalties:
 - 2 to 5 years in prison.

(IC 18-623)

* *Document parental involvement and consent.*

IDAHO BAN ON GENDER-AFFIRMING CARE FOR MINORS



VULNERABLE CHILD PROTECTION ACT: BAN ON GENDER AFFIRMING CARE

Effective 1/1/24 (unless blocked by court...)

- “A medical provider shall not engage in [certain specified] practices upon a child for the purpose of attempting to alter the appearance of or affirm the child’s perception of the child’s sex if that perception is inconsistent with the child’s biological sex...”
 - “‘Child’ means any person under 18 years of age.”
 - “‘Sex’ means the immutable biological and physiological characteristics, specifically the chromosomes and internal and external reproductive anatomy, genetically determined at conception and generally recognizable at birth, that define an individual as male or female.”

(IC 18-1506C(2)-(3))

GENDER AFFIRMING CARE ON MINORS: PENALTIES

- “Any medical professional convicted of a violation of this section shall be guilty of a felony and shall be imprisoned in the state prison for a term of not more than ten (10) years.”
(IC 18-1506C(5))
- Felony conviction may lead to adverse licensure action, e.g.,
“Every person licensed to practice medicine ... in this state is subject to discipline by the [Board of Medicine] upon any of the following grounds:
“(1) Being convicted of a felony, pleading guilty to a felony, or the finding of guilt by a jury or court of commission of a felony....”
(IC 54-1814(1))

GENDER AFFIRMING CARE ON MINORS: PROHIBITED ACTIONS

If performed on a child:

“(a) Performing surgeries that sterilize or mutilate, or artificially construct tissue with the appearance of genitalia that differs from the child’s biological sex,

[e.g.,] castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, clitoroplasty, vaginoplasty, vulvoplasty, ovariectomy, or reconstruction of the fixed part of the urethra with or without metoidioplasty, phalloplasty, scrotoplasty, or the implantation of erection or testicular prostheses;

“(b) Performing a mastectomy; ...

“(d) Removing any otherwise healthy or nondiseased body part or tissue.”

(IC 18-1506C(3))

GENDER AFFIRMING CARE ON MINORS: PROHIBITED ACTIONS

If done to a child:

“(c) Administering or supplying the following medications that induce profound morphologic changes in the genitals of a child or induce transient or permanent infertility:

- (i) Puberty-blocking medication to stop or delay normal puberty;
- (ii) Supraphysiological doses of testosterone to a female; or
- (iii) Supraphysiological doses of estrogen to a male...”

(IC 18-1506C(3))

Remember: requires prohibited intent, i.e., “for the purpose of attempting to alter the appearance of or affirm the child’s perception of the child’s sex if that perception is inconsistent with the child’s biological sex.”

GENDER AFFIRMING CARE ON MINORS: EXCEPTIONS

“(a) Necessary to the health of the person on whom it is performed and is performed by a person licensed in the place of its performance as a medical practitioner,

- except that a surgical operation or medical intervention is never necessary to the health of the child on whom it is performed if it is for the purpose of attempting to alter the appearance of or affirm the child’s perception of the child’s sex if that perception is inconsistent with the child’s biological sex;

“(b) For the treatment of any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of gender transition procedures...”

(IC 18-1506C(4)(a))

GENDER AFFIRMING CARE ON MINORS: EXCEPTIONS

“(c) Performed in accordance with the good faith medical decision of a parent or guardian of a child born with a medically verifiable genetic disorder of sex development, including:

“(i) A child with external biological sex characteristics that are ambiguous and irresolvable, such as a child born having 46, XX chromosomes with virilization, 46, XY chromosomes with undervirilization, or with both ovarian and testicular tissue; or

“(ii) When a physician has otherwise diagnosed a disorder of sexual development in which the physician has determined through genetic testing that the child does not have the normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female.”
(IC 18-1506C(4)(c))

POE V. LABRADOR, NO. 1:23-CV-269-BLW (D. ID. 2023)

- On May 31, 2023, transgender minor and parents of transgender minors filed complaint alleging that IC 18-1506C violates:
 - 14th Amendment's guarantee of equal protection under the law.
 - Whether a person may receive certain medical treatments depends on their sex and discriminates against transgender minors.
 - 14th Amendment's protection of right of parents to make decisions concerning their children.
 - See, e.g., *Washington v. Glucksberg*, 521 U.S. 702 (1997) and *Troxel v. Granville*, 530 U.S. 57 (2000).
 - Due process guarantees because HB71 was published without fair notice that the laws are unconstitutional.
- On July 21, 2023, plaintiffs filed a motion for preliminary injunction staying enforcement of the law.

NO SURPRISE BILLING RULES 45 CFR PART 149



NO SURPRISE BILLING RULES

INSURED PATIENTS

- Limits amount out of network (OON) provider/facility may bill patient and payer.
- Only applies to:
 - Hospital or freestanding emergency dept.
 - Hospital, hospital outpatient dept, or ASC.
- Independent dispute resolution (IDR) process to resolve disputes about charges.

(45 CFR 149.410-.450)

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SELF-PAY PATIENTS

- Providers/facilities must give patient a good faith estimate of charges.
- Patient-provider dispute resolution (PPDR) process if actual bill is substantially in excess (i.e., > \$400) of good faith estimate.
- Notice of rights to patient.
(45 CFR 149.610-.620)

NO SURPRISE BILLING RULES ENFORCEMENT

- Limited payment from patients and payers.
 - Self-pay patients: payment may be capped through PPDR process if actual charges are substantially in excess of GFE.
 - Insured patients: OON provider's payment from patients and payers may be limited.
- State has primary enforcement obligations.
- If state fails to enforce, CMS may impose:
 - \$10,000 civil penalty
 - Corrective action plan

(No Surprise Act § 2799D; 45 CFR 150.513; 86 FR 51730)

[HTTPS://DOI.IDAHO.GOV/CONSUMERS/ HEALTH-INSURANCE/NOSURPRISES/](https://doi.idaho.gov/consumers/health-insurance/nosurprises/)

https://doi.idaho.gov/consumers/health-insurance/nosurprises/

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Unexpected Medical Bills and No Surprises Act

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Effective January 1, 2022, the federal No Surprises Act provides new protections for unexpected or excessive medical bills consumers may have received from medical providers. The Department of Insurance is able to help Idahoans understand and utilize these new consumer protections, regardless of whether they have health insurance.

The Department will be posting further information on the No Surprises Act soon, including details on how consumers can appeal decisions of health insurance companies or health care providers if they believe that those decisions are in violation of the No Surprises Act's consumer protections.

No Surprises Act resources for health care providers

No Surprises Act resources for health insurance companies

— How are insured consumers protected in an emergency situation?

Prior to this new law, if a consumer received emergency care or air ambulance transportation, the consumer sometimes owed the difference between what the insurance company would have paid and the amount the medical provider charged for the services.

With this new law, under certain circumstances, the consumer will only be responsible for any applicable deductibles, co-

IDAHO PATIENT ACT IC 48-301 et seq.



TO INITIATE “EXTRAORDINARY COLLECTION ACTION” W/OUT PENALTY

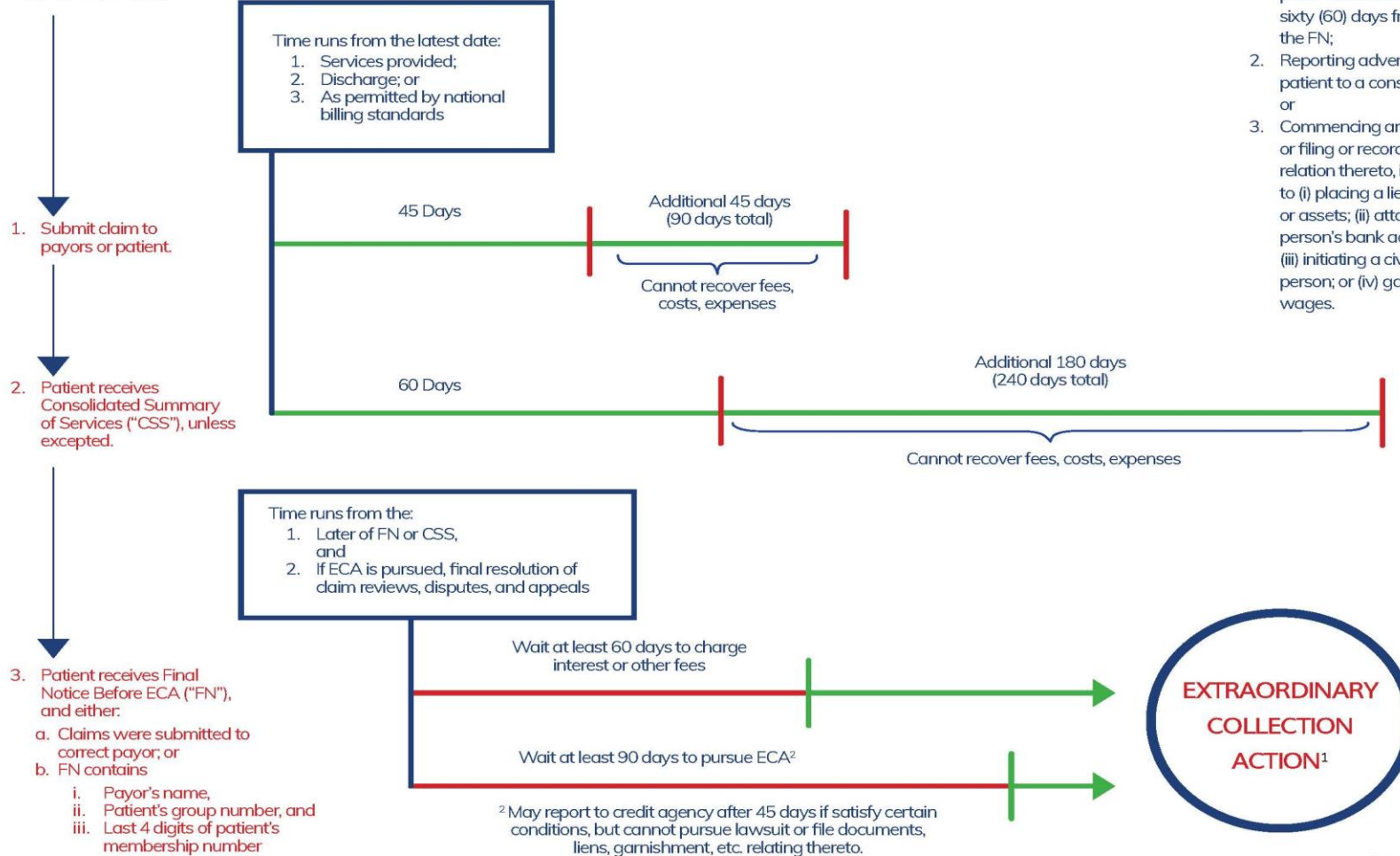
- **w/in 45/90 days** after services or discharge, submit charges to patient or payers identified by patient.
- **w/in 60/240 days** after services or discharge, submit “consolidated summary of services” to patient.
 - Exception: single billing entity that provides final statement and info re billing 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.

IDAHO PATIENT ACT TIMELINES (Idaho Code 48-304 and 306)

TO BRING AN EXTRAORDINARY COLLECTION ACTION ("ECA")¹



¹The Idaho Patient Act only applies to "Extraordinary Collection Actions", i.e.,

1. Selling, transferring, or assigning a patient's debt to any third-party prior to sixty (60) days from patient's receipt of the FN;
2. Reporting adverse information about the patient to a consumer reporting agency; or
3. Commencing any judicial or legal action or filing or recording any document in relation thereto, including but not limited to (i) placing a lien on a person's property or assets; (ii) attaching or seizing a person's bank account or other property; (iii) initiating a civil action against any person; or (iv) garnishing an individual's wages.

² May report to credit agency after 45 days if satisfy certain conditions, but cannot pursue lawsuit or file documents, liens, garnishment, etc. relating thereto.

IDAHO PATIENT ACT: LIMITS ON FEES

- Cannot recover costs, expenses, or fees for extraordinary collection action unless complied with process in IC 48-304.
 - May still collect principal but may be subject to penalties.
- Limits on fees:
 - **Uncontested judgment against patient:** principal owed + up to lesser of \$350 or 100% of principal + pre- and post-judgment interest
 - **Contested judgment against patient:** principal owed + up to lesser of \$700 or 100% of principal + pre- and post-judgment interest.
 - **Post-judgment motions and writs:** up to \$75/\$25 per successful motion or writ + Service fees.
 - May apply for more if fees grossly disproportionate
 - **If patient prevails:** recovers all costs, expenses and fees and has no liability.
(IC 48-305)

IDAHO PATIENT ACT: ENFORCEMENT AND PENALTIES

- If bring extraordinary collection action without complying with IC 48-304 or -306:
 - Patient has no liability for collection costs, expenses and fees.
 - Provider is liable to patient for greater of:
 - \$1,000, or
 - Damages suffered by patient due to violation.
 - If provider willfully or knowingly violated the statute, court may award greater of:
 - \$3,000, or
 - 3x damages suffered by patient due to violation. Patient is entitled costs + reasonable attorneys fees.

(IC 48-311)

FRAUD AND ABUSE LAWS



- False Claims Act (“FCA”)
- Ethics in Patient Referrals Act (“Stark”)
- Anti-Kickback Statute (“AKS”)
- Eliminating Kickbacks in Recovery Act (“EKRA”)
- Civil Monetary Penalties Laws (“CMPL”)
- Idaho Anti-Kickback Statute

FALSE CLAIMS ACT

- Cannot knowingly submit a false claim for payment to the federal govt.
- 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)

Penalties

- Repayment plus interest
- Civil monetary penalties of \$11,803* to \$23,607* per claim
- Admin penalty \$22,427* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid (42 USC 1320a-7a(a); 42 CFR 1003.210; 45 CFR 102.3; 86 FR 70740)

➤ *Subject to qui tam claims*

ANTI-KICKBACK STATUTE

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered 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
 - \$112,131* civil penalty
 - 3x damages
 - Exclusion from Medicare/Medicaid
(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)
- *Automatic False Claims Act violation*
(42 USC 1320a-7a(a)(7))

IDAHO ANTI-KICKBACK STATUTE

- Service provider (including healthcare providers) 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.

Penalties

- \$5000 fine by Dept of Insurance
(IC 41-348)

ELIMINATING KICKBACK IN RECOVERY ACT (“EKRA”)

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery homes 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))
- *Beware if you operate or deal with a lab.*
 - *Applies to private or public payors.*

CIVIL MONETARY PENALTIES LAW

Prohibits certain specified conduct, e.g.:

- Submitting false or fraudulent claims, misrepresenting facts relevant to services, or engaging in other fraudulent practices.
- Violating Anti-Kickback Statute or Stark law.
- Violating EMTALA.
- Failing to report and repay an overpayment.
- Failing to grant timely access.
- Misusing “HHS”, “CMS”, “Medicare”, “Medicaid”, etc.
- Failing to report adverse action against providers.
- Offering inducements to program beneficiaries.
- Hospitals offering inducements to physicians to limit services.
- Submitting claims for services ordered by, or contracting with, an excluded entity.

(42 USC 1320a-7a; 42 CFR 1003.200-1100)

ETHICS IN PATIENT REFERRALS ACT (“STARK”)

- If physician (or family member) has financial relationship with entity:
 - Physician may not refer patients to entity for designated health services (“DHS”), and
 - Entity may not bill Medicare or Medicaid for such DHS unless arrangement fits within a regulatory exception (safe harbor).

(42 USC 1395nn; 42 CFR 411.353 and 1003.300)

Penalties

- No payment for services provided per improper referral.
 - Repayment w/in 60 days.
 - Civil penalties.
 - \$27,750* per claim
 - \$174,172* per scheme
- (42 CFR 411.353, 1003.310; 45 CFR 102.3)
- *Likely False Claims Act violation*
 - *Likely Anti-Kickback Statute violation*

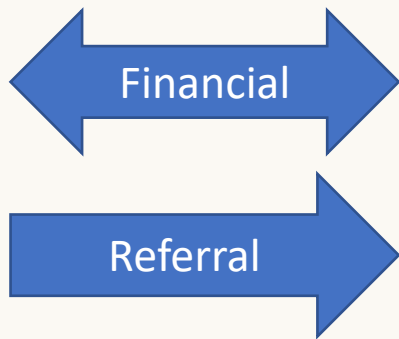
STARK

Only applies if:

Physician

- MD
- DO
- Dentist
- Oral surgeon
- Podiatrist
- Optometrist
- Chiropractor

(42 CFR 411.351 and
411.353)



Designated Health Service (“DHS”)

- Inpatient/outpatient hospital services
- Outpatient prescription drugs
- Radiology and certain imaging services
- Radiation therapy and supplies
- Clinical laboratory services
- Physical, occupational, or speech therapy
- Home health services
- Durable medical equipment and supplies
- Prosthetics and orthotics
- Parenteral and enteral nutrients, equipment, and supplies

RED FLAGS: INDUCEMENTS TO PATIENTS

- Routinely waiving copays and deductibles.
- “Insurance only” billing.
- Prompt pay discounts.
- Free or discounted items or services, including free equipment, supplies, etc.
- Patient reward or incentive programs.
- Loss leaders.
- “Thank you” gifts.
- Free transportation.
- Paying premiums.
- Write offs.
- “Refer a friend” incentives.
- Raffles or give aways.
- Any other remuneration to induce referrals.

Consider:

- Payor source
- Statutory or regulatory safe harbors or exceptions
- Advisory opinions
- Risk of fraud/abuse/waste

RED FLAGS: REMUNERATION TO REFERRAL SOURCES

- Free or discounted space, items or services
- “Thank you” gifts
- Professional courtesies
- Payments based on referrals
- Payment more or less than FMV
- Payment for unnecessary services
- Sharing or splitting fees
- Subsidizing practice costs
- Investment opportunities with little or no risk or contributions
- Any other remuneration to induce referrals.

Consider:

- Statutory or regulatory safe harbors or exceptions
- Advisory opinions
- Risk of fraud and abuse

RED FLAGS: GROUP COMPENSATION

NON-PHYSICIANS

- Stark does not apply.
- AKS bona fide employee exception likely applies.
- EKRA prohibits comp based on referrals for labs or other items covered by EKRA.
(42 CFR 1001.952(i); 18 USC 220)

PHYSICIANS

- Stark applies if group provides DHS.
- AKS applies if group provides items or services payable by Medicare/Medicaid.
- EKRA prohibits comp based on referrals for labs or other items covered by EKRA.
(42 CFR 411.357(c), (d) and (l); 1001.952(d), (i); 18 USC 220)

RED FLAGS: GROUP COMPENSATION

Stark (Physicians)

- Non-owners
 - Employee safe harbor
 - Contractor safe harbor (42 CFR 411.357(c), (d), (l))
 - Group practice safe harbors (42 CFR 411.355)
- Owners or profit sharing
 - Rural providers.
 - **Physician services.***
 - **In-office ancillary services exception.***

(42 CFR 411.355)

*** Must qualify as a “group practice” under 42 CFR 411.352.**

AKS (Physicians)

- Non-owners
 - Employee safe harbor
 - Contractor safe harbor (42 CFR 411.1001(d), (i))
- Owners or profit sharing.
 - If group, qualify as a “**group practice**” under Stark.
 - Unified business with centralized decision-making, pooling of expenses and revenues, and no satellite offices operating as separate profit centers.
 - Ancillary services satisfy the “**in-office ancillary services**” exception under Stark.

(42 CFR 1001.952(p))

“GROUP PRACTICE”

- Operate as single legal entity.
- 2+ physicians.
- Physicians provide services through shared office space, facilities, equipment and personnel.
- At least 75% of services performed by and billed through the group.
- Physicians in group perform at least 75% of physician encounters.
- Distribution of overhead expenses and income determined prospectively before receipt of payment.
- Operate as unified business with centralized decision-making, consolidated billing, accounting, financial reporting.
- Compensation is not based on the volume or value of referrals except as permitted in 42 CFR 411.352(i).

(42 CFR 411.352)

“GROUP PRACTICE” COMPENSATION

Paying Based on Overall Profits

- May pay group members share of overall profits that is not directly related to volume or value of referrals for DHS.
 - > 5 physicians: must have at least 5 physicians in profit pool.
 - ≤ 5 physicians: all are included in profit pool.
 - Cannot have different groups of 5 for different DHS.
- Profits deemed not to be based on referrals if:
 - Overall profits divided per capita.
 - Overall profits distributed based on distribution of non-DHS.
 - DHS revenues $< 5\%$ of total revenue, and portion of DHS Revenue distributed to physician $\leq 5\%$ of total compensation.

(42 CFR 411.352(i)(1))

“GROUP PRACTICE” COMPENSATION

Paying Based on Productivity

- May pay group members based on DHS they personally perform and “incident to” the physician’s services.
 - Not DHS ordered by physician by performed by others except “incident to” DHS.
- Productivity compensation deemed not to be based on referrals if:
 - Productivity based on physician’s total patient encounters or RVUs personally performed by the physician.
 - Services on which productivity bonus is based are not DHS whether or not payable by Medicare/Medicaid.
 - DHS revenues < 5% of total revenue, and portion of DHS Revenue distributed to physician \leq 5% of total compensation.

(42 CFR 411.352(i)(2))

GROUP COMPENSATION



- Beware “eat what you kill” compensation structures in which physician’s compensation varies based on DHS actually performed or provided by others, e.g.,
 - The more DHS the physician orders, prescribes or refers, the more compensation the physician receives.
 - Physician receives direct credit and/or a percentage of revenue for each DHS the physician prescribes, orders or refers.
 - Physician is in a subgroup of less than 5 physicians that shares in profits from DHS.
 - Physician is in more than one group of 5 physicians that share in profits from DHS.

IN-OFFICE ANCILLARY SERVICES EXCEPTION

Under Stark, physician may refer in-office ancillary services to others in the group if:

- Services furnished by referring physician, member of the group, or individual supervised by group member.
 - For contracted physicians, must contract directly with provider and provide services in group's facilities.
- Services performed in “same building” as group or “centralized building” owned or leased fulltime by group.
- Services billed by the performing/supervising physician or group practice under number assigned to physician or group.
- For MRI, CT, and PETs, must provide written notice of other entities from which the patient may obtain the services.

(42 CFR 411.355(b); 411.351)

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)



HIPAA PRIVACY AND SECURITY RULES

PRIVACY RULE

- May not access, use or disclose protected health info (PHI) unless:
 - Patient's authorization.
 - HIPAA exception.
- Implement safeguards.
- Give patient rights to PHI.
- Mitigate any breaches.

(45 CFR 164.501 et seq.)

SECURITY RULE

- Perform periodic risk assessments.
- Must protect and secure e-PHI:
 - Administrative safeguards
 - Technical safeguards
 - Physical safeguards

(45 CFR 164.301 et seq.)

Cyberattack on Mountain View Hospital still ongoing after two weeks

🕒 Published at 9:00 am, June 10, 2023 | Updated at 9:12 am, June 10, 2023



Logan Ramsey, EastIdahoNews.com

**Why you need to
comply with
Security Rule**



☰ **CNN** politics SCOTUS Congress Facts First 2024 Elections

Cyberattack forces Idaho hospital to send ambulances elsewhere

By Sean Lyngaas, CNN
Published 5:33 PM EDT, Wed May 31, 2023

[f](#) [t](#) [e](#) [l](#)

HIPAA CIVIL PENALTIES

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none"> • \$127* to \$63,973* per violation • Up to \$1,919,173* per type per year • No penalty if correct w/in 30 days • OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none"> • \$1,280* to \$63,973* per violation • Up to \$1,919,173* 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	<ul style="list-style-type: none"> • \$12,794* to \$63,973* per violation • Up to \$1,919,173* per type per year • Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none"> • \$63,973 to \$1,919,173* per violation • Up to \$1,919,173* per type per year • Penalty is mandatory

HIPAA: AVOIDING “WILLFUL NEGLIGENCE”

- ✓ Have required policies in place.
- ✓ Implement security rule’s administrative, physical and technical safeguards.
- ✓ Periodically conduct and document risk assessment.
 - ✓ See ONC’s Risk Assessment Tool,
<https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>
- ✓ Have business associate agreements (“BAAs”) in place.
- ✓ Conduct and document periodic HIPAA training.
- ✓ Respond promptly to suspected problems and correct them within 30 days.
- ✓ Investigate and, if necessary, timely report breaches of protected health information (“PHI”).

HIPAA: COMMON PROBLEMS

- Mistakenly believing that HIPAA only applies to medical records.
- E-mailing or texting PHI via unencrypted platform.
- Maintaining PHI on unencrypted devices, e.g., laptops, cell phones, portable media.
- Disclosing PHI on social media, including responding to internet posts.
- Disclosing info to employers, lawyers, or agencies improperly.
- Failing to respond properly or timely to patient requests to access information.
 - Patient has right to direct you to send electronic records to third parties.
 - Must produce records created by other parties if maintained in designated record set.

HIPAA: HOT ISSUES

- Patient's right to access information.
 - OCR's Right to Access Initiative.
 - Read *Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524*, available at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>
- Proposed rule issued 1/21/21.
 - Stay tuned.
- Request for info re HIPAA “bounty” issued 4/6/22.
 - Individuals recover percentage of fines or settlements.
- FTC and OCR warnings re tracking technology.
- FTC action on security.
- Modifications to 42 CFR part 2 re federally assisted substance use disorder programs.

INFORMATION BLOCKING RULE, 45 CFR 171



45 CFR part 171

INFO BLOCKING RULE

- Applies to “actors”
 - Healthcare providers.
 - Developers or offerors of certified health IT.
 - Not providers who develop their own IT.
 - Health info network/exchange.

(45 CFR 171.101)

- Prohibits info blocking, i.e., practice that is likely to interfere with access, exchange, or use of electronic health info, and
 - Provider: knows practice is unreasonable and likely to interfere.
 - Developer/HIN/HIE: knows or should know practice is likely to interfere.

(45 CFR 171.103)

INFO BLOCKING RULE: PENALTIES

DEVELOPERS, HIN, HIE

- Complaints to ONC
 - <https://www.healthit.gov/topic/information-blocking>.
 - ONC investigations
 - Final Rule:
 - Civil monetary penalties of up to \$1,000,000 per violation
- (42 CFR 1003.1420)

HEALTHCARE PROVIDERS

- “Appropriate disincentives to be established by HHS.”
- Waiting for rule.



INFO BLOCKING: EXAMPLES

- Refusing to timely respond to requests.
- Charging excessive fees.
- Imposing unreasonable administrative hurdles.
- Imposing unreasonable contract terms, e.g., EHR agreements, BAAs, etc.
- Implementing health IT in nonstandard ways that increase the burden.
- Others?

NOT INFO BLOCKING

- Action required by law.
 - HIPAA, 42 CFR part 2, state privacy laws, etc.
 - Laws require conditions before disclosure, e.g., patient consent.
- Action is reasonable under the circumstances.
- Action fits within regulatory exception.

INFO BLOCKING EXCEPTIONS



[HTTPS://WWW.HEALTHIT.GOV/TOPIC/INFORMATION-BLOCKING](https://www.healthit.gov/topic/information-blocking)

The screenshot shows a web browser window displaying the HealthIT.gov website. The browser's address bar shows the URL <https://www.healthit.gov/topic/information-blocking>. The website header includes the HealthIT.gov logo, navigation links for TOPICS, BLOG, NEWS, DATA, and ABOUT ONC, and a search bar. A banner at the top right promotes the 'NEW: Health IT Feedback Portal' and includes links for CONTACT and EMAIL UPDATES. The main content area features a breadcrumb trail: HealthIT.gov > Topics > Information Blocking. A sidebar on the left contains a menu for 'Information Blocking' and a button for 'Report Information Blocking'. The main heading is 'Information Blocking', followed by the sub-heading 'What is information blocking?'. The text explains that information blocking is a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI). A red octagonal icon with a white lowercase 'i' is positioned to the right of this text. Below this, there is a link to 'View our Information Blocking Frequently Asked Questions (FAQs)'. The next sub-heading is 'What are examples of practices that could constitute information blocking?'. The text states that Section 4004 of the Cures Act specifies certain practices that could constitute information blocking. A list of practices is partially visible, including 'Practices that restrict authorized access, exchange, or use under applicable state or federal law of such information for treatment and other permitted purposes under such applicable law'. On the right side, there is a 'Additional Resources' section with links to 'Fact Sheets', 'Webinars', 'FAQs', and 'Report Information Blocking'. The browser's taskbar at the bottom shows various application icons, including Windows, search, file explorer, and several instances of Microsoft Edge. The system tray on the right shows the weather as 'Rain/snow', the time as '10:54 PM', and the date as '3/16/2022'.

DISCRIMINATION



ANTI-DISCRIMINATION LAWS

LAWS

- Civil Rights Act Title VI
- Americans with Disability Act
- Age Discrimination Act
- Rehabilitation Act § 504
 - HHS has proposed new rules
- Affordable Care Act § 1557
 - HHS has proposed expansive new rules.
- State discrimination laws

RISKS

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

ANTI-DISCRIMINATION LAWS

Persons with Disabilities (e.g., hearing, sight, etc.)

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

Persons with Limited English Proficiency

- 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.

ANTI-DISCRIMINATION LAWS



- About HHS
- Programs & Services
- Grants & Contracts
- Laws & Regulations

Home > About > News > HHS Office for Civil Rights Settles Complaint with Florida Health Center that Failed to Provide Effective Communication for a Patient...

News
Blog
HHS Live
Podcasts
Media Guidelines for HHS Employees



FOR IMMEDIATE RELEASE
May 10, 2023

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Office for Civil Rights Settles Complaint with Florida Health Center that Failed to Provide Effective Communication for a Patient's Caregiver

Resolution agreement requires the Federally Qualified Health Center to fully comply with the non-discrimination requirements of federal civil rights laws

The U.S. Department of Health and Human Services' Office for Civil Rights (OCR), entered into a Voluntary Resolution Agreement with MCR Health, Inc., to resolve a disability discrimination complaint based on Section 504 of the

ADDITIONAL RESOURCES



HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE

Free content:

- Recorded webinars
- Client alerts
- White papers
- Other



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Healthcare is a massive industry that needs specialized legal advice.

Healthcare spending represents about a fifth of US GDP. Few sectors are as complex and highly regulated. In an ultra-competitive environment, our industry-experienced team takes care of clients' legal issues so they can focus on business.

Our team provides holistic guidance on regulatory issues, including Stark, Anti-Kickback Statute, HIPAA, Medicare/Medicaid, and similar state laws. We handle provider and payor contracting; mergers, acquisitions, and joint ventures; data privacy and security; licensing, credentialing and medical staff issues; government investigations and False Claim Act litigation; antitrust and trade regulation; employment; real estate; tax; employee benefits; and administrative or civil litigation. Given our combined experience, there is not much our healthcare clients face that we

Primary Contacts

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QUESTIONS?



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