CITIZENS' COUNCIL FOR HEALTH FREEDOM
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MODEL STATE LEGISLATION

Government-Established ACA Health Insurance Exchanges Prohibited

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Exchange Prohibited.** No American Health Benefit Exchange within the meaning of that term in the federal Affordable Care Act (Public Laws 111-148 and 111-152) shall be created, operate, or exist in this state.

Subd. 2. **Funding Prohibited.** No funding, whether federal, state, or private shall be used by the State of [insert State] to create, operate or maintain an American Health Benefit Exchange within the meaning of that term in the federal Affordable Care Act (Public Laws 111-148 and 111-152).

Subd. 3. **Data Privacy.** No person, employer, company, government agency, or organization may transfer or share private data, public data, non-public data, confidential data, medical records data, insurance claims data, identifiable data, individually-identifiable health information, tax data or any other data on persons or employers with an American Health Benefit Exchange within the meaning of that term in the federal Affordable Care Act (Public Laws 111-148 and 111-152) or with any entity under contract with or connected with an American Health Benefit Exchange.

Subd. 4. **Citation.** This section shall be known as and may be cited as the "[insert state] Healthcare Marketplace Preservation Act."

EFFECTIVE DATE. This section is effective the day following final enactment.

CITIZENS' COUNCIL FOR HEALTH FREEDOM
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MODEL STATE LEGISLATION

Direct Primary Care (DPC) Agreements

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Definition.** For purposes of this section, the following term has the meaning given.

(a) "direct primary care agreement" means a written agreement that:

(1) is between a patient or the patient's legal representative and a primary care provider;

(2) allows either party to terminate the agreement in writing, without penalty or payment of a termination fee, at any time or after notice of not more than 60 days as specified in the agreement;

(3) describes the health care services to be provided in exchange for the patient's payment of a periodic fee to the primary care provider;

(4) specifies the periodic fee required and any additional fees that may be charged;

(5) permits the periodic fee and any additional fees to be paid by a third party;

(6) prohibits the primary care provider from charging or receiving additional compensation for health care services included in the periodic fee; and

(7) conspicuously and prominently states that the direct primary care agreement does not constitute health insurance and does not satisfy the individual health insurance mandate that may be required by federal law.

Subd. 2. **Not regulated as insurance.** A direct primary care agreement does not constitute a health plan, a policy or certificate of accident and sickness insurance, a subscriber contract or service plan, a health maintenance contract or certificate, a health benefit certificate, or health coverage. Direct primary care agreements and primary care providers who are a party to a direct primary care agreement are, with respect to those agreements, exempt from all rules or laws regulating a health plan, a policy or certificate of accident and sickness insurance, a subscriber contract or service plan, a health maintenance contract or certificate, a health benefit certificate, or health coverage.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Non-Coercive Patient Consent Required

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Patient consent to release of records.** (a) A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without:

(1) a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release;

(2) specific authorization in law; or

(3) a representation from a provider that holds a signed and dated consent from the patient authorizing the release.

(b) A provider or health care facility shall not withhold services or treatment or refuse to provide services or treatment to a patient solely because the patient or the patient's legally authorized representative refuses to authorize or alters in any way the provider's or health care facility's consent form.

EFFECTIVE DATE. This section is effective the day following final enactment.

CITIZENS' COUNCIL FOR HEALTH FREEDOM
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MODEL STATE LEGISLATION

Prescription Monitoring Program: Audits, Accountability, and Transparency

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Random audits.** The board shall conduct random audits, on at least a quarterly basis, of electronic access by permissible users, to ensure compliance with permissible use as defined in this section. A permissible user whose account has been selected for a random audit shall respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being conducted. Failure to respond may result in deactivation of access to the electronic system and referral to the appropriate health licensing board, or the commissioner of human services, for further action. The board shall report the results of random audits to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance and government data practices.

Subd. 2. **Appropriate access by delegates.** A permissible user who has delegated the task of accessing the data to an agent or employee shall audit the use of the electronic system by delegated agents or employees on at least a quarterly basis to ensure compliance with permissible use as defined in this section. When a delegated agent or employee has been identified as inappropriately accessing data, the permissible user must immediately remove access for that individual and notify the board within seven days. The board shall notify all permissible users associated with the delegated agent or employee of the alleged violation.

Subd. 3. **Removal of access upon termination of employment**. A permissible user who delegates access to the data to an agent or employee shall terminate that individual's access to the data within three business days of the agent or employee leaving employment with the permissible user. The board may conduct random audits to determine compliance with this requirement.

Subd. 4. **Patient information on record access.** A patient who has been prescribed a controlled substance may access the prescription monitoring program database in order to obtain information on access by permissible users to the patient's data record, including the name and organizational affiliation of the permissible user and the date of access. The board must release a minimum of 12 months of data, or the entire time period stored in the database, whichever is greater. In order to obtain this information, the patient must complete, notarize, and submit a request form developed by the board. The board shall make this form available to the public on the board's website.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Universal Patient Data Consent Form

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Release or disclosure of health records.**
Health records may only be disclosed as specified in this section.

Subd. 2. **Patient consent to release of records.**
A provider, or a person who receives health records from a provider, may not release a patient's health records without:

(1) a signed and dated consent form as provided in this section from the patient or the patient's legally authorized representative authorizing the release;

(2) specific authorization in law; or

(3) a representation from a provider that holds a signed and dated consent form as provided in this section, from the patient authorizing the release.

Subd. 3. **Duration of consent.**
A patient's consent is valid for one year or for a period specified in the consent. A provider must provide the duration options listed in the "Universal Patient Data Consent Form" and must not condition treatment upon patient agreement to a specific duration of consent.

Subd. 4. **Required consent form for patient data disclosure.**
A provider must use the following form to obtain patient consent to disclose, release, or use health care records as provided in this section:

Patient Data Consent Form.

Patient's Notice of Data Rights:

(a) Your treatment is not conditioned upon granting or refusing consent below for use, sharing, or release of health information.
(b) State law guarantees certain patient privacy and consent rights under *[STATUTORY REFERENCE]*.
(c) You may revoke or modify your consent to share health records in writing at any time, except that a revocation or modification has no effect on any health records released prior to the date of revocation or modification.

Patient's Medical Consent.

Please read the following carefully and check either "yes" or "no" to each item below.

..... Yes ..... No **Obtaining Medical Records:** I consent to [the above health care provider] communicating with my current and future health care providers to obtain any and all previous medical records necessary for my treatment as defined under the federal Health Insurance Portability and Accountability Act (HIPAA). See attached definition.

..... Yes ..... No **Releasing Information for Treatment:** I consent to [the above health care provider] sharing information from my medical record with current and future health care providers involved in my treatment as defined under HIPAA. See attached definition.

..... Yes ..... No **Releasing Information for Payment:** I consent to [the above health care provider] sharing my information for the purpose of billing and payment as defined under HIPAA. See attached definition. This sharing of information includes insurers or third parties responsible for payment of my medical bills.

..... Yes ..... No **Releasing Information for Health Care Operations:** I consent to [the above health care provider] sharing my information for health care operations as defined
under HIPAA. See attached definition. This includes information sharing for activities unrelated to treatment for my medical condition.

..... Yes ..... No **Releasing Information for Medical or Scientific Research:** I consent to [the above health care provider] releasing my medical information for medical or scientific
research.

..... Yes ..... No **Disclosure of Presence:** I authorize [the above health care provider] to disclose my presence to any person who inquires about me using my full name. This disclosure is limited to acknowledging my presence and a one-word description of my condition: critical, serious, fair, or good.

Health Information Exchange.

..... Yes ..... No **Access:** I authorize [the above health care provider] to use a health information exchange (HIE), record locator service (RLS), patient information service (PIS),
clinical data repository (CDR), or master patient index (MPI) for the purpose of accessing my patient identifying information and information about the location of my medical records.
See attached definitions.

..... Yes ..... No **Release:** I authorize [the above health care provider] to release my patient identifying information and information about where my medical records are located
to an HIE, RLS, PIS, CDR, or MPI. See attached definitions.

Consent Duration.

I understand that under state law, my consent to release my health records is limited by my determination below, unless specifically authorized in state law for a differing length of time.

For all other purposes described above, I authorize my consent to be valid for the following length of time:
..... One year
..... Three years
..... Indefinitely (unless I revoke or modify)

PATIENT SIGNATURE
Patient Name: ..... Date of Birth: ...../...../.....
If patient is not signing, name and relationship to patient: .....
Signature: ..... Date: ...../...../.....

Federal HIPAA Definitions (Code of Federal Regulations, title 45, section 164.501)
(a) "Health care operations" means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) conducting quality assessment and improvement activities, including outcomes, evaluation, and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from the activities; patient safety activities, as defined in Code of Federal Regulations, title 42, section 3.20; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;
(2) reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of nonhealth care professionals, accreditation, certification, licensing, or credentialing activities;
(3) except as prohibited under Code of Federal Regulations, title 45, section 164.502(a)(5)(i), underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care, including stop-loss insurance and excess of loss insurance, provided that the requirements of Code of Federal Regulations, title 45, section 164.514(g), are met, if applicable;
(4) conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
(5) business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development, or improvement of methods of payment or coverage policies; and
(6) business management and general administrative activities of the entity, including, but not limited to:
(i) management activities relating to implementation of and compliance with the requirements of this subchapter;
(ii) customer service, including the provision of data analyses for policyholders, plan sponsors, or other customers, provided that protected health information is not disclosed to the policyholder, plan sponsor, or customer;
(iii) resolution of internal grievances;

(iv) the sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following the activity will become a covered entity and due diligence related to the activity; and

(v) consistent with the applicable requirements of Code of Federal Regulations, title 45, section 164.514, creating de-identified health information or a limited data set, and fund-raising for the benefit of the covered entity.

(b) "Payment" means:

(1) the activities undertaken by:

(i) a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan, except as prohibited under Code of Federal Regulations, title 45, section 164.502(a)(5)(i); or

(ii) a health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) the activities in clause (1) relate to the individual to whom health care is provided and include, but are not limited to:

(i) determinations of eligibility or coverage (including coordination of benefits or the determination of cost-sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) risk-adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) utilization review activities, including precertification and preauthorization of services,
concurrent and retrospective review of services; and

(vi) disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social Security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider or health plan.

(c) "Treatment" means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

[STATE] **Definitions** (*[STATUTORY REFERENCE]*)**.**

(a) "Clinical data repository" means a real time database that consolidates data from a variety of clinical sources to present a unified view of a single patient and is used by a state-certified health information exchange service provider to enable health information exchange among health care providers that are not related health care entities as defined in *[STATUTORY REFERENCE]*. This does not include clinical data that

are submitted for public health purposes required or permitted by law, including any rules adopted by the commissioner.

(b) "Health care provider" means a person, hospital, or health care facility, organization, or corporation that is licensed, certified, or otherwise authorized by the laws of this state to provide health care.

(c) "Health information exchange" means a legal arrangement between health care providers and group purchasers to enable and oversee the business and legal issues involved in the electronic exchange of health records between the entities for the delivery of patient care.

(d) "Master patient index" means an electronic database that holds unique identifiers of patients registered at a care facility and is used by a state-certified health information exchange service provider to enable health information exchange among health care providers that are not related health care entities as defined in *[STATUTORY REFERENCE]*. This does not include data that are submitted for public health purposes required or permitted by law, including any rules adopted by a state public health entity.

(e) "Patient information service" means a service providing the following query options: a record locator service or a master patient index or clinical repository.

(f) "Record locator service" means an electronic index of patient-identifying information that directs providers in a health information exchange to the location of patient health records held by providers and group purchasers.

Subd. 5. **Failure to check "Yes" or "No."** A failure to check "Yes" or "No" on a form prepared pursuant to this section is presumed to be a "No" and a provider must not disclose or release any health record under the relevant paragraph.

Subd. 6. **Exceptions.** (a) This section does not apply to a release of or a request for psychotherapy notes as defined under Code of Federal Regulations, title 45, section 164.501, as amended. Pursuant to federal law, providers must use a separate consent form. (b) Patient records may not be shared with an insurance company if the patient pays out-of-pocket in full and requests nondisclosure, as required in Code of Federal Regulations, title 45, section 164.522(a)(1)(vi).

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Individual Rights in Declared Emergencies

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Refusal of treatment.** Notwithstanding laws, rules, or orders made or promulgated in response to a national security emergency or peacetime emergency, individuals have a fundamental right to refuse medical treatment, testing, physical or mental examination, vaccination, participation in experimental procedures and protocols, collection of specimens, and preventive treatment programs. An individual who has been directed to submit to medical procedures and protocols because the individual is infected with or reasonably believed to be infected with or exposed to a toxic agent that can be transferred to another individual or a communicable disease, and the agent or communicable disease is the basis for which the national security emergency or peacetime emergency was declared, and who refuses to submit to them may be ordered to be placed in isolation or quarantine according to parameters set forth in law.

Subd. 2. **Information given**. Before performing examinations, testing, treatment, or vaccination of an individual under subdivision 1, a health care provider shall notify the individual of the right to refuse the examination, testing, treatment, or vaccination, and the consequences, including isolation or quarantine, upon refusal.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

COVID-19 and Contact Tracing Bill of Rights

NOTE: *For the benefit of those who may use this model legislation, we have retained all the references to Minnesota statutes. This will allow legislators in others states to review the links to either adopt this language along with this model legislation or locate similar language or statutes in their own state.*

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given.

(a) "Commissioner" means the commissioner of health.

(b) "Contact tracing" means identifying individuals who may be at risk of contracting COVID-19 through contact, in a manner consistent with known or suspected modes of COVID-19 transmission, with an individual who has tested positive for COVID-19.

(c) "COVID-19 testing" means a diagnostic test used to detect the virus that causes COVID-19 in order to make a diagnosis of COVID-19.

(d) "Tested positive for COVID-19" means an individual who has received a positive diagnostic test for COVID-19 and is currently contagious.

Subd. 2. **Testing and contact tracing bill of rights.** (a) Notwithstanding any law to the contrary, the following requirements on behalf of individuals, patients, and residents must be met by any program established by the commissioner of health that involves COVID-19 testing or contact tracing:

(1) no testing on an individual shall be performed without the consent of the individual being tested;

(2) if an individual tests positive for COVID-19, the individual must be informed that the individual is not required to cooperate with contact tracing, and may refuse to provide requested contact information;

(3) if the commissioner of health or the commissioner's contracted vendor is conducting contact tracing, the commissioner or vendor must provide the individual with a Tennessen warning in accordance with Minnesota Statutes, section 13.04, subdivision 2; and

(4) results of any testing performed on an individual by a provider as defined under Minnesota Statutes, section 144.291, shall be considered a health record under Minnesota Statutes, section 144.292, and shall not be disclosed or released without consent from the individual in accordance with Minnesota Statutes, section 144.293, subdivision 2.

(b) Any contact tracing data collected by the commissioner of health or the commissioner's contracted vendor pursuant to a program that identifies an individual are classified as private data on individuals as defined in Minnesota Statutes, section 13.02, subdivision 12. Notwithstanding Minnesota Statutes, section 13.3805, paragraph (b),

clause (3), the commissioner shall establish procedures and safeguards to ensure that any data collected under a program including an individual's address of residence is not released by the commissioner or its contracted vendor in a form that identifies a specific individual unless the individual has provided consent for its release.

(c) Notwithstanding Minnesota Statutes, sections 144.419 to 144.4196, if an asymptomatic individual refuses to be tested for COVID-19 as part of a COVID-19 screening process, the commissioner of health shall not have the authority to pursue an ex parte order under Minnesota Statutes, section 144.4195, authorizing the isolation or quarantine of the individual.

EFFECTIVE DATE. This section is effective the day following final enactment.

NOTE: *For the benefit of those who may use this model legislation, we have retained all the references to Minnesota statutes. This will allow legislators in others states to review the links to either adopt this language along with this model legislation or locate similar language or statutes in their own state.*

MODEL STATE LEGISLATION

Universal Patient Data Consent Form

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Release or disclosure of health records.** Health records can be released or disclosed as specified in subdivisions 2 to 9.

Subd. 2. **Patient consent to release of records.** A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without:

(1) a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release;

(2) specific authorization in law; or

(3) a representation from a provider that holds a signed and dated consent from the patient authorizing the release.

Subd. 3. **Release from one provider to another.**
A patient's health record, including, but not limited to, laboratory reports, x-rays, prescriptions, and other technical information used in assessing the patient's condition, or the pertinent portion of the record relating to a specific condition, or a summary of the record, shall promptly be furnished to another provider upon the written request of the patient. The written request shall specify the name of the provider to whom the health record is to be furnished. The provider who furnishes the health record or summary may retain a copy of the materials furnished. The patient shall be responsible for the reasonable costs of furnishing the information.

Subd. 4. **Duration of consent.** Except as provided in this section, a consent is valid for one year or for a period specified in the consent or for a different period provided by law.

Subd. 5. **Exceptions to consent requirement.** (a) This section does not prohibit the release of health records:

(1) for a medical emergency when the provider is unable to obtain the patient's consent due to the patient's condition or the nature of the medical emergency;

(2) to other providers within related health care entities when necessary for the current treatment of the patient; or

(3) to a health care facility licensed by this chapter, chapter [if applicable], or to the same types of health care facilities licensed by this chapter and chapter [if applicable] that are licensed in another state when a patient:

(i) is returning to the health care facility and unable to provide consent; or

(ii) who resides in the health care facility, has services provided by an outside resource

under Code of Federal Regulations, title 42, section 483.75(h), and is unable to provide consent.

(b) A provider may release a deceased patient's health care records to another provider for the purposes of diagnosing or treating the deceased patient's surviving adult child.

Subd. 6. **Consent does not expire.** Notwithstanding subdivision 4, if a patient explicitly gives informed consent to the release of health records for the purposes and restrictions in clause (1), (2), or (3), the consent does not expire after one year for:

(1) the release of health records to a provider who is being advised or consulted with in connection with the releasing provider's current treatment of the patient;

(2) the release of health records to an accident and health insurer, health service plan corporation, health maintenance organization, or third-party administrator for purposes of payment of claims, fraud investigation, or quality of care review and studies, provided that:

(i) the use or release of the records complies with sections [state Insurance Fair Information Reporting Act, if applicable];

(ii) further use or release of the records in individually identifiable form to a person other than the patient without the patient's consent is prohibited; and

(iii) the recipient establishes adequate safeguards to protect the records from unauthorized disclosure, including a procedure for removal or destruction of information that identifies the patient; or

(3) the release of health records to a program in the welfare system, defined as "including the Department of Human Services, local social services agencies, county welfare agencies, county public health agencies, county veteran services agencies, county housing agencies, private licensing agencies, the public authority responsible for child support enforcement, human services boards, community mental health center boards, state hospitals, state nursing homes, the ombudsman for mental health and developmental disabilities, Native American tribes to the extent a tribe provides a service component of the welfare system, and persons, agencies, institutions, organizations, and other entities under contract to any of the above agencies to the extent specified in the contract" count to the extent necessary to coordinate services for the patient.

Subd. 7. **Record locator or patient information service.** (a) A provider or group purchaser may not release patient identifying information and information about the location of the patient's health records to a record locator or patient information service without consent from the patient. The Department of Health may not access the record locator or patient information service or receive data from the service. Only a provider may have access to patient identifying information in a record locator or patient information service. Except in the case of a medical emergency, a provider participating in a health information exchange using a record locator or patient information service does not have access to patient identifying information and information about the location of the patient's health records unless the patient specifically consents to the access. A consent does not expire but may be revoked by the patient at any time by providing written notice of the revocation to the provider.

(b) A health information exchange maintaining a record locator or patient information service must maintain an audit log of providers accessing information in the service that at least contains information on:

(1) the identity of the provider accessing the information;

(2) the identity of the patient whose information was accessed by the provider;

(3) the date the information was accessed; and

(4) the purpose given for the access.

(c) Upon request by a patient who is the subject of the data, a health information exchange maintaining a record locator or patient information service must make the audit log available.

(d) No group purchaser may in any way require a provider to participate in a record locator or patient information service as a condition of payment or participation.

(e) A provider or an entity operating a record locator or patient information service must provide a consent mechanism under which patients may elect to include their identifying information and information about the location of their health records in a record locator or patient information service. At a minimum, a consent form must include a description of the information that would be included in the service and a signature line solely for signifying the patient's consent to include their information in a record locator or patient information service. A provider participating in a health information exchange with a record locator or patient information service who receives a patient's request to include all of the patient's information in the record locator or patient information service, to have a specific provider contact excluded from the record locator or patient information service, or to opt out of the record locator or patient information service is responsible for including or removing that information accordingly.

Subd. 8. **Documentation of release.** (a) In cases where a provider releases health records without patient consent as authorized by law, the release must be documented in the patient's health record. In the case of a release under section [law enforcement agency statute], the documentation must include the date and circumstances under which the release was made, the person or agency to whom the release was made, and the records that were released.

(b) When a health record is released using a representation from a provider that holds a consent from the patient, the releasing provider shall document:

(1) the provider requesting the health records;

(2) the identity of the patient;

(3) the health records requested; and

(4) the date the health records were requested.

Subd. 9. **Warranties regarding consents, requests, and disclosures.** (a) When requesting health records using consent, a person warrants that the consent:

(1) contains no information known to the person to be false; and

(2) accurately states the patient's desire to have health records disclosed or that there is specific authorization in law.

(b) When requesting health records using consent, or a representation of holding a consent, a provider warrants that the request:

(1) contains no information known to the provider to be false;

(2) accurately states the patient's desire to have health records disclosed or that there is specific authorization in law; and

(3) does not exceed any limits imposed by the patient in the consent.

(c) When disclosing health records, a person releasing health records warrants that the person:

(1) has complied with the requirements of this section regarding disclosure of health records;

(2) knows of no information related to the request that is false; and (3) has complied with the limits set by the patient in the consent.

(d) If a person falsely warrants any of the provisions in (a) through (c), the person is guilty of a misdemeanor.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Prohibiting Tax Penalty for Failure to Purchase Government-Approved Health Insurance

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Definitions.** For purposes of this section, the following terms have the meanings given.

(a) "Health care service" means any service, treatment, or provision of a product for the care of a physical or mental disease, illness, injury, defect, or condition, or to otherwise maintain or improve physical or mental health, subject to all laws and rules regulating health service providers and products within the state of [insert State].

(b) "Mode of securing" means to purchase directly or on credit or by trade, or to contract for third-party payment by insurance or other legal means as authorized by the state of, or to apply for or accept employer-sponsored or government-sponsored health care benefits under such conditions as may legally be required as a condition of such benefits, or any combination of the same.

(c) "Penalty" means any civil or criminal fine, tax, salary or wage withholding, surcharge, fee, or any other imposed consequence established by law or rule of a government or its subdivision or agency that is used to punish or discourage the exercise of rights protected under this section.

Subd. 2. **Statement of public policy.** (a) The power to require or regulate a person's or an employer's choice in the mode of securing health care services, or to impose a penalty related to that choice, is not found in the Constitution of the United States of America, and is therefore a power reserved to the people pursuant to the Ninth Amendment, and to the several states pursuant to the Tenth Amendment. The state of [insert State] hereby exercises its sovereign power to declare the public policy of the state of [insert State] regarding the right of all persons and all employers residing in the state in choosing the mode of securing health care services, which is consistent with the constitutionally recognized inalienable right of liberty, whereas every person and every employer within the state of [insert State] is and shall be free to choose or decline to choose any mode of securing health care services without penalty or threat of penalty.

(b) The policy stated under this section shall not be applied to impair any right of contract related to the provision of health care services to any person or group.

Subd. 3. **Enforcement.** The professional license of any officer of a court sitting within the state of [insert State], who acts to impose, collect, enforce, or effectuate any penalty in the state of [insert State] that violates the public policy set forth in this section, shall be suspended for a period of one year.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Three Bills to Protect Newborn Genetic Privacy

Consent for Newborn Genetic Screening:

Subdivision 1. **Definition.** For purposes of this section, "newborn screening" means is a public health program of screening in infants shortly after birth for conditions that are treatable, but not clinically evident in the newborn period.

Subd. 2. **Parental Consent Requirements.** Parents are permitted to refuse newborn genetic screening or to choose private newborn genetic screening. Notwithstanding any other state or federal law or regulation, prior to conducting newborn genetic screening, a health care facility or health care provider must receive the express, separate, written, voluntary, informed consent of the parents or guardian of a newborn child. A general consent permitting treatment signed by the parents or guardian at admission to a facility does not fulfill this requirement. This consent requirement cannot be waived for any reason.

Subd. 3. **Limitation on Blood Spot Collection**. The Commissioner of Health shall limit the number of bloodspots and the quantity of blood drawn from a newborn for newborn genetic screening to the amount needed to conduct newborn screening on the child. Additional blood for prospective purposes shall not be collected without the express, separate, written, voluntary, informed consent of the parent or guardian of the newborn child.

EFFECTIVE DATE. This section is effective the day following final enactment.

Consent for Retention, Sharing and Use of Newborn Dried Blood Spots:

Subd. 1. **Definitions.** For purposes of this section, "newborn dried blood spots" means the blood that is collected unto a special filter paper y a health care worker from the heel of a newborn at home or at a health care facility and submitted for newborn genetic screening.

Subd. 2. **Parental Consent Requirements.** Notwithstanding any other state or federal law or regulation, the newborn bloodspots taken for newborn genetic screening may not be retained by the Commissioner of Health or any other facility longer than three weeks after the test results have been received and must be destroyed unless express, separate, written, voluntary, informed consent is received. The consent form must use easy to understand language that does not threaten to penalize the parents or claim that the child will be hurt in any way for refusing to consent to the retention of the newborn bloodspots. If parents consent to the retention of newborn bloodspots, the bloodspots may not be disseminated,

shared, analyzed, or used for test development, public health studies, newborn studies, genetic or medical research, forensics, law enforcement or any other purpose without the express, separate, written, voluntary, informed consent of the parent or guardian, or the express, separate, written, voluntary, informed consent of the adult who was a minor at the time the newborn dried bloodspots were retained. A general consent permitting treatment signed by the parents or guardian for a home birth or at admission to a birthing or other health care facility does not fulfill this requirement. These consent requirements cannot be waived for any reason.

EFFECTIVE DATE. This section is effective the day following final enactment.

Consent for Retention, Sharing and Use of Newborn Genetic Screening Test Results:

Subdivision 1. **Parental Consent Requirements.** Notwithstanding any other state or federal law or regulation, the test results of newborn genetic screening may not be retained by the Commissioner of Health or any other facility longer than three weeks from the testing, and must be destroyed unless express, separate, written, voluntary, informed consent is received. The consent form must use easy to understand language that does not threaten to penalize the parents or claim that the child will be hurt in any way for refusing to consent to the retention of newborn genetic screening test results. If parents consent to the retention of newborn screening test results, the test results may not be disseminated, shared, analyzed, or used for test development, public health studies, newborn studies, genetic or medical research, forensics, law enforcement or any other purpose without the express, separate, written, voluntary, informed consent of the parent or guardian, or the express, separate, written, voluntary, informed consent of the adult who was a minor at the time the newborn screening test results were retained. A general consent permitting treatment signed by the parents or guardian for a home birth or at admission to a birthing or other health care facility does not fulfill this requirement. These consent requirements cannot be waived for any reason.

EFFECTIVE DATE. This section is effective the day following final enactment.

The Newborn Screening Saves Lives Act of 2014 that Congress passed and was signed into law in December 2014 and sunset January 19, 2017, the last day of the Obama presidency:

PUBLIC LAW 113–240—DEC. 18, 2014 128 STAT. 2857

SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH. 42 USC 289 note.

(a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

(b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act. Applicability.

(c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations. Deadlines.

Approved December 18, 2014.

No consent = unconstitutional (Michigan lawsuit):

https://pacer.courtdrive.com/ecf.mied.uscourts.gov/doc1/097112056867/caseid=327162__de_seq_num=627__magic_num=77058934

MODEL STATE LEGISLATION

Ivermectin Available to Patients

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Ivermectin Available Over the Counter.** Pharmacies that sell products for the purpose of treating or relieving pain and illness caused for influenza and other viruses are required to make ivermectin available to customers in over-the-counter purchases for human consumption. Ivermectin must be available over the counter in quantities and doses sufficient for prophylaxis and treatment.

Subd. 2. **No prohibitions on prescribing or dispensing ivermectin.** No physician or other health care professional may be prohibited from prescribing ivermectin. Pharmacists and other workers in the pharmacy may not refuse to dispense ivermectin prescriptions ordered by a physician or clinician with prescribing privileges.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Right to Prescribe and Dispense Prescription Drugs for Off-Label Purposes without Retribution

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Definitions.** For purposes of this section, the following terms have the meanings given.

(a) "Disciplinary action" means any action taken by a health-related licensing board against a licensee, including but not limited to revocation, limitation, suspension, or denial of a license or any other disciplinary action taken by a health-related licensing board against the licensee for unprofessional conduct.

(b) "Health-related licensing board" has the meaning given in [insert statute].

(c) "Off-label use" means prescribing a prescription drug for treatments other than those stated in the labeling approved by the United States Food and Drug Administration.

(d) "Pharmacist" means any person licensed by the Board of Pharmacy under [insert statute].

(e) "Prescriber" means a physician licensed under [insert statute], a physician assistant licensed under [insert statute], a dentist licensed under [insert statute], or an advanced practice registered nurse licensed under [insert statute].

Subd. 2. **General provision.**

(a) Notwithstanding any law to the contrary, a prescriber is authorized to prescribe a U.S. Food and Drug Administration (FDA) approved prescription drug for an off-label use, and a pharmacist is authorized to dispense the prescribed drug for an off-label use pursuant to a valid prescription order.

(b) This subdivision does not apply to a controlled substance.

Subd. 3. **Professional conduct.**

(a) Notwithstanding any law to the contrary, a prescriber or pharmacist shall not face retribution or disciplinary action hospital privileges or credentials solely on the basis that a prescriber prescribed an FDA approved prescription drug for off-label use or a pharmacist dispensed the prescription drug prescribed for off-label use pursuant to a valid prescription order from a health-related licensing board or employer, including loss of employment or

(b) Any action taken by a prescriber or pharmacist authorized under this section shall not be considered unprofessional conduct.

Subd. 4. **Immunity from civil liability.** Notwithstanding any law to the contrary, a prescriber or pharmacist is immune from civil liability for damages, administrative fines, or penalties for acts, omissions, health care decisions, or the rendering of or the

failure to render health care services if the prescriber or pharmacist is acting pursuant to this section.

Subd. 5. **Professional conduct.**

(a) Any recommendation, prescription, use, or opinion of a prescriber or pharmacist related to a treatment for COVID-19, including a treatment that is not recommended or regulated by a health-related licensing board, the [insert state health department], a professional association, or the United States Food and Drug Administration, must not be considered unprofessional conduct.

(b) Any action taken by a prescriber or pharmacist pursuant to this section must not be considered unprofessional conduct.

(c) This subdivision applies retroactively to any disciplinary action occurring on or after March 12, 2020.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Right of Hospitalized Patients to Receive Treatment from Their Own Doctors

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Definitions.** For purposes of this section, the following terms have the meanings given.

(a) Authorized to treat" means the authority of licensed physicians and other licensed health care practitioners to write orders, prescribe medication and other treatments, order consultations, and discharge the patient.

(b) "Current relationship" means the patient has been treated by or communicated with the licensed physician or other licensed health care practitioner within the last five years.

(c) "Hospital privileges" means the authority given by hospitals to licensed physicians and other licensed health care practitioners to admit and treat hospitalized patients.

(d) "Disciplinary action" means any action taken by a health-related licensing board against a licensee, including but not limited to revocation, limitation, suspension, or denial of a license or any other disciplinary action taken by a health-related licensing board against the licensee for unprofessional conduct.

Subd. 2. **General Provision**.

(a) Patients have a right to be admitted to a hospital and treated during hospitalization by the licensed physician or other licensed health care practitioner with whom they have a current relationship.

(b) At the request of a hospitalized patient, or if the patient is unable to make the request, at the request of the spouse of the patient, a parent of the patient, the patient's guardian, or the patient's power of attorney, a licensed physician or other licensed health care practitioner with whom the patient has a current relationship is authorized to treat the patient.

(c) A physician licensed by this state may not face disciplinary action solely for treating a patient with whom they have a current relationship in a hospital where they do not have hospital privileges.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Right of Hospitalized Patients to Receive Treatment from Their Own Doctors

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Background regarding federal requirements for price transparency in hospitals.** (a) Section 1001 of the "Patient Protection and Affordable Care Act Of 2010", Pub.L. 111-148, as amended by Section 10101 of the "Health Care And Education Reconciliation Act Of 2010", Pub.L. 111-152, amended Title XXVII of the "Public Health Service Act", Pub.L. 78-410, in part, by adding a new section 2718(e), requiring, in part, that each hospital operating within the United States establish, update, and make public a list of the hospital's standard charges for the items and services that the hospital provides;

(b) Effective January 1, 2021, the federal centers for Medicare and Medicaid services published the final rule to implement the law, codified at 45 CFR 180;

(c) In its summary of the final rule, CMS states that information on hospital standard charges is necessary for the public to "make more informed decisions about their care" and that the "impact of these final policies will help to increase market competition, and ultimately drive down the cost of health care services, making them more affordable for all patients;"

(d) On July 9, 2021, President Biden, building upon efforts of past presidents, issued the "Executive Order on Promoting Competition in the American economy", directing the Secretary of the United States Department of Health and Human Services to support new and existing price transparency initiatives for hospitals.

Subd. 2. **Definitions.** For the purposes of this section, the following terms have the meanings given.

(a) "Collection Action" means any of the following actions taken with respect to a debt for items and services that were purchased from or provided to a patient by a hospital on a date during which the hospital was not in material compliance with hospital price transparency laws.

(b) "Hospital Price Transparency Laws" means Section 2718(e) of the "Public Health Service (PHS) Act", Pub.L. 78-410, as amended, and rules adopted by the United States Department of Health and Human Services implementing Section 2718(e).

(c) "Items and Services" or "Items or Services" means "Items and Services" as defined in 45 CFR 180.20.

(d) “Consumer” means the patient that receives treatment from a hospital or the patient’s guardian.

(e) “Material Compliance” means information regarding the cost of items or services provided by a hospital must be available:

(1) As a comprehensive machine-readable file with all items and services listed; and
(2) As a display of shoppable services in a consumer-friendly format.

Subd. 3. **General provisions.** (a) A hospital that is not in material compliance with hospital price transparency laws on the date that items or services are purchased from or provided to a patient by the hospital shall not initiate or pursue a collection action against the patient or patient guarantor for a debt owed for the items or services.

(b) A patient or patient guarantor is not responsible for the cost of items or services provided to the patient by the hospital if the hospital was not in material compliance with hospital price transparency laws on a date on or after the effective date of this section that items or services were purchased on or provided to the patient.

(c) A hospital shall directly inform the patient or patient guarantor about the machine-readable file and the display of shoppable services and provide information to easily locate the display.

EFFECTIVE DATE. This section is effective the day following final enactment.

MODEL STATE LEGISLATION

Right of Cancer Patients to Protect Their Medical Data

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Subdivision 1. **Data collected by the state of [insert State] cancer surveillance system.** Notwithstanding any law to the contrary, data collected on individuals by the state of [insert State] cancer surveillance system, including names and personal identifiers of persons, shall be private. Any disclosure is declared to be a misdemeanor and punishable as such. An officer or employee of the commissioner of health may interview patients or relatives of such patient, only after the informed consent of the patient as well as the consent of the patient's attending physician have been given.

Subd. 2. **Sharing of cancer patient data to non-[insert State] and federal government agencies.** (a) No information collected from a patient may be shared outside of state borders without the patient's informed consent.

(b) Information shared with patient consent with statewide cancer registries of other states, or the federal government may not contain any personal identifiers unless the patient has specifically consented in writing to the sharing of identifiers.

EFFECTIVE DATE. This section is effective the day following final enactment.