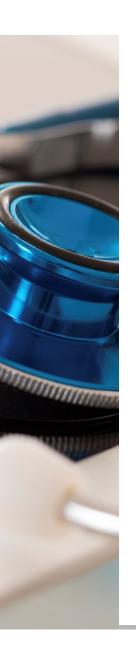


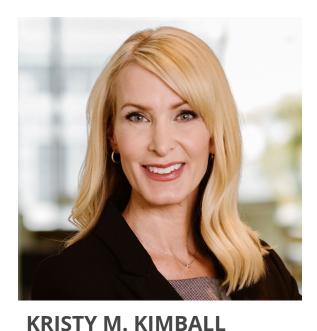
UNIQUE COMPLIANCE CONCERNS APPLICABLE TO UTAH

Kristy M. Kimball and Blaine Benard





PRESENTERS

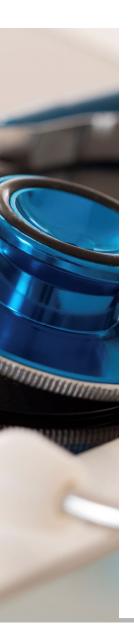


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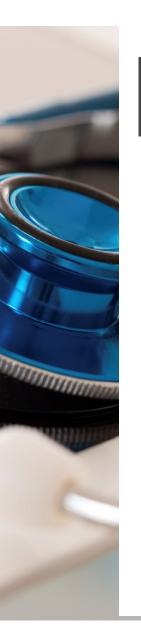


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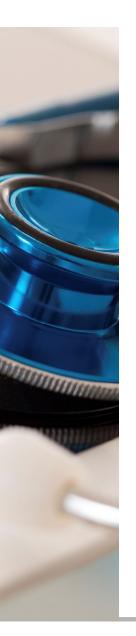




UTAH ANTI-FRAUD AND ABUSE LAWS

- Utah False Claims Act
- Licensure-Specific laws
 - Disclosure of Self-Referrals
 - Prohibition of Fee-Splitting



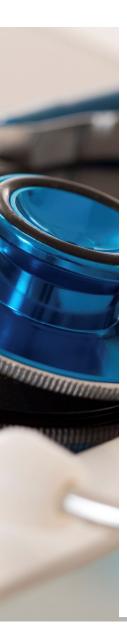


UTAH FALSE CLAIMS ACT

Anti-Kickback Provision

- Under the Utah False Claims Act, "[a] person may not solicit, offer, pay, or receive a kickback or bribe in return for or to induce" the following:
 - the purchasing, leasing, or ordering of any goods or services for which payment is or may be made, in whole or in part, pursuant to a medical benefit program; or
 - the referral of an individual to another person for the furnishing of any goods or services for which payment is or may be made, in whole or in part, pursuant to a medical benefit program.
- A "medical benefit program" is a benefit paid or payable to a recipient or a provider under a program administered by the state under:
 - (a) Titles V and XIX of the federal Social Security Act (Medicaid);
 - (b) Title X of the federal Public Health Services Act (Family Planning Program);
 - (c) the federal Child Nutrition Act of 1966 as amended by P.L. 94-105; and
 - (d) any programs for medical assistance of the state.
- <u>Utah Code Ann. § 26-20-4(2).</u> A "kickback or bribe" under the statute "includes rebates, compensation, or any other form of remuneration" that is: "(i) direct or indirect; (ii) overt or covert; or (iii) in cash or in kind[.]" *Id.* § 26-20-4(1) & (1)(a). However, "a kickback or bribe" would "not include a rebate paid to the state under 42 U.S.C. § 1396r-8 or any state supplemental rebates."
- A violation of this restriction is grounds for criminal and civil enforcement actions.

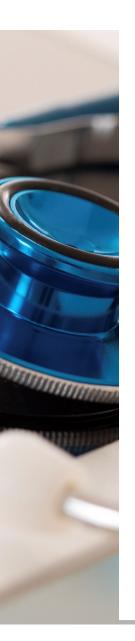




UTAH FALSE CLAIMS ACT

- The Utah False Claims Act specifically addresses claims for medical benefits as follows:
- A person may not make or present or cause to be made or presented to an employee or officer of the state a claim for a medical benefit:
 - which is wholly or partially false, fictitious, or fraudulent;
 - for services which were not rendered or for items or materials which were not delivered;
 - which misrepresents the type, quality, or quantity of items or services rendered;
 - representing charges at a higher rate than those charged by the provider to the general public;
 - for items or services which the person or the provider knew were not medically necessary in accordance with professionally recognized standards;
 - which has previously been paid;
 - for services also covered by one or more private sources when the person or provider knew of the private sources without disclosing those sources on the claim; or
 - where a provider:
 - unbundles a product, procedure, or group of procedures usually and customarily provided or performed as a single billable product or procedure into artificial components or separate procedures; and bills for each component of the product, procedure, or group of procedures:
 - as if they had been provided or performed independently and at separate times; and
 - the aggregate billing for the components exceeds the amount otherwise billable for the usual and customary single product or procedure.
- In addition to the above prohibition, a person may not:
 - fail to credit the state for payments received from other sources;
 - recover or attempt to recover payment in violation of the provider agreement from:
 - a recipient under a medical benefit program; or
 - the recipient's family;
 - falsify or alter with intent to deceive, any report or document required by state or federal law, rule, or Medicaid provider agreement;
 - retain any unauthorized payment as a result of acts described by this section; or
 - aid or abet the commission of any act prohibited by this section. Utah Code Ann. § 26-20-7. A violation of this restriction is grounds for criminal and civil enforcement actions.





LICENSURE-SPECIFIC PROHIBITIONS

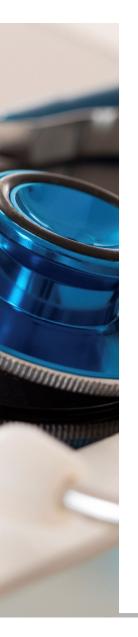
ANTI-KICKBACK PROVISIONS

- Dentists: For dentists and dental hygienists, the Utah legislature has defined "[u]nprofessional conduct" to include "sharing professional fees with an unlicensed person or paying any person for sending or referring a patient[.]" Utah Code Ann. § 58-69-502(1)(a).
- Pharmacists: Under Utah's Pharmacy Practice Act, "[u]nprofessional conduct" for pharmacists includes the following:
 - (i) paying or offering rebates to any health care provider, or receiving or soliciting rebates from any health care provider; or
 - (ii) paying, offering, receiving, or soliciting compensation in the form of a commission, bonus, rebate, kickback, or split fee arrangement with any health care provider for the purpose of obtaining referrals.*

Utah Code § 58-17b-502(2)(a).

- * These restrictions do not apply to (1) "giving or receiving price discounts based on purchase volume;" (2) "passing along pharmaceutical manufacturers' rebates; or" (3) "providing compensation for services to a veterinarian." Utah Code § 58-17b-502(2)(b).
- **Hearing Instrument Specialists:** "Unprofessional conduct" by hearing instrument specialists includes "paying any professional person any consideration of any kind for referral of a patient." Utah Code Ann. § 58-46a-501(9).

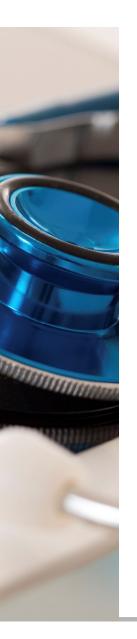




LICENSURE-SPECIFIC PROHIBITIONS

- **DISCLOSURE OF SELF-REFERRALS:** Various Utah Licensure statutes and/or rules require the disclosure of self-referrals for healthcare providers. Below are just a couple of examples:
 - <u>Physicians—Medical Doctors</u>: Medical doctors "may not refer patients, clients, or customers to any clinical laboratory, ambulatory or surgical care facilities, or other treatment or rehabilitation services such as physical therapy, cardiac rehabilitation, radiology services, dispensing optical lens facility, or lithotripsy, in which the medical doctor or a member of the medical doctor's immediate family has any financial relationship as that term is described in 42 U.S.C. § 1395nn), i.e., the Stark Law, unless the medical doctor, "at the time of making the referral discloses that relationship, in writing, to the patient, client or customer." Utah Code Ann. § 58-67-801(1). This written disclosure "shall also state that the patient may choose any facility or service center for purposes of having the laboratory work or treatment service performed." Id. § 58-67-801(2).
 - <u>Dentists</u>: Dentists and dental hygienists "may not refer patients to any clinical laboratory or health care facility in which the dentist, dental hygienist, or a member of the dentist's or dental hygienist's immediate family has any financial relationship as that term is described in 42 U.S.C. § 1395nn," i.e., the Stark Law, unless the dentist or dental hygienist, "at the time of making the referral discloses that relationship, in writing, to the patient." Utah Code Ann. § 58-69-805(1). This written disclosure "shall also state that the patient may choose any facility or laboratory for the work or treatment." Id. § 58-69-805(2).

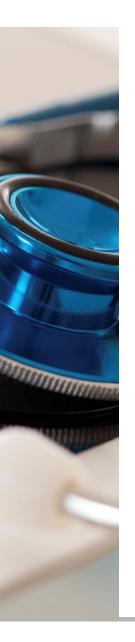




LICENSURE-SPECIFIC PROHIBITIONS

- PROHIBITION OF FEE-SPLITTING. Many Utah-specific licensure statutes/rules also address fee-splitting. Below are a few examples:
 - <u>Physicians—Medical Doctors</u>: The Utah Medical Practice Act Rule provides that unprofessional conduct includes "directly or indirectly giving or receiving any fee, commission, rebate or other compensation for professional services not actually and personally rendered or supervised; however, nothing in this section shall preclude legal relationships within lawful professional partnerships, corporations or associations, or the relationship between an approved supervising physician and physician assistants or advanced practice nurses supervised by them[.]" Utah Admin. Code R. 156-67-502(4).
 - <u>Chiropractors</u>: Utah's Chiropractic Physician Practice Act provides that unprofessional conduct includes "directly or indirectly giving or receiving any fee, commission, rebate, or other compensation for professional services not actually rendered or supervised. This restriction does not preclude legal relationships within lawful professional partnerships, corporations, or associations[.]" Utah Code Ann. § 58-73-501(13).
 - Optometrists: The Utah Optometry Practice Act defines unprofessional conduct to include "directly or indirectly giving or receiving any fee, commission, rebate, or other compensation for professional services not actually and personally rendered, except as part of a legal relationship within a lawful professional partnership, corporation, or association[.]" Utah Code Ann. § 58-16a-502(5).





INFORMED CONSENT

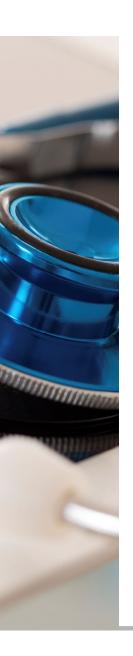
It shall be a <u>defense to any malpractice action</u> against a health care provider based upon alleged failure to obtain informed consent if:

- (a) the <u>risk of the serious harm</u> which the patient actually suffered was <u>relatively minor</u>;
- (b) the risk of serious harm to the patient from the health care provider was commonly known to the public;
- (c) prior to receipt of care the patient stated that he would <u>accept the health care involved regardless</u> <u>of the risk</u>; or that he did not want to be informed of the matters to which he would be entitled to be informed;
- (d) the health care provider, after considering all of the attendant facts and circumstances, used reasonable discretion as to the manner and extent to which risks were disclosed, if the health care provider reasonably believed that additional disclosures could be expected to have a substantial and adverse effect on the patient's condition; or
- (e) the patient or the patient's representative executed a written consent which sets forth the <u>nature</u> <u>and purpose of the intended health care</u> and which contains a declaration that the <u>patient accepts</u> <u>the risk of substantial and serious harm</u>, if any, in hopes of obtaining desired beneficial results of health care and which acknowledges that health care providers involved have explained the patient's condition and the proposed health care in a satisfactory manner and that <u>all questions asked about</u> <u>the health care and its attendant risks have been answered in a manner satisfactory to the patient</u> or the patient's representative.

If healthcare provider fails to comply with Specific Consent for Pelvic Region Exam then it is presumed that he/she lacked informed consent

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■ U.C.A. § 78B-3-406



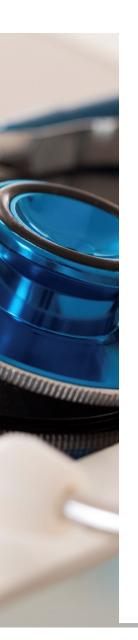
SPECIFIC CONSENT FOR PELVIC REGION EXAMS

For any procedure involving contact with the "pelvic region" an additional consent form must be completed prior to the patient receiving anesthesia or sedation. The "pelvic region" is defined broadly under Utah law as the patient's sexual organs, including but not limited to, lower abdomen, vagina, labia, penis, testes, scrotum, buttocks and anus.

- Requires specific content in form:
 - Heading at top of form in 18-point bold face type "CONSENT FOR EXAMINATION OF PELVIC REGION"
 - Specifies the nature and purpose of the patient examination;
 - Names health care providers to perform the patient examination;
 - States whether there may be a student or resident authorized to:
 - perform an additional patient examination; or
 - observe the patient examination, (in person or electronically); and
 - (vi) provides the patient with a series of check boxes that allow the patient to:
 - consent to the patient examination for diagnosis or treatment and an additional patient examination performed by a student or resident for an educational or training purpose;
 - consent to the patient examination only for diagnosis or treatment; or
 - refuse to consent to the patient examination.

• U.C.A. § 58-1-509; *Effective 5/14/2019*

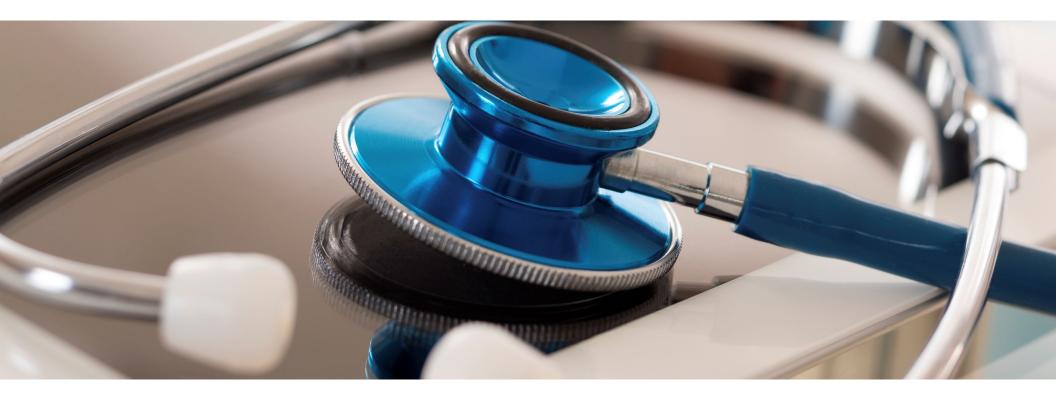




CORPORATE PRACTICE OF MEDICINE

- Utah does not have a corporate practice of medicine statute.
 - Utah statutes also allow licensed physicians, dentists, osteopathic physicians and chiropractors to form professional corporations for the purpose of providing professional services.
 - A physician may be employed by a person or corporation so long as that individual or entity does not interfere with the physician's practice of medicine.





MANDATORY REPORTING OF ADVERSE ACTION UNDER STATE LAW









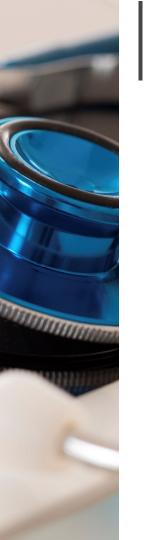
A health care facility must report any of the following events to DOPL within 60 days after the event occurs regarding a licensed health care provider:

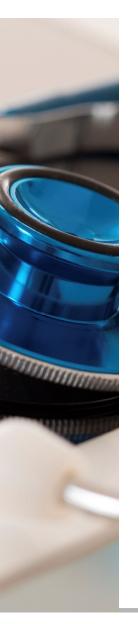
- •terminating employment of an employee for cause related to the employee's practice as a licensed health care provider;
- terminating or restricting privileges for cause;
- •terminating, suspending, or restricting membership or privileges for acts of unprofessional, unlawful, incompetent, or negligent conduct related to practice as a licensed health care provider;
- •subjecting a licensed health care provider to disciplinary action for a period of more than 30 days;
- •a finding that a licensed health care provider has violated professional standards or ethics;
- •a finding of incompetence in practice as a licensed health care provider;
- •a finding of acts of moral turpitude by a licensed health care provider; or
- •a finding that a licensed health care provider is engaged in abuse of alcohol or drugs. UCA § 58-13-5

"Health care facility" means general acute hospitals, specialty hospitals, home health agencies, hospices, nursing care facilities, residential-assisted living facilities, birthing centers, ambulatory surgical facilities, small health care facilities, abortion clinics, facilities owned or operated by health maintenance organizations, end stage renal disease facilities, and any other health care facility which the committee designates by rule.

"Licensed health care provider" means any provider who is licensed by DOPL (e.g. physician, PA, RN, LPN, CNM, clinical laboratory technologist, pharmacist, physical therapist, physical therapist assistant, respiratory therapist, podiatric physician, psychologist, audiologist, speechlanguage pathologist, clinical social worker, athletic trainer, etc.)







MANDATORY

ENFORCEMENT

REPORTING TO LAW

UNDER UTAH LAW

Reporting to Law Enforcement

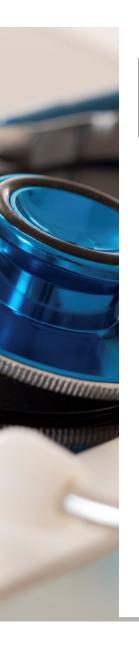
UCA § 76-10-2204

- Utah law now holds that an individual is guilty of a class B misdemeanor if they: (i) know that a Practitioner is diverting 500 or more morphine milligram equivalents* to another person** for an unlawful purpose; and (ii) fail to report to law enforcement.
- The bill defines "Practitioner" as an individual who is either (i) allowed to "administer, dispense, distribute, or prescribe a drug in the course of professional practice;" or (ii) who is employed by such an individual. Thus, the law broadly applies to those licensees involved in providing medications to patients in any manner (e.g., nurses, physicians, nurse practitioners, physician assistants, and pharmacists) as well as those employed by such individuals.

NOTE: This law does not apply if the individual is precluded from reporting under HIPAA or 42 CFR Part 2 (records of an alcohol or drug abuse treatment center).

- *calculated in accordance with guidelines developed by the Centers for Disease Control and Prevention (CDC).
- **this is a fairly new law, which has yet to be interpreted. Most drug diversion in hospitals is due to the individual having an addiction issue, and thus, they normally aren't diverting to "another" but keeping it for themselves.



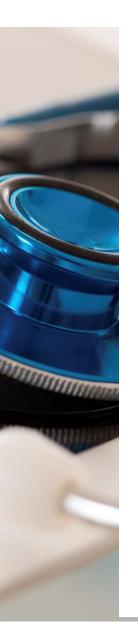


NPDB Reports

- Don't forget NPDB Reporting.
 - The National Practitioner Data Bank (NPDB) is an information clearinghouse created by Congress.
 - Goals are to improve health care quality, protect the public, and reduce health care fraud and abuse.
 - NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to eligible entities to facilitate comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers.

MANDATORY REPORTING TO NPDB UNDER FEDERAL LAW



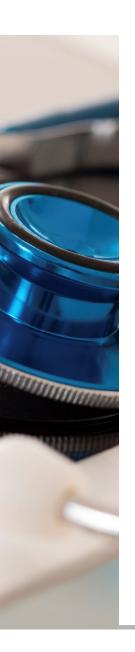


MANDATORY REPORTING TO NPDB UNDER FEDERAL LAW

NPDB Reports

- Certain entities are required to file a report with the NPDB when a specified event occurs related to any health care provider licensed by DOPL* and providing care within their facility.
- The NPDB Guidebook is a great resource.
 https://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp
 - Entities have <u>30 days</u> from when the event occurs, to report (but if miss deadline, doesn't negate your obligation to report, even if late).
 - There are many reasons that trigger a report, and it is often a very fact-specific analysis to determine if a NPDB is required. When it isn't clear-cut, always contact legal counsel.
- *ANY health care provider who is licensed by DOPL (e.g. physician, PA, RN, LPN, CNM, clinical laboratory technologist, pharmacist, physical therapist, physical therapist assistant, respiratory therapist, podiatric physician, psychologist, audiologist, speech-language pathologist, clinical social worker, athletic trainer, etc.)



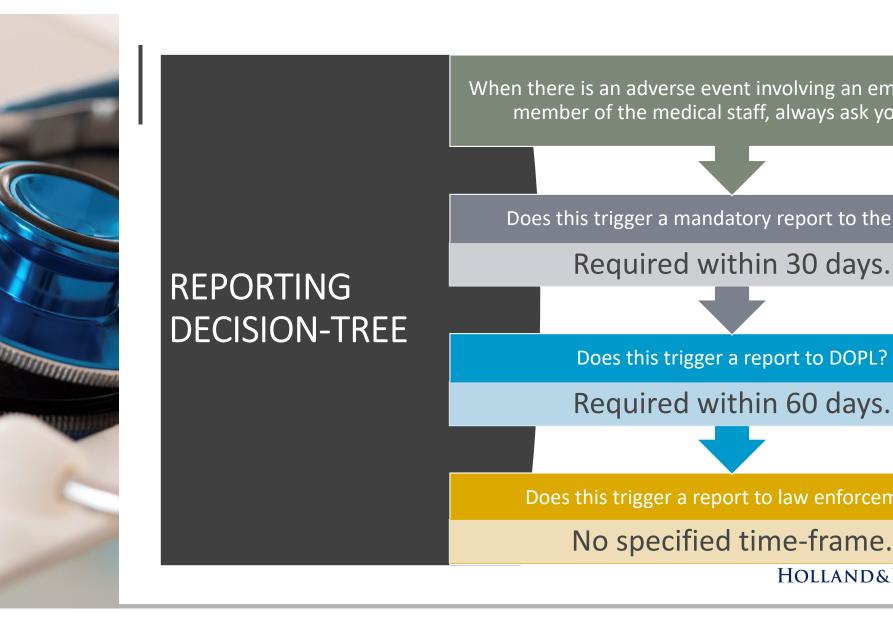


NPDB Reports

MANDATORY REPORTING TO NPDB UNDER FEDERAL LAW

- SANCTIONS FOR FAILING TO REPORT:
 - Loss of immunity protections for 3
 years (immunity under Title IV for
 professional review actions it takes
 against physicians and dentists.)
 - HHS may instigate an investigation.





When there is an adverse event involving an employee or a member of the medical staff, always ask yourself:

Does this trigger a mandatory report to the NPDB?

Required within 30 days.

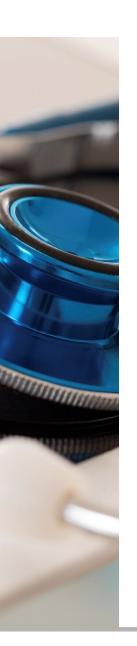
Does this trigger a report to DOPL?

Does this trigger a report to law enforcement?

No specified time-frame.

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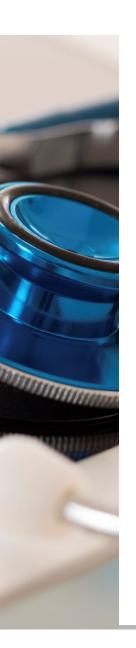




MEDICAL DECISION-MAKING OF INCAPACITATED ADULTS UNDER UTAH LAW

- Healthcare providers are generally required to have an adult patient's consent before they can administer any type of medical care.
 - An adult is presumed to have the capacity to make healthcare decisions ("Capacity") when they can:
 - (i) understand the nature, extent, or probable consequences of health status and healthcare alternatives;
 - (ii) make a rational evaluation of the burdens, risks, benefits, and alternatives of accepting or rejecting healthcare; and
 - (iii) communicate a decision.





MEDICAL DECISION-MAKING OF INCAPACITATED ADULTS UNDER UTAH LAW (CONT.)

- To overcome the presumption that a particular patient has Capacity, a physician, APRN, or physician assistant who has personally examined the adult patient must:
 - Find that the patient lacks Capacity;
 - Record the finding in the patient's medical chart and indicate whether the patient is likely to regain Capacity; and
 - Make a reasonable effort to communicate the determination to the patient, other healthcare providers, or healthcare facilities that the medical provider would routinely inform of such a finding, and any known surrogate decision maker (e.g., an appointed agent, guardian or a Default Surrogate Decision-Maker).

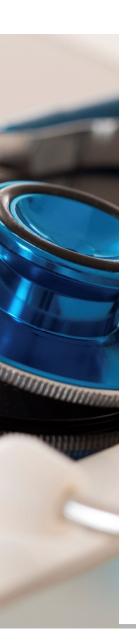




MEDICAL DECISION-MAKING OF INCAPACITATED ADULTS UNDER UTAH LAW (CONT.)

- When a patient lacks Capacity, a surrogate decision-maker must make decisions on the patient's behalf. This could be:
 - A **legal agent** formerly designated by the patient.
 - A court-appointed **legal guardian**. (An agent has priority over a legal guardian.)
 - Absent an agent or legal guardian, Utah law designates who can act as a "Default Surrogate Decision-Maker."
- Default Surrogate Decision-Maker: The following family members (if they are over 18 years of age, have Capacity themselves, are available, and have not been disqualified by the Incapacitated Patient or a court) can act as a Surrogate Decision-Maker:
 - The patient's spouse, unless the patient is divorced or legally separated;
 - a child;
 - a parent;
 - a sibling;
 - a grandchild; or
 - a grandparent
- What if none of the above?

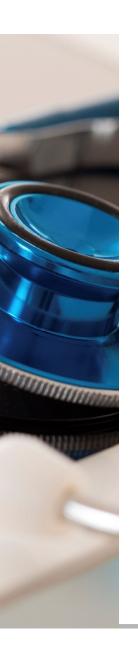




MINORS' ABILITY TO CONSENT TO MEDICAL TREATMENT UNDER UTAH LAW

- For purposes of consenting to their own general medical care, the following minors are treated as adults:
 - Legally emancipated minors;
 - Those in active military service;
 - Unaccompanied homeless minors 15 years of age or older; and
 - Minors who are lawfully married.
- Additionally, a parent or legal guardian can permit their child to consent to their own care by executing a written authorization allowing the minor to (1) have a confidential relationship with the provider and (2) consent to their own treatment

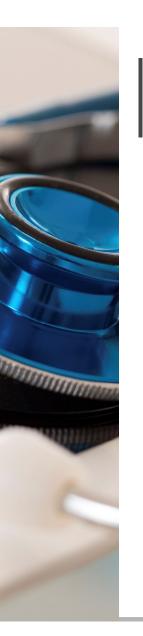




MINORS' ABILITY TO CONSENT TO MEDICAL TREATMENT UNDER UTAH LAW (CONT.)

- Additionally, a handful of Utah statutes provide minors with authority to consent to their own care for specific types of medical treatment:
 - Any minor who "is or professes to be afflicted with a sexually transmitted disease" can consent to examination and treatment for the STD.
 - Any minor female who is pregnant can consent to medical services related to her pregnancy or childbirth.
 - Any minor who is or has been married or judicially emancipated can consent to vaccinations for epidemic infections and communicable diseases, and for examinations and vaccinations required to attend school.
 - Any minor parent who has custody of a minor child or any minor who is pregnant may consent to vaccinations for epidemic infections and communicable diseases; for examinations and vaccinations required to attend school; and for the human papillomavirus (HPV) vaccine, provided the minor also represents to the provider that they are "abandoned," as that term is defined in U.C.A. § 76-5-109.





2021 UTAH LEGISLATIVE SESSION

- Healthcare-related bills
 - 33 (pending or already passed)
 - 8 more expected bills
 - 2 Joint Resolutions

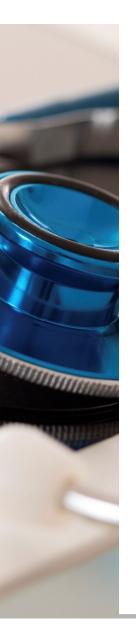




TOP AREAS FOR 2021 LEGISLATION

- Mental Health 5
- Pharmacy Regulations 5
- Vaccination/Immunization 4
- Direction to UDOH to seek additional federal funding for Medicaid programs – 4
- Creation of new Government Councils or Task Forces 3
- Medical Cannabis 3
- Telehealth 2





HEALTH CARE BILLS

1.	HB0036	Telehealth Mental Health Program	Ward, R.
2.	HB0085	Controlled Substance Database Access Amendments	Hall, C.
3.	<u>HB0110</u>	Health Care Payment Amendments	Winder, M.
4.	HB0117S04	Vaccine Reporting Requirements	Ward, R.
5.	<u>HB0149</u>	Health Care Amendments	Ward, R.
6.	HB0178S01	Pharmacy Practice Modifications	Thurston, N.
7.	<u>HB0210</u>	Qualifying Conditions for Medical Cannabis	Bennion, G.
8.	HB0226	Long-term Care Patient and Consumer Rights Protection	Ballard, M.G.
9.	HB0233	Education Immunization Modifications	Strong, M.A.
10.	HB0259	Lead Exposure Education and Testing Amendments	Barlow, S.
11.	<u>HB0265</u>	Pharmacy Software Amendments	Lesser, R.
12.	<u>HB0288</u>	Education and Mental Health Coordinating Council	Peterson, V.
13.	<u>HB0308</u>	Covid-19 Vaccine Amendments	Spendlove, R.
14.	<u>HB0350</u>	Mental Health Records Confidentiality Amendments	Eliason, S.
15.	HB0363	Medicaid Waiver for New Mothers	Ward, R.
16.	HB0384	Health Data Privacy Act	Strong, M.A.
17.	HCR017	Concurrent Resolution Recognizing August 31 as Overdose Awareness Day	Eliason, S.
18.	HJR013	Joint Resolution Declaring Racism a Moral and Public Health Crisis	Hollins, S.

19.	SB0041S01	Mental Health Access Amendments	Escamilla, L.
20.	SB0047	Mental Health Crisis Intervention Council	Thatcher, D.
21.	<u>SB0081</u>	Medical Cannabis Electronic Verification System Deadline Amendments	Vickers, E.
22.	<u>SB0083S03</u>	POLST Order Amendments	Iwamoto, J.
23.	SB0128S01	Family Planning Services Amendments	Kitchen, D.
24.	SB0140	Pharmacy Benefit Amendments	Vickers, E.
25.	SB0155S01	988 Mental Health Crisis Assistance	Thatcher, D.
26.	SB0173	Medical Records Amendments	Mayne, K.
27.	SB0177	Pharmacy Practice Revisions	Vickers, E.
28.	SB0192S01	Medical Cannabis Act Amendments	Vickers, E.
29.	SB0208	Employee Medical Procedure Protection Act	Kennedy, M.
30.	HB0034	Medical Respite Care Pilot Program	Dunnigan, J.
31.	HB0164	Abortion Requirements Amendments	Ward, R.
32.	HB0202	Health Care Consumer Protection Act	Thurston, N.
33.	HB0253	Abortion Amendments	Christiansen, S.
34.	HB0333	Medicaid Amendments	Eliason, S.
35.	SB0158	Children's Health Coverage Amendments	Escamilla, L.





78B-4-517: IMMUNITY RELATED TO COVID-19

- "A person is immune from civil liability for damages or an injury resulting from exposure of an individual to COVID-19 on the premises owned or operated by the person, or during an activity managed by the person."
- "Does not apply to:
 - a) willful misconduct;
 - b) reckless infliction of harm; or
 - c) intentional infliction of harm."





26-3-2.6: VACCINE REPORTING REQUIREMENT

"USIIS" means the Utah Statewide Immunization Information System

- 2) A vaccine provider shall:
 - a) regularly provide vaccine information to USIIS; and
 - b) provide information regarding the department's online opt out form described in Subsection (3)(a) to an individual's parent or guardian.
- 3) The department:
 - a) shall maintain a link to an online opt out form on the homepage of USIIS's website that can be submitted electronically;
 - b) may not require notarization;
 - c) shall delete all vaccine information regarding the individual who submitted the form; and
 - d) after receiving an opt out form, may not maintain or share any future vaccine information regarding the individual who submitted the opt out form.





75-2a-103 POLST: PROVIDER ORDER FOR LIFE SUSTAINING TREATMENT

- i. the provisions of Title 46, Chapter 4, Uniform Electronic Transactions Act, apply to any signature required on the POLST order;
- ii. a verbal confirmation satisfies the requirement for a signature from an individual under Subsection (3)(b)(ii) or (iii), if:
 - A. requiring the individual to sign the POLST order in person or electronically would require significant difficulty or expense; and
 - B. a licensed health care provider witnesses the verbal confirmation and signs the POLST order attesting that the health care provider witnessed the verbal confirmation.





78B-5-618 PATIENT ACCESS TO MEDICAL RECORDS

- Explicitly requires providers to deliver medical records to a patient or requesting party in the digital or electronic medium used by the provider if an electronic copy is requested.
- Provider may only charge \$25 for the electronic record regardless of how many pages.
- Other restrictions on responding to requests from low income or indigent patients.





13-58-201 MISREPRESENTATION OF HEALTH INSURANCE COVERAGE

- 1) A health care provider or a health care provider's representative may not represent to an enrollee that the health care provider is a contracted provider under the enrollee's health benefit plan if the health care provider is not a contracted provider under the enrollee's health benefit plan.
- 2) A knowing or intentional violation of Subsection (1) is a deceptive act or practice under Section <u>13-11-4</u>.



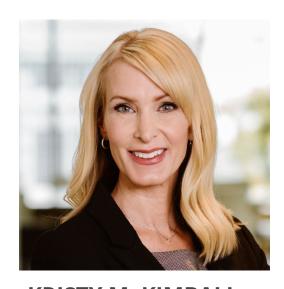
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