

Informed Consent Rights in U.S. Nursing Homes: An Overview of State & Federal Requirements

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Introduction

The 1987 federal Nursing Home Reform Law, which applies to all nursing homes that are reimbursed by the government under the Medicare and/or Medicaid programs, provides for numerous nursing home resident rights. Among these are several important requirements that relate directly to the concept of informed consent. One such requirement is the resident's right to be fully informed in language he or she can understand of his or her total health status, including, but not limited to, medical condition.¹ The resident also has the right to choose an attending physician, to be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being, to participate in planning care and treatment or changes in care and treatment (unless adjudged incompetent) and to refuse treatment (regardless of whether doing so may be detrimental).²

While these requirements are explicitly protective of a resident's rights to be fully informed of and participate meaningfully in his or her own care treatment and planning, and to accept or refuse treatment, they are not always interpreted as mandating informed consent to treatment. This interpretive disconnect may explain why so few residents are involved in the formulation of their own care plans. A July 2012 assessment by the federal Office of the Inspector General found that, in a review of three hundred and seventy-five randomly selected nursing facility records, ninety-one percent of the records did not contain evidence that the resident, the resident's family or the resident's legal representative participated in the care planning process.³ Every resident in this study was administered an antipsychotic drug.

In an effort to address, at least in part, the large scale inappropriate use of antipsychotic drugs on nursing home residents, Senators Kohl (D-WI), Grassley (R-IA), and Blumenthal (D-CT) introduced "The Improving Dementia Care Treatment in Older Americans Act" in the fall of 2012.⁴ The bill provided specific protocols for physicians and health care providers to follow when prescribing antipsychotic drugs to people with dementia. It also provided for the implementation of prescriber education programs. The bill did not pass in the 112th Congress.

Given the need for clarity regarding residents' rights to provide informed consent to (or rejection of) medication and other treatment, the potential for federal legislative action to explicitly provide for a right to informed consent (through reintroduction of this bill or introduction of a new bill in Congress), and the potential for states to address this issue in their

¹ 42 C.F.R. § 483.10(b)(3). Accessed at <http://www.law.cornell.edu/cfr/text/42/483.10>.

² *Id.* at (d)(1 - 4). If a resident is judged incompetent under the laws of the state, "the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf." § 483.10(a)(3).

³ "Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs," The Office of The Inspector General, pages 8, 15. July 2012. Available at: <https://oig.hhs.gov/oei/reports/oei-07-08-00151.pdf>.

⁴ S. 3604 (112th): Improving Dementia Care Treatment for Older Adults Act of 2012. Accessed at <http://www.govtrack.us/congress/bills/112/s3604>.

own laws and regulations, we thought it would be valuable to identify current state laws and rules regarding informed consent. Thus, a fundamental purpose of this report is to provide stakeholders – including nursing home residents, providers, advocates and regulators – with information on how each state approaches this issue. These individuals can use the report to identify what explicit protections exist for residents in their state and, where applicable, review the laws of other states to shape better policies in their states.⁵

Second, every state’s law is evaluated as to whether it is more or less protective than “The Improving Dementia Care Treatment in Older Americans Act.” This is important because the bill (as introduced in 2012) includes a preemption clause. Section 5(e) of the bill reads, “Nothing in this paragraph shall preempt any provision of State or Federal law that provides broader rights with respect to informed consent for residents of facilities.” In other words, to any extent that a state law mandates stronger informed consent protections for its nursing home residents, those standards apply.

The following sections begin with an overview of The Improving Dementia Care Treatment in Older Adults Act. This is followed by each state’s informed consent law (or lack thereof), including the law’s title, excerpts of relevant text and a brief summary and analysis of the law. Links to the laws are provided in footnotes. For ease of reference, the table of contents, above, provides internal links to each of the state sections. The appendices provide the text of Section 5 of the 2012 federal bill, the text of the current federal informed consent requirement for participation in experimental research and a chart listing the states and indicating whether or not, based on our findings, they currently provide strong or weak informed consent protections to nursing home residents in their states.

⁵ It is believed that this will be particularly valuable for residents, families, LTC Ombudsman and others who may not have a formal legal background or access to legal databases. Many of the laws identified are buried in state code, and were not easily accessible via Google and similar search engines. Wherever possible, we identified and cited to a freely available website link.

The Federal Bill: The Improving Dementia Care Treatment in Older Adults Act

Following is a summary of Section 5 of the Improving Dementia Care Treatment in Older Adults Act. The text of Section 5 is provided, in its entirety, in Appendix 1.⁶

Section 5 of the bill sets forth a standardized protocol for obtaining informed consent from an older adult with dementia. The self-proscribed limitations of this bill are important. For instance, this protocol only applies to obtaining informed consent from an older adult with dementia. Therefore, it would not apply to the administration of antipsychotic drugs to someone without dementia. Conversely, this protocol would not apply to the administration of any other sort of drug, besides an antipsychotic, to a nursing home resident with dementia.

These are important limitations, given the fact that other medications, particularly psychoactive medications, can be used inappropriately on residents with dementia. A serious concern of resident advocates, since the inception of the federal campaign to reduce antipsychotic drugging,⁷ is that nursing homes may simply shift to different inappropriate drugging practices rather than change their practices to comply with standards for nonpharmacological interventions in caring for their residents with dementia. Likewise, inappropriate and/or abusive use of psychotic medications by nursing homes is not limited to residents with dementia. There have been numerous cases, especially since the advent of so-called atypical antipsychotics, where the drugs have been utilized inappropriately on residents who do not have dementia, including inappropriate use on individuals who have a psychotic condition.

The bill would require a facility to obtain the informed consent prior to the prescription of an antipsychotic drug, or, if the resident is already receiving antipsychotic drugs, after the resident's first drug regimen review. This is an important provision because many people come into a facility having already been administered antipsychotics and, too often, those drugs are simply continued with little or no evaluation (of their effect on the individual) or attempts at reduction, as required by current federal minimum standards of care.

The bill provides three specific steps which the facility must take in obtaining informed consent:

1. The facility, with the "involvement of the prescriber," must inform the resident, or the resident's surrogate or designated healthcare agent, of any possible risks or side effects of the

⁶ *Id.* See also

<http://www.aging.senate.gov/minority/public/index.cfm/2011/11/overprescribed-the-human-and-taxpayers-costs-of-antipsychotics-in-nursing-homes> for the U.S. Senate Special Committee on Aging's November 2011 hearing, "Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes."

⁷ See LTCCC's [nursinghome411.org](http://www.nursinghome411.org) website for more information on the national campaign to reduce inappropriate antipsychotic drug use at <http://www.nursinghome411.org/articles/?category=antipsychotic>.

antipsychotic drugs, including any mention of a “black box warning.”⁸ The facility must also inform the resident of all treatment modalities that were attempted prior to the use of an antipsychotic. The bill provides for the Secretary of the Department of Health and Human Services to add additional disclosure requirements, as he or she deems appropriate.

2. The resident, or his or her surrogate or health care agent, must provide consent to the administration of the antipsychotic. The bill is silent as to the form of consent (i.e., whether it can be verbal or must be in writing).

3. The administration of the antipsychotic must be in accordance with the resident’s care plan, which includes non-pharmacological interventions that can appropriately address underlying causes of behavioral disorders. In other words, if a resident’s care plan called for a non-pharmacological means of treatment, administering an antipsychotic to address that same problem would be inappropriate. Alternative protocols can only be used in an emergency, or when an incapacitated resident does not have a clearly identified surrogate or health care agent.

Additionally, the bill provides that none of the above shall preempt any state or federal laws that furnish stronger informed consent rights to a nursing home resident. This is an important provision since a number of states have stronger protections than those the federal bill would provide.

⁸ For the text of the FDA’s 2005 health advisory concerning the application of black box warnings to antipsychotic drugs, visit:
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm053171.htm>.

State Informed Consent Laws

Important Research Notes on the State Laws

What is Included

The following sections of the report cover the state laws identified as providing or supporting the right to informed consent in the nursing home care and/or antipsychotic drugging context. Some states' resident rights provisions were most relevant in this regard, though many states' resident rights provisions simply reiterate the basic protections provided by the federal Nursing Home Reform Law. A number of states address informed consent in other laws or rules, such as in their medical malpractice laws, general patient rights laws or mental health laws. In many cases it was unclear as to whether a law applied broadly (to include nursing home residents) or not; in these cases we attempted to make as clear as possible what our understanding of the state law was and the basis for making such determinations. In addition, we included the text of state laws that we identified as providing strong informed consent language. If a strong law did not pertain to nursing home residents this was noted in our summary for the state.

Each section includes the title of the law, relevant excerpts from the law and a brief description and analysis of the law (including whether it is stronger or weaker than the federal bill proposed in 2012). A link to where each law can be found on-line is provided in footnotes.

Important Limitations

It is important to note that this report only covers state laws and regulations. It does not include case law (court decisions). Particularly since longstanding federal law requires that residents be informed about their care needs, participate in care planning and have the right to decline treatment, state courts may interpret the federal and/or their state's standards to encompass the right to informed consent (whether or not it is explicitly provided for in the law). LTCCC and numerous other stakeholders believe that this is the correct interpretation of the existing law, based on its requirements that residents have the right to participate in their care planning and reject any proposed care or treatment. Our research into state laws indicated that a number of the states appear to approach the issue similarly (i.e., informed consent is referenced in a way that indicates an acceptance of it as a right integral to the rights provided by the Nursing Home Reform Law and other laws). Fundamentally, nursing home residents do not forfeit their rights as US citizens when they enter a nursing home and, like citizens everywhere, have the right not to be given powerful and dangerous drugs without their consent. It is difficult to imagine any other context, outside of a prison, where an adult's right to informed consent would be called into question.

Research Methodology

The following informed consent laws were identified through internet searches conducted through June 2013. We started by researching provisions of the public health code for every state and manually looked for nursing home residents' rights, or more broadly, a nursing home section of the state's public health code. When no results were found, we conducted word

filter searches on LexisNexis.⁹ In June we conducted a second round of research for all states, including a review and update of our previous findings, using the Westlaw Next and Justia.com databases and the Google search engine. For each state, the search terms used were “nursing home informed consent,” “elder law informed consent” and “nursing home patient rights.”

Alabama

Alabama Code- Title 38 Public Welfare- Ch. 9 Protection of Aged Adults and Adults with a Disability- 6. Protective placement or other protective services¹⁰

(j) As far as is compatible with the mental and physical condition of the adult in need of services or claimed to be in need of services under this chapter, every reasonable effort shall be made to assure that no action is taken without the full and informed consent of the person.

Summary and Analysis:

- Alabama’s public welfare statute includes an informed consent provision for aged and disabled adults. However, it is limited to individuals who are in court-ordered protective placement or other protective services. It does not apply to nursing home residents (specifically) or to patients (generally) in the state.
- The Alabama Mental Health Consumers Rights Act (22-56-4)(b) states that a consumer of mental health services within an “inpatient, residential or outpatient setting has the right to be fully informed on an individual basis, when need, concerning services provided with information presented in a setting and in language appropriate to the consumer’s condition and ability to understand.”¹¹ This is valuable in that it confirms and elaborates on the existing federal requirement that residents be informed of treatment, however it does not address consent.
- Though these two statutes provide for informed consent protections in certain circumstances, the federal bill provides specific protections regarding nursing home resident’s rights and the manner in which valid informed consent is to be obtained. Thus, nursing home residents in this state would likely benefit from passage of the federal bill.

⁹ For example, searching for inf! /1 cons! (root inf, root cons, one word apart from each other, as in informed consent) or refus! /2 med! or refus! /2 treat! (root refus, root med/treat to look for a refusal of medicine/medical procedure or treatment).

¹⁰ Accessed at <http://law.onecle.com/alabama/public-welfare/38-9-6.html>.

¹¹ Accessed at <http://codes.lp.findlaw.com/alcode/22/2/56/22-56-4>.

Alaska

Alaska Statutes- Title 47: Welfare, Social Services, and Institutions- Chapter 30- Mental Health, Article 10- Patients Rights- 47.30.825.: Patient medical rights¹²

(c) A patient who is capable of giving informed consent has the right to give and withhold consent to medication and treatment in all situations that do not involve a crisis or impending crisis as described in AS 47.30.838(a)(1). A facility shall follow the procedures required under AS 47.30.836 - 47.30.839 before administering psychotropic medication.

Alaska Statutes – Title 47: Welfare, Social Services, and Institutions – Chapter 30 – Mental Health, Article 10 – Patient’s Rights, Section 47.30.837 – Informed Consent¹³

(a) A patient has the capacity to give informed consent for purposes of AS 47.30.836 if the patient is competent to make mental health or medical treatment decisions and the consent is voluntary and informed.

(b) When seeking a patient's informed consent under this section, the evaluation facility¹⁴ or designated treatment facility shall give the patient information that is necessary for informed consent in a manner that ensures maximum possible comprehension by the patient.

(c) If an evaluation facility or designated treatment facility has provided to the patient the information necessary for the patient's consent to be informed and the patient voluntarily consents, the facility may administer psychotropic medication to the patient unless the facility has reason to believe that the patient is not competent to make medical or mental health treatment decisions. If the facility has reason to believe that the patient is not competent to make medical or mental health treatment decisions and the facility wishes to administer psychotropic medication to the patient, the facility shall follow the procedures of AS 47.30.839.

(d)

(2) “informed” means that the evaluation facility or designated treatment facility has given the patient all information that is material to the patient's decision to give or withhold consent, including

¹² Accessed at <http://statutes.laws.com/alaska/title-47/chapter-47-30/article-10/sec-47-30-825>.

¹³ Accessed at <http://statutes.laws.com/alaska/title-47/chapter-47-30/article-10/sec-47-30-837>.

¹⁴ Alaska law (Alaska Stat. § 47.30.915. : Alaska Statutes - Section 47.30.915.: Definitions) defines an “evaluation facility” as including “a medical facility licensed under AS 47.32. AS 47.32.010. Purpose and Applicability. establishes “centralized licensing and related administrative procedures for the delivery of services in this state by the entities listed in... this section. These include assisted living and nursing facilities. Accessed at <http://codes.lp.findlaw.com/akstatutes/47/47.32./47.32.010>.

- (A) an explanation of the patient's diagnosis and prognosis, or their predominant symptoms, with and without the medication;
- (B) information about the proposed medication, its purpose, the method of its administration, the recommended ranges of dosages, possible side effects and benefits, ways to treat side effects, and risks of other conditions, such as tardive dyskinesia;
- (C) a review of the patient's history, including medication history and previous side effects from medication;
- (D) an explanation of interactions with other drugs, including over-the-counter drugs, street drugs, and alcohol;
- (E) information about alternative treatments and their risks, side effects, and benefits, including the risks of nontreatment; and
- (F) a statement describing the patient's right to give or withhold consent to the administration of psychotropic medications in nonemergency situations, the procedure for withdrawing consent, and notification that a court may override the patient's refusal....

Summary and Analysis:

- Alaska's informed consent protections apply to nursing home residents. This means that any nursing home resident receiving antipsychotic medication is protected under statutes (47.30.825) and (47.30.837) regarding their right to informed consent.
- Alaska law describes the essential elements of "informed" in this context. As per section (2E) of statute (47.30.837), the patient must be told of the alternatives and risks as well as side effects and benefits of receiving a medication. This would presumably include informing the resident of the FDA black box warnings for antipsychotic drugs.
- Alaskan facilities are required to inform the patient "in a manner that ensures maximum possible comprehension."
- As a result of these requirements, the Alaskan informed consent law would likely be more protective than the proposed federal bill.

Arkansas

Arkansas Code – Title 20 – Public Health and Welfare, Subtitle 2 – Health and Safety, Chapter 10, Long-Term Care Facilities and Services, Subchapter 12 – Protection of Long-Term Care Facility Residents, A.C.A. 20-10-1204 – Resident’s Rights¹⁵

(a)(6) The right to be adequately informed of his or her medical condition and proposed treatment unless the resident is determined to be unable to provide informed consent under Arkansas law, the right to be fully informed in advance of any nonemergency changes in care or treatment that may affect the resident's well-being, and except with respect to a resident adjudged incompetent, the right to participate in the planning of all medical treatment, including the right to refuse medication and treatment unless otherwise indicated by the resident's physician and to know the consequences of such actions;

(a)(7)(a) The right to refuse medication or treatment and to be informed of the consequences of such decisions unless determined unable to provide informed consent under state law. When the resident refuses medication or treatment, the facility shall notify the resident or the resident's legal representative of the consequences of such a decision and shall document the resident's decision in his or her medical record.

Summary and Analysis:

- Arkansas’ public health and welfare laws include a section on the rights of long term care facility residents (20-10-1204) which includes provisions similar to current federal requirements that nursing home residents must be informed of treatment plans, be provided opportunities to participate in their development and have the right to refuse treatment.
- While the law does not affirmatively require informed consent, it references “informed consent” in these provisions. This implies that the longstanding rights to be informed of, participate in and refuse treatment incorporate the right to informed consent of treatment.¹⁶
- Because it does not affirmatively aver the right to informed consent, the federal bill would likely provide stronger protections.

¹⁵ Accessed at <http://law.justia.com/codes/arkansas/2010/title-20/subtitle-2/chapter-10/subchapter-12/20-10-1204/>.

¹⁶ This corroborates the view of LTCCC and others that informed consent is implicit in the residents’ rights stemming from the 1987 Nursing Home Reform Law.

California

California Code of Regulations, Title 22. Social Security, Section 72527¹⁷

(a) Patients have the rights enumerated in this section and the facility shall ensure that these rights are not violated. ... Patients shall have the right:

(3) To be fully informed by a physician of his or her total health status and to be afforded the opportunity to participate on an immediate and ongoing basis in the total plan of care including the identification of medical, nursing and psychosocial needs and the planning of related services.

(4) To consent to or to refuse any treatment or procedure or participation in experimental research.

(5) To receive all information that is material to an individual patient's decision concerning whether to accept or refuse any proposed treatment or procedure. The disclosure of material information for administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function shall include the disclosure of information listed in Section 72528(b).

(7) To be encouraged and assisted throughout the period of stay to exercise rights as a patient and as a citizen, and to this end to voice grievances and recommend changes in policies and services to facility staff and/or outside representatives of the patient's choice, free from restraint, interference, coercion, discrimination or reprisal.

(10) To be free from mental and physical abuse.

(24) To be free from psychotherapeutic drugs and physical restraints used for the purpose of patient discipline or staff convenience and to be free from psychotherapeutic drugs used as a chemical restraint as defined in Section 72018, except in an emergency which threatens to bring immediate injury to the patient or others. If a chemical restraint is administered during an emergency, such medication shall be only that which is required to treat the emergency condition and shall be provided in ways that are least restrictive of the personal liberty of the patient and used only for a specified and limited period of time.

(b) A patient's rights, as set forth above, may only be denied or limited if such denial or limitation is otherwise authorized by law. Reasons for denial or limitation of such rights shall be documented in the patient's health record.

(c) If a patient lacks the ability to understand these rights and the nature and consequences of proposed treatment, the patient's representative shall have the rights specified in this section to the extent the right may devolve to another, unless the representative's authority is

¹⁷ Accessed at

<http://government.westlaw.com/linkedslice/default.asp?Action=TOC&RS=GVT1.0&VR=2.0&SP=CCR-1000>. [Note: Access to California Code of Regulations is free on Westlaw. This and the following regulation are under Title 22.]

otherwise limited. The patient's incapacity shall be determined by a court in accordance with state law or by the patient's physician unless the physician's determination is disputed by the patient or patient's representative.

(d) Persons who may act as the patient's representative include a conservator, as authorized by Parts 3 and 4 of Division 4 of the Probate Code (commencing with Section 1800), a person designated as attorney in fact in the patient's valid Durable Power of Attorney for Health Care, patient's next of kin, other appropriate surrogate decisionmaker designated consistent with statutory and case law, a person appointed by a court authorizing treatment pursuant to Part 7 (commencing with Section 3200) of Division 4 of the Probate Code, or, if the patient is a minor, a person lawfully authorized to represent the minor.

(e) Patients' rights policies and procedures established under this section concerning consent, informed consent and refusal of treatments or procedures shall include, but not be limited to the following:

(1) How the facility will verify that informed consent was obtained or a treatment or procedure was refused pertaining to the administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability of the patient to regain the use of a normal bodily function.

(2) How the facility, in consultation with the patient's physician, will identify consistent with current statutory case law, who may serve as a patient's representative when an incapacitated patient has no conservator or attorney in fact under a valid Durable Power of Attorney for Health Care.

§ 72528. Informed Consent Requirements.¹⁸

(a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.

(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following:

(1) The reason for the treatment and the nature and seriousness of the patient's illness.

(2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.

(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.

(4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.

¹⁸ *Id.*

- (5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.
- (6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.
- (c) Before initiating the administration of psychotherapeutic drugs, or physical restraints, or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function, facility staff shall verify that the patient's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure. The facility shall also ensure that all decisions concerning the withdrawal or withholding of life sustaining treatment are documented in the patient's health record.
- (d) This section shall not be construed to require obtaining informed consent each time a treatment or procedure is administered unless material circumstances or risks change.
- (e) There shall be no violation for initiating treatment without informed consent if there is documentation within the patient's health record that an emergency exists where there is an unanticipated condition in which immediate action is necessary for preservation of life or the prevention of serious bodily harm to the patient or others or to alleviate severe physical pain, and it is impracticable to obtain the required consent, and provided that the action taken is within the customary practice of licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances.
- (f) Notwithstanding Sections 72527(a)(5) and 72528(b)(4), disclosure of the risks of a proposed treatment or procedure may be withheld if there is documentation of one of the following in the patient's health record:
- (1) That the patient or patient's representative specifically requested that he or she not be informed of the risk of the recommended treatment or procedure. This request does not waive the requirement for providing the other material information concerning the treatment or procedure.
 - (2) That the licensed healthcare practitioner acting within the scope of his or her professional licensure relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the patient that the patient would not have been able to rationally weigh the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a patient's representative gave informed consent as set forth herein.
- (g) A general consent provision in a contract for admission shall only encompass consent for routine nursing care or emergency care. Routine nursing care, as used in this section, means a treatment or procedure that does not require informed consent as specified in Section 72528(b)(1) through (6) or that is determined by the licensed healthcare practitioner acting within the scope of his or her professional licensure not to require the disclosure of information material to the individual patient. Routine nursing care includes, but is not limited to, care that does not require the order of a licensed healthcare practitioner acting within the scope of his or her professional licensure. This section does not preclude the use of informed consent forms for any specific treatment or procedure at the time of admission or at any other time. All consent provisions or forms shall indicate that the patient or incapacitated patient's representative may revoke his or her consent at any time.

(h) If a patient or his or her representative cannot communicate with the licensed healthcare practitioner acting within the scope of his or her professional licensure because of language or communication barriers, the facility shall arrange for an interpreter.

(1) An interpreter shall be someone who is fluent in both English and the language used by the patient and his or her legal representative, or who can communicate with a deaf person, if deafness is the communication barrier.

(2) When interpreters are used, documentation shall be placed in the patient's health record indicating the name of the person who acted as the interpreter and his or her relationship to the patient and to the facility.

Summary and Analysis:

- California law provides for informed consent, particularly in the antipsychotic drugging context, with considerable specificity.
- Responsibility for ensuring that informed consent requirements are followed fall to the “licensed healthcare practitioner.”
- While California has a strong informed consent law, the inclusion of some specific requirements in the federal bill (such as referencing the FDA’s “black box warning” in providing informed consent to a resident), makes it likely that the federal bill would provide stronger protections to residents in California.

Colorado

Colorado Revised Statutes – Title 25 – Health, Article 1 – Administration, Part 1 – Department of Public Health and Environment, Section 25-1-120 – Nursing Facilities – Rights of Patients¹⁹

(1) The department shall require all skilled nursing facilities and intermediate care facilities to adopt and make public a statement of the rights and responsibilities of the patients who are receiving treatment in such facilities and to treat their patients in accordance with the provisions of said statement. The statement shall ensure each patient the following:

(f) The right to be adequately informed of his medical condition and proposed treatment, unless otherwise indicated by his physician, and to participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by his physician, and to know the consequences of such actions....

¹⁹ Accessed at <http://www.lexisnexis.com/hottopics/colorado/>. [Note: Access to Colorado Revised Statutes is free on LexisNexis.]

Summary and Analysis:

- Colorado’s health law includes a section for the rights of patients in nursing facilities. While the statute includes a right to be adequately informed regarding the patient’s own medical condition, there is no provision providing for informed consent.
- The federal bill would likely provide stronger protections for nursing home residents in this state.

Connecticut

Connecticut General Statutes – Title 19a – Public Health and Well-Being, Chapter 368v – Health Care Institutions, Sec. 19a-550. (Formerly Sec. 19-622). Patients' bill of rights²⁰

(b) The patient’s bill of rights shall provide that each such patient:

(1) Is fully informed, as evidenced by the patient's written acknowledgment, prior to or at the time of admission and during the patient's stay, of the rights set forth in this section and of all rules and regulations governing patient conduct and responsibilities;

(3) Is entitled to choose the patient's own physician and is fully informed, by a physician, of the patient's medical condition unless medically contraindicated, as documented by the physician in the patient's medical record, and is afforded the opportunity to participate in the planning of the patient's medical treatment and to refuse to participate in experimental research;

(8) is free from mental and physical abuse, corporal punishment, involuntary seclusion and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the patient's medical symptoms. Physical or chemical restraints may be imposed only to ensure the physical safety of the patient or other patients and only upon the written order of a physician that specifies the type of restraint and the duration and circumstances under which the restraints are to be used, except in emergencies until a specific order can be obtained.

Summary and Analysis:

- Connecticut’s public health code contains a patients’ bill of rights for residents of health care institutions, including nursing home residents.
- While the law does not specifically state “informed consent,” it does require that

²⁰ Accessed at <http://www.cga.ct.gov/2011/pub/chap368v.htm#Sec19a-550.htm>.

patients are informed and acknowledge in writing, during the course of their residency, of their rights including (as excerpted above) their medical treatment, right to be free of chemical restraints, etc....

- A relevant informed consent law in Connecticut is one regarding the rights of patients with Psychiatric Disabilities (17a-543)²¹ which states that no patient shall receive medication for treatment of psychiatric disabilities without informed consent of the patient, unless it is necessary under certain special circumstances. It is also worthwhile to note that Connecticut has informed consent laws related to Sterilization (45a-691) and HIV (19a-583).
- Though it provides for written acknowledgment in several relevant aspects of resident care, the absence of explicit informed consent protection in Connecticut law suggests that the federal bill would likely provide greater protections for residents of nursing homes in this state.

Delaware

Delaware Code - Title 16 – Health and Safety, Chapter 11 – Nursing Facilities and Similar Facilities, Subchapter II – Rights of Patients, Sec. 1121 – Patient’s Rights²²

(4) Each patient shall receive from the attending physician or the resident physician of the facility complete and current information concerning the patient's diagnosis, treatment and prognosis in terms and language the patient can reasonably be expected to understand, unless medically inadvisable. The patient or resident shall participate in the planning of the patient's or resident's medical treatment, including attendance at care plan meetings, may refuse medication or treatment, be informed of the medical consequences of all medication and treatment alternatives and shall give prior informed consent to participation in any experimental research after a complete disclosure of the goals, possible effects on the patient and whether or not the patient can expect any benefits or alleviation of the patient's condition. In any instance of any type of experiment or administration of experimental medicine, there shall be written evidence of compliance with this section, including the signature of the patient, or the signature of the patient's guardian or representative if the patient has been adjudicated incompetent. A copy of signed acknowledgment or informed consent, or both when required, shall be forwarded to each signer and a copy shall be retained by the facility.

²¹ Accessed at http://www.lawserver.com/law/state/connecticut/ct-laws/connecticut_statutes_17a-543.

²² Accessed at <http://delcode.delaware.gov/title16/c011/sc02/index.shtml>.

(20) Every patient and resident shall be fully informed, in language the patient or resident can understand, of the patient's or resident's rights and all rules and regulations governing patient or resident conduct and the patient's or resident's responsibilities during the stay at the facility.

Summary and Analysis:

- Delaware's nursing home residents' rights law provides for informed consent only for participation in an experiment or when receiving experimental treatment. The resident must consent to this type of procedure in writing. The requirement that consent be in writing is not present in existing federal law regarding experimental treatment or in the proposed federal bill.²³
- Delaware law includes extensive requirements for informed consent in regard to disclosure of patient information.²⁴ However these do not relate to consent to care.
- Due to the significant limitations in Delaware's informed consent law, the federal bill would likely provide stronger protections for residents in this state.

District of Columbia

District of Columbia Code Annotated- Div. I Government of District- Title 7 Human Health Care and Safety- Subtitle C. Mental Health- Ch. 12A Mental Health Consumers' Right Protections- .08 Administration of Medication²⁵

(a) Except as provided in this section, no consumer shall be administered medication for the purpose of mental health treatment without his or her informed consent. In seeking a consumer's informed consent, the Department or other provider shall present the consumer with information about the proposed medication, including the purpose for its administration, possible side effects, and its potential risks and benefits, as well as information about feasible alternative treatments.

²³ Source: Code of Federal Regulations 42 C.F.R. § 483.10(b) (4) (a resident has the right to refuse experimental treatment, but does not have to consent to the treatment in writing).

²⁴ Title 16-Health and Safety Regulatory Provisions Concerning Public Health, Chapter 12. Informed Consent and Confidentiality, Subchapter II. Confidentiality of Personal Health Information. Accessed at <http://delcode.delaware.gov/title16/c012/sc02/index.shtml>.

²⁵ Accessed at <http://law.justia.com/codes/district-of-columbia/2012/division-i/title-7/subtitle-c/chapter-12a/section-7-1231-08.html>.

- The informed consent laws that exist in the District are: the law excerpted above (7-1231.08), which relates to “Mental Health Patients;” the section of the law pertaining to care for people with intellectual disabilities and that which pertains to patients with HIV.
- The mental health patients to whom this law pertains are, according to its statutory definition, those who come under Title 21, Chapter 5: Hospitalization of the Mentally Ill. Thus, it is unlikely that these protections encompass nursing home resident care.
- Since District of Columbia lacks an informed consent law that includes nursing home residents, the federal bill would likely provide greater protections for these individuals.

Florida

Florida Statutes – Title 29 – Public Health, Chapter 400 – Nursing Homes and Related Health Care Facilities, Part II – Nursing Homes, Section 400.022 – Resident’s Rights²⁶

(1) All licensees of nursing home facilities shall adopt and make public a statement of the rights and responsibilities of the residents of such facilities and shall treat such residents in accordance with the provisions of that statement. The statement shall assure each resident the following:

(j) The right to be adequately informed of his or her medical condition and proposed treatment, unless the resident is determined to be unable to provide informed consent under Florida law, or the right to be fully informed in advance of any nonemergency changes in care or treatment that may affect the resident’s well-being; and, except with respect to a resident adjudged incompetent, the right to participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by the resident’s physician; and to know the consequences of such actions.

(k) The right to refuse medication or treatment and to be informed of the consequences of such decisions, unless determined unable to provide informed consent under state law. When the resident refuses medication or treatment, the nursing home facility must notify the resident or the resident’s legal representative of the consequences of such decision and must document the resident’s decision in his or her medical record. The nursing home facility must continue to provide other services the resident agrees to in accordance with the resident’s care plan.

²⁶ Accessed at http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0400/Sections/0400.022.html.

FL ST Chapter 394 – Mental Health, § 394.459 Rights of Patients, (3) Right to express and informed patient consent²⁷

(a) 1. Each patient entering treatment shall be asked to give express and informed consent for admission or treatment. If the patient has been adjudicated incapacitated or found to be incompetent to consent to treatment, express and informed consent to treatment shall be sought instead from the patient's guardian or guardian advocate. If the patient is a minor, express and informed consent for admission or treatment shall also be requested from the patient's guardian. Express and informed consent for admission or treatment of a patient less than 18 years of age shall be required from the patient's guardian, unless the minor is seeking outpatient crisis intervention services under s. 394.4784. Express and informed consent for admission or treatment given by a patient who is under 18 years of age shall not be a condition of admission when the patient's guardian gives express and informed consent for the patient's admission pursuant to s. 394.463 or s. 394.467.

2. Before giving express and informed consent, the following information shall be provided and explained in plain language to the patient, or to the patient's guardian if the patient is 18 years of age or older and has been adjudicated incapacitated, or to the patient's guardian advocate if the patient has been found to be incompetent to consent to treatment, or to both the patient and the guardian if the patient is a minor: the reason for admission or treatment; the proposed treatment; the purpose of the treatment to be provided; the common risks, benefits, and side effects thereof; the specific dosage range for the medication, when applicable; alternative treatment modalities; the approximate length of care; the potential effects of stopping treatment; how treatment will be monitored; and that any consent given for treatment may be revoked orally or in writing before or during the treatment period by the patient or by a person who is legally authorized to make health care decisions on behalf of the patient.

Summary and Analysis:

- Florida's requirements for nursing homes under Title 29 (above) reference informed consent in terms of a resident's capacity in its discussion of the right to be informed of and refuse treatment. This supports the contention that informed consent is incorporated in the federally mandated requirements that residents have the right to be informed of treatment and to refuse treatment. It is worthwhile to note that this section explicitly states that a "nursing home facility must continue to provide other services the resident agrees to in accordance with the resident's care plan." In other

²⁷ Accessed at

http://www.leg.state.fl.us/statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=394.459&URL=0300-0399/0394/Sections/0394.459.html.

words, a facility cannot simply use the refusal of treatment as a basis for discharging a resident.

- The only explicit informed consent provisions identified fall under the state’s mental health law [394.459] and do not apply to the general nursing home population. Key principles to informed consent [per Patient’s Bill of Rights]:
 - The proposed treatment;
 - The purpose of the treatment to be provided;
 - The common risks;
 - Benefits;
 - Side effects;
 - The specific dosage range for the medication, when applicable;
 - Alternative treatment modalities;
 - The approximate length of care;
 - The potential effects of stopping treatment;
 - How treatment will be monitored;
 - *That any consent given for treatment may be revoked orally or in writing before or during the treatment period by the patient or by a person who is legally authorized to make health care decisions on behalf of the patient.*
- Because Florida’s informed consent law does not provide rights to patients in general or to nursing home residents specifically, the federal bill would likely provide stronger protections to Florida’s nursing home residents.

Georgia

Georgia Code - Title 31 – Health, Chapter 8 – Care and Protection of Indigent and Elderly Patients, Article 5 – Bill of Rights for Residents of Long-Term Care Facilities, Section 31-8-108 – Required Care, Treatment and Services; Rights in Regard Thereto; Experimental Research or Treatment²⁸

(b) In the provision of care, treatment, and services to the resident by the facility, each resident or guardian shall be entitled to the following:

(2) To participate in the overall planning of the resident's care and treatment. The resident or guardian shall be informed of this right each time a substantial change in the treatment plan is made;

²⁸ Accessed at <http://law.justia.com/codes/georgia/2010/title-31/chapter-8/article-5/31-8-108/>.

(3) To refuse medical treatment, dietary restrictions, and medications for the resident. The resident or guardian shall be informed of the probable consequences of such refusal, the refusal shall be noted in the resident's medical records, and the resident's attending physician shall be notified as soon as practical. If such refusal apparently would be seriously harmful to the health or safety of the resident, the facility shall either refer the resident to a hospital or notify a responsible family member or, if such a family member is not readily available, the county department of family and children services. If such refusal would be harmful to the health or safety of others, as documented in the resident's medical records by the resident's physician, this subsection shall not apply. Any facility or employee of such facility which complies with this paragraph shall not be liable for any damages resulting from such refusal;

(5) To have any significant change in the resident's health status reported to persons of his choice by the facility within a reasonable time; and

(6) To obtain from the resident's physician or the physician attached to the facility a complete and current explanation concerning the resident's medical diagnosis, treatment, and prognosis in language the resident can understand. Each resident shall have access to all information in the medical records of the resident and shall be permitted to inspect and receive a copy of such records unless medically contraindicated. The facility may charge a reasonable fee for duplication, which fee shall not exceed actual cost.

Summary and Analysis:

- The Georgia nursing home resident's bill of rights addresses substantially the same rights as those which exist in federal law. It does not specify or address in any way the concept of informed consent on its own.
- It is worthwhile to note that under Georgia law it is the responsibility of the resident's physician or the "physician attached to the facility" to completely explain to the resident details of his or her medical diagnosis, treatment, and prognosis. This is a more protective concept of informed than exists in the federal bill, which only requires that the prescriber of medication be involved in the information process.
- Due to the fact the Georgia law does not specifically provide for informed consent, the federal bill would likely provide greater protections to residents in this state.

Hawaii

Hawaii Revised Statutes – Division 4 – Courts and Judicial Proceedings, Title 36 – Civil Remedies and Defenses and Special Proceedings, Chapter 671 – Medical Torts, Part I – General Provisions, Section 671-3 – Informed Consent²⁹

(b) The following information shall be supplied to the patient or the patient's guardian or legal surrogate prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure:

- (1) The condition to be treated;
- (2) A description of the proposed treatment or procedure;
- (3) The intended and anticipated results of the proposed treatment or procedure;
- (4) The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures;
- (5) The recognized material risks of serious complications or mortality associated with:
 - (A) The proposed treatment or procedure;
 - (B) The recognized alternative treatments or procedures; and
 - (C) Not undergoing any treatment or procedure; and
- (6) The recognized benefits of the recognized alternative treatments or procedure....

Summary and Analysis:

- Hawaiian law provides a general means of redress for patients who are not provided an opportunity for informed consent to treatment. The information that must be provided to the patient is very similar to that in the proposed federal law.
- The law is silent as to whether a physician must inform a resident personally, or if the resident must provide written consent to treatment.
- Because it specifically mandates informed consent in nursing home settings, the proposed federal bill would likely provide stronger protections for nursing home residents in Hawaii.

²⁹ Accessed at <http://law.justia.com/codes/hawaii/2011/division4/title36/chapter671/671-3>.

Idaho

Idaho Code Annotated- Title 39. Health and Safety- Ch. 45 The Medical Consent and Natural Death Act- .06 Sufficiency of consent³⁰

Consent, or refusal to consent, for the furnishing of health care, treatment or procedures shall be valid in all respects if the person giving or refusing the consent is sufficiently aware of pertinent facts respecting the need for, the nature of, and the significant risks ordinarily attendant upon such a person receiving such care, 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. As used in this section, the term “in the same community” refers to that geographic area ordinarily served by the licensed general hospital at or nearest to which such consent is given.

Summary and Analysis:

- Though Idaho does not have an informed consent law specifically for nursing home resident care, the general medical consent provisions in the law provide several broad informed consent protections.
- The medical consent law states that if a person has capacity, they have the right to refuse consent for health care, treatment or procedures. A refusal is valid if the person making it has been informed of the need, nature and significant risks the care offered in order to insure that refusal is being made after being reasonably informed.
- These protections are, however, somewhat vague. For example, the law does not detail in what form the consent must be obtained or when this consent must be given.
- As a result of these weaknesses, the federal bill would likely provide stronger protections.

³⁰ Accessed at <http://www.legislature.idaho.gov/idstat/Title39/T39CH45SECT39-4506.htm>.

Illinois

Illinois Statutes- Ch. 210 Health Facilities and Regulations- Act 45. Nursing Home Care Act- Art. II Rights and Responsibilities- Part 1. Sec. 2-106.1- Residents Rights- Drug Treatment³¹

(a) A resident shall not be given unnecessary drugs. An unnecessary drug is any drug used in an excessive dose, including in duplicative therapy; for excessive duration; without adequate monitoring; without adequate indications for its use; or in the presence of adverse consequences that indicate the drugs should be reduced or discontinued. The Department shall adopt, by rule, the standards for unnecessary drugs contained in interpretive guidelines issued by the United States Department of Health and Human Services for the purposes of administering Titles XVIII and XIX of the Social Security Act.

(b) Psychotropic medication shall not be prescribed without the informed consent of the resident, the resident's guardian, or other authorized representative. "Psychotropic medication" means medication that is used for or listed as used for antipsychotic, antidepressant, antimanic, or antianxiety behavior modification or behavior management purposes in the latest editions of the AMA Drug Evaluations or the Physician's Desk Reference. The Department shall adopt, by rule, a protocol specifying how informed consent for psychotropic medication may be obtained or refused. The protocol shall require, at a minimum, a discussion between (i) the resident or the resident's authorized representative and (ii) the resident's physician, a registered pharmacist (who is not a dispensing pharmacist for the facility where the resident lives), or a licensed nurse about the possible risks and benefits of a recommended medication and the use of standardized consent forms designated by the Department. Each form developed by the Department (i) shall be written in plain language, (ii) shall be able to be downloaded from the Department's official website, (iii) shall include information specific to the psychotropic medication for which consent is being sought, and (iv) shall be used for every resident for whom psychotropic drugs are prescribed. In addition to creating those forms, the Department shall approve the use of any other informed consent forms that meet criteria developed by the Department.

In addition to any other penalty prescribed by law, a facility that is found to have violated this subsection, or the federal certification requirement that informed consent be obtained before administering a psychotropic medication, shall thereafter be required to obtain the signatures of 2 licensed health care professionals on every form purporting to give informed consent for the administration of a psychotropic medication, certifying the personal knowledge of each health care professional that the consent was obtained in compliance with the requirements of this subsection.

³¹ Accessed at

<http://www.ilga.gov/legislation/ilcs/ilcs4.asp?DocName=021000450HArt.+II+Pt.+1&ActID=1225&ChapterID=21&SeqStart=4200000&SeqEnd=6300000>.

Summary and Analysis:

- The Illinois Nursing Home Care Act includes a provision for residents rights regarding drug treatment and specifically regarding antipsychotic drugs, stating that informed consent is necessary for medication to be administered.
- Section (a) states that a resident may not be given unnecessary drugs and elaborates on how a facility can identify an unnecessary drug.
- Section (b) states that for the administration of a psychotropic drug to a nursing home patient, the patient or his guardian must first provide informed consent. The types of drugs considered to be psychotropic are described and the protocol for obtaining informed consent is given. The specificity of this section and the clarity with which it states the steps that the facility must take to protect patient's rights and interests provide substantive protections.
- Section (b) describes a minimum standard for obtaining informed consent, stating that the resident's physician or a registered pharmacist that *doesn't* dispense medicine at that facility or a licensed nurse must have a discussion with the resident or the resident's guardian to explain the risks and benefits of the medication and must use a standardized consent form designated by the state.
- The requirement that consent must be in writing is a strong protection. In addition, the state's adaptation of a standardized form is laudable. Particularly since the law requires that the form be in plain English and downloadable from the state's website, it provides significant opportunities for transparency in the process and accountability should a provider fail to meet these standards.
- The form must also include specific information regarding the psychotropic medication for which the informed consent is being sought. This provides the resident (and his or her representative) the opportunity to become truly informed regarding the medicine he is to be given before consenting to it.
- As a result of these requirements, Illinois law provides significantly stronger informed consent protections for nursing home residents than the federal bill (particularly as regards the use of psychotropic medications).

Indiana

Ind. Code § 16-36-1.5-4.5 : Indiana Code - Section 16-36-1.5-4.5: Physician; written consent from patient required³²

Before providing mental health services, a physician who is licensed under IC 25-22.5 must obtain consent from each patient as provided in IC 34-18-12.

Ind. Code § 16-36-1.5-4 : Indiana Code - Section 16-36-1.5-4: Mental health provider; consent from patient required³³

Before providing mental health services, a mental health provider must obtain consent from each patient.

Ind. Code § 16-28-14-2 : Indiana Code - Section 16-28-14-2: Obtaining informed consent³⁴

(a) A health facility shall attempt to obtain informed consent from:

- (1) a patient; or
- (2) a patient's legal guardian;

for a patient to participate in immunization programs....

Ind. Code- Section 34-18-12-3: Informed written consent; explanation of proposed treatment, outcome, and risks³⁵

The explanation given in accordance with section 2(3) of this chapter must include the following information:

- (1) The general nature of the patient's condition.
- (2) The proposed treatment, procedure, examination, or test.
- (3) The expected outcome of the treatment, procedure, examination, or test.
- (4) The material risks of the treatment, procedure, examination, or test.
- (5) The reasonable alternatives to the treatment, procedure, examination, or test.

³² Accessed at <http://codes.lp.findlaw.com/incode/16/36/1.5/16-36-1.5-4.5>. Title 16 Article 36 addresses "Medical Consent" generally.

³³ Accessed at <http://codes.lp.findlaw.com/incode/16/36/1.5/16-36-1.5-4>.

³⁴ Accessed at <http://codes.lp.findlaw.com/incode/16/28/14/16-28-14-2>. Article 28 addresses "Health Facilities."

³⁵ Accessed at <http://www.in.gov/legislative/ic/2010/title34/ar18/ch12.pdf>. Title 34 is "Civil Law and Procedure." Article 18 applies to medical malpractice.

Summary and Analysis:

- Indiana requires informed consent for the provision of mental health services.
- Section (34-18-12-3), the Indiana’s medical malpractice law, states what must be included in the explanation given when informed consent is obtained, including the expected outcomes, potential risks and reasonable alternatives to the proposed treatment.
- The only informed consent requirement specific to nursing home resident care (16-28-14-2) relates solely to immunization.
- Because of its specific provisions addressing the drugging context, the federal bill would likely provide greater protections for nursing home residents in this state.

Iowa

Iowa Code – Title IV – Public Health, Subtitle 3 – Health Related Professions, Chapter 147 – General Provisions, Health-Related Professions, Malpractice, Section 147.137 – Consent in Writing³⁶

A) Consent in writing to any medical or surgical procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given. Consent in writing meets the requirements of this section if it:

1. Sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable.
2. Acknowledges that the disclosure of that information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.
3. Is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, is signed by a person who has legal authority to consent on behalf of that patient in those circumstances.

CHAPTER 81 NURSING FACILITIES - DIVISION I. GENERAL POLICIES 441—81.1(249A)

Definitions.³⁷

³⁶ Accessed at <http://coolice.legis.iowa.gov/Cool-ICE/default.asp?category=billinfo&service=iowaCode&input=147.137>.

³⁷ Source: Human Services Policy Manual. Available at http://www.dhs.state.ia.us/policyanalysis/PolicyManualPages/Manual_Documents/Rules/441-81.pdf.

Informed consent” means a resident’s agreement to allow something to happen that is based on a full disclosure of known facts and circumstances needed to make the decision intelligently, i.e., with knowledge of the risks involved or alternatives.

Resident’s Bill of Rights

481—58.39 (135C) Residents’ rights in general.³⁸

58.39(9) Each resident or responsible party shall be fully informed by a physician of the resident’s health and medical condition unless medically contraindicated (as documented by a physician in the resident’s record). Each resident shall be afforded the opportunity to participate in the planning of the resident’s total care and medical treatment, which may include, but is not limited to, nursing care, nutritional care, rehabilitation, restorative therapies, activities, and social work services. Each resident only participates in experimental research conducted under the U.S. Department of Health and Human Services protection from research risks policy and then only upon the resident’s informed written consent. Each resident has the right to refuse treatment except as provided by Iowa Code chapter 229. In the case of a confused or mentally retarded individual, the responsible party shall be informed by the physician of the resident’s medical condition and be afforded the opportunity to participate in the planning of the resident’s total care and medical treatment, to be informed of the medical condition, and to refuse to participate in experimental research.(II)

a. The requirement that residents shall be informed of their conditions, involved in the planning of their care, and advised of any significant changes in either shall be communicated to every physician responsible for the medical care of residents in the facility. (II)

b. The administrator or designee shall be responsible for working with attending physicians in the implementation of this requirement. (II)

c. If the physician determines or in the case of a confused or intellectually disabled resident the responsible party determines that informing the resident of the resident’s condition is contraindicated, this decision and reasons for it shall be documented in the resident’s record by the physician. (II)

d. The resident’s plan of care shall be based on the physician’s orders. It shall be developed upon admission by appropriate facility staff and shall include participation by the resident if capable. Residents shall be advised of alternative courses of care and treatment and their consequences when such alternatives are available. The resident’s preference about alternatives shall be elicited and honored if feasible.

³⁸ Accessed at

[http://search.legis.state.ia.us/nxt/gateway.dll/ar/iac/4810_inspections%20and%20appeals%20department%205b481_5d/0580_chapter%2058%20nursing%20facilities/ r 4810 0580_0390.xml?fn=document-frame.htm\\$f=templates\\$3.0](http://search.legis.state.ia.us/nxt/gateway.dll/ar/iac/4810_inspections%20and%20appeals%20department%205b481_5d/0580_chapter%2058%20nursing%20facilities/ r 4810 0580_0390.xml?fn=document-frame.htm$f=templates$3.0)

Summary and Analysis:

- Iowa's medical malpractice laws include informed consent provisions that are, generally speaking, similar to the standards in the proposed federal bill. Iowa's law is more protective in one important respect: it requires consent in writing. The proposed federal bill does not specify whether patients must provide consent in writing or orally.
- Iowa's nursing home law also references informed consent which is helpful in providing clarity that general patient care requirements are applicable to nursing homes as well (though nursing homes are not exempt from general state laws they are sometimes, inappropriately, treated as such).
- Importantly, the Iowa law includes several provisions that specify how the physician and nursing home administrator are to be involved in planning resident care and informing the resident of his or her options and treatment alternatives.
- Because of the specificity in which informed consent is addressed in Iowa law, the federal bill would probably not provide for stronger resident protections in this state.

Kansas

Kansas Statutes Annotated- Ch. 59 Probate Code- Art. 29 Care and Treatment for Mentally Ill Persons- .78 Rights of Patients³⁹

(a) Every patient being treated in any treatment facility, in addition to all other rights preserved by the provisions of this act, shall have the following rights:

(6) not to be subject to such procedures as psychosurgery, electroshock therapy, experimental medication, aversion therapy or hazardous treatment procedures without the written consent of the patient or the written consent of a parent or legal guardian, if such patient is a minor or has a legal guardian provided that the guardian has obtained authority to consent to such from the court which has venue over the guardianship following a hearing held for that purpose;

(7) to have explained, the nature of all medications prescribed, the reason for the prescription and the most common side effects and, if requested, the nature of any other treatments ordered...

Summary and Analysis:

- Kansas lacks an informed consent law that pertains to nursing home residents.

³⁹ Accessed at http://kansasstatutes.lesterama.org/Chapter_59/Article_29/#59-2978.

- The informed consent law excerpted above applies to people in a mental health treatment facility.
- Kansas also has informed consent statutes that relate to abortion (KSA 65-6709), infants (65-1,157a) and refusal of medication/treatment laws pertaining to labor and industry determinations (44-556), abortions (65-28, 103), infectious diseases (65-129b).
- While Kansas has numerous informed consent laws, none of them relate to nursing home resident care. Thus, the federal bill would provide entirely new protections for nursing home residents in this state.

Kentucky

Kentucky Revised Statutes– Title XVIII – Public Health, Chapter 216 – Health Facilities and Services, Long-Term Care Facilities, Section 216.515 – Rights of Residents – Duties of Facilities – Actions.⁴⁰

Every resident in a long-term-care facility shall have at least the following rights:

(26) Any resident whose rights as specified in this section are deprived or infringed upon shall have a cause of action against any facility responsible for the violation. The action may be brought by the resident or his guardian. The action may be brought in any court of competent jurisdiction to enforce such rights and to recover actual and punitive damages for any deprivation or infringement on the rights of a resident. Any plaintiff who prevails in such action against the facility may be entitled to recover reasonable attorney's fees, costs of the action, and damages, unless the court finds the plaintiff has acted in bad faith, with malicious purpose, or that there was a complete absence of justifiable issue of either law or fact. Prevailing defendants may be entitled to recover reasonable attorney's fees. The remedies provided in this section are in addition to and cumulative with other legal and administrative remedies available to a resident and to the cabinet.

KRS Chapter 199 - PROTECTIVE SERVICES FOR CHILDREN - ADOPTION -199.011Definitions for chapter.⁴¹

(14) "Voluntary and informed consent" means that at the time of the execution of the consent the consenting person was fully informed of the legal effect of the consent, that the consenting person was not given or promised anything of value except those expenses allowable under

⁴⁰ Accessed at <http://www.lrc.ky.gov/statutes/chapter.aspx?id=38222>.

⁴¹ Accessed at <http://www.lrc.ky.gov/statutes/chapter.aspx?id=38096>.

KRS 199.590(6), that the consenting person was not coerced in any way to execute the consent, and that the consent was voluntarily and knowingly given. If at the time of the execution of the consent the consenting person was represented by independent legal counsel, there shall be a presumption that the consent was voluntary and informed. The consent shall be in writing, signed and sworn to by the consenting person and include....

Summary and Analysis:

- Kentucky law has basic residents' rights provisions that largely follow federal minimum standards. In addition, as excerpted above, Kentucky law provides for a private right of action for infringement of the rights of a resident.
- The language excerpted above from KRS Chapter 199 relates to informed consent in adoption. It is included here as an example of informed consent language that specifically addresses issues such as coercion, and includes not only a requirement that consent be in writing but also that it be signed and sworn to by the person consenting.
- There are no provisions in Kentucky law providing for informed consent either specifically for nursing home residents or for patients in general. Thus, the federal bill would provide stronger protections for nursing home residents in the state.

Louisiana

Louisiana Revised Statutes– Title 40 – Public Health and Safety, Part 22 – Uniform Consent Law, Section 40:1299.39.5 – Consent to Medical Treatment; Methods of Obtaining Consent⁴²

A. Notwithstanding any other law to the contrary, written consent to medical treatment means the voluntary permission of a patient, through signature, marking, or affirmative action through electronic means pursuant to R.S. 40:1299.40.1, to any medical or surgical procedure or course of procedures which sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures; acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner; and is evidenced by a signature, marking, or affirmative action through electronic means, by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances. Such consent shall

⁴² Accessed at <http://www.legis.state.la.us/lss/lss.asp?folder=114>.

be presumed to be valid and effective, in the absence of proof that execution of the consent was induced by misrepresentation of material facts.

Louisiana Administrative Code- Title 48 – Public Health –General, Chapter 97. Nursing Homes, Subchapter C. Resident Rights, §9733. Statement of Rights and Responsibilities⁴³

6. the right to be adequately informed of his medical condition and proposed treatment, unless otherwise indicated by the resident's physician; to participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by the resident's physician; and to be informed of the consequences of such actions;

9. the right to be treated courteously, fairly, and with the fullest measure of dignity and to receive a written statement and oral explanations of the services provided by the home, including statements and explanations required to be offered on an as-needed basis;

10. the right to be free from mental and physical abuse and from physical and chemical restraints, except those restraints authorized by the attending physician for a specified and limited period of time or those necessitated by an emergency:

- a. in case of an emergency, restraint may only be applied by a qualified licensed nurse, who shall set forth, in writing, the circumstances requiring the use of the restraint, and, in case of a chemical restraint, the attending physician shall be consulted immediately thereafter;
- b. restraints shall not be used in lieu of staff supervision or merely for staff convenience or resident punishment, or for any reason other than resident protection or safety....

Summary and Analysis:

- Louisiana’s public health law (Title 40) includes a provision providing for informed consent that specifies written.
- This right is not referenced in the state’s nursing home law (Title 48). However, the resident’s rights section of that law, in addition to the typical provisions following federal requirements, provides for the right “to receive a written statement and oral explanations of the services provided by the home, including statements and explanations required to be offered on an as-needed basis....” This lends support to the argument that the basic resident’s rights to participate in care planning and reject proposed treatment encompass the right to informed consent.

⁴³ Accessed at <http://doa.louisiana.gov/osr/lac/lac48.htm>.

- The resident’s rights provision relating to freedom from physical and chemical restraints is included in the excerpt above because of its strong language curtailing the use of such restraints.
- While the public health law defines informed consent it does not include language providing an affirmative right to it. We were unable to find language that asserted such a right.
- Thus, the federal bill would likely provide stronger protections for Louisiana nursing home residents.

Maine

Code of Maine Rules -14-193 Dept. of Human Services- Office of Adult Mental Health. Ch.1 Rights of Recipients of Mental Health Services-Part B. Rights in Inpatient and Residential Settings⁴⁴

A. Right to informed consent. Recipients have the right to informed consent for all treatment.
 D. Informed consent to treatment. Informed consent to treatment is obtained only where the recipient possesses capacity to make a reasoned decision regarding the treatment, the recipient or the recipient's guardian is provided with adequate information concerning the treatment, and the recipient or guardian makes a voluntary choice in favor of the treatment. Informed consent must be documented in each case in accordance with this section.

4. Documentation. The informed consent of a recipient or his or her guardian to a particular treatment shall be documented to show:

- a. From whom consent is obtained, whether recipient or guardian;
- b. If consent is given by the recipient, a signed statement that the recipient possesses capacity to give informed consent;
- c. That adequate information, including at a minimum all the elements listed in section D(2) of this rule, was provided;
- d. The signature of the recipient or, where applicable, the signature of a guardian, indicating consent. In residential programs, a signature is necessary for psychotropic medication treatment only.

e. Exceptions to Written Consent

In cases of unanticipated treatment needs, the informed consent of a guardian may be obtained by telephone, but that oral consent shall be confirmed in writing in accordance with this section as soon as practicable.

⁴⁴ Accessed at <http://www.maine.gov/sos/cec/rules/10/chaps10.htm#193>.

Summary and Analysis:

- The Maine Law for Mental Health Services establishes strict informed consent standards. However, this applies specifically to individuals receiving services in or from a mental health facility, agency or program. It does not appear to apply to nursing home residents. Maine's legal provisions for nursing home residents' rights are silent as to informed consent.
- Following is an overview of the informed consent provisions in the mental health services law, included here because we believe that their strength and specificity are instructive to the discussion of such rights for nursing home residents.
 - The law specifies the necessary steps to achieving informed consent for patients with capacity and those who lack capacity.
 - It establishes a standard for the amount of information and documentation that must be provided for the recipient of a treatment in Section (D2).
 - Section (D4) requires informed consent to be documented and provides requirements for the written consent to be considered valid. This provision offers a high level of protection for the patient because written consent provides proof of the patient's involvement with their own treatment and their execution of their patients rights.
- Because Maine's informed consent law does not appear to extend to nursing home care, the federal bill would strengthen protections for nursing home residents in this state.

Maryland

Code of Maryland Regulations - Title 10 Department of Health and Mental Hygiene- Subtitle 07 Hospitals- Chapter 09 Residents' Bill of Rights: Comprehensive Care Facilities and Extended Care Facilities- .08 Resident's Rights and Services.⁴⁵

C. A resident has the right to:

- (8) Be fully informed in advance about care and treatment, and of proposed changes in that care or treatment;
- (9) Participate in planning care and treatment, or changes in care or treatment;
- (11) Consent to or refuse treatment, including the right to accept or reject artificially administered sustenance in accordance with State law....

⁴⁵ Accessed at <http://www.dsd.state.md.us/comar/getfile.aspx?file=10.07.09.08.htm>.

E. The resident or, when applicable, the resident's health care representative, has the right to be fully informed, in a language that the resident or representative can reasonably be expected to understand, of complete and current information about the resident's diagnosis, treatment, and prognosis, unless it would be medically inadvisable as documented by the resident's attending health care provider. If this determination has been made, the health care provider shall, upon written request:

- (1) Make a summary of the undisclosed portion of the medical record available to the resident or health care representative;
- (2) Insert a copy of the summary in the medical record of the resident;
- (3) Permit examination and copying of the medical record by another health care provider; and
- 4) Inform the resident or health care representative of the resident's or health care representative's right to select another health care provider.

Summary and Analysis:

- Maryland's residents' rights law (10.07.09.08) includes similar provisions to current federal requirements in terms of the rights to be informed about care and refuse treatment. In addition, it explicitly provides for a resident's right to "consent to or refuse treatment...." However, it does not provide any explanation or detail in this regard.
- The federal bill likely would offer a higher level of protection for residents by setting specific parameters for informed consent, such as by establishing when informed consent should be obtained and what the protocol should be.

Massachusetts

Massachusetts General Laws Annotated- Ch. 111.Public Health Section 70E – Patients' or Residents' Rights.⁴⁶

Every patient or resident of a facility shall have the right:

(l) to informed consent to the extent provided by law....

Every patient or resident of a facility shall be provided by the physician in the facility the right:

(a) to informed consent to the extent provided by law....

⁴⁶ Accessed on the Commonwealth of Massachusetts' website at <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section70E>.

Massachusetts General Laws, Part I, Title XVI Public Health, Chapter 111L Biotechnology, Section 2 Definitions⁴⁷

“Informed consent”, the written consent for the donation of gametes or embryos used for research conducted pursuant to this chapter which complies with the requirements of a duly appointed institutional review board, acting in accordance with 45 C.F.R. 46.116 and 45 C.F.R. 46.117, as may be amended from time to time. The written consent shall be in a language understandable to the donor or patient and shall include all reasonably foreseeable risks, discomforts or benefits of the procedure to the donor or patient.

Summary and Analysis:

- Massachusetts’ residents’ rights law (111-70E) provides that every patient or resident in a facility has the right to informed consent. However, it does not state any specific requirements, other than “to the extent provided by law.”
- In addition, there are no indications of what Massachusetts deems qualifies as valid informed consent, including when or by whom such consent must be obtained or in what form (verbal or written). The Massachusetts statute appears to lack protocol for how informed consent should be obtained altogether.
- Informed consent is addressed more expansively in other sections of the Massachusetts Public Health Law, such as those relating to HIV testing ,consent to abortion for women under 18 and in the chapter on biotechnology (as excerpted above). In the context of biotechnology, written consent is required, and the writing must be in language understandable to the patient and include a description of the foreseeable risks and benefits.
- Though informed consent is described or defined in other sections of the public health law, the absence of a definition specifically related to the requirements under residents rights indicates that it is likely that the proposed federal law would provide more protections for residents of nursing homes in this state.

⁴⁷ Accessed at

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111L/Section2>.

Michigan

Michigan Public Health Code – Section 333.21734 Nursing home; bed rails; provisions; guidelines; liability.⁴⁸

(1) ...[A] nursing home shall give each resident who uses a hospital-type bed or the resident's legal guardian, patient advocate, or other legal representative the option of having bed rails. A nursing home shall offer the option to new residents upon admission and to other residents upon request. Upon receipt of a request for bed rails, the nursing home shall inform the resident or the resident's legal guardian, patient advocate, or other legal representative of alternatives to and the risks involved in using bed rails. A resident or the resident's legal guardian, patient advocate, or other legal representative has the right to request and consent to bed rails for the resident. A nursing home shall provide bed rails to a resident only upon receipt of a signed consent form authorizing bed rail use and a written order from the resident's attending physician that contains statements and determinations regarding medical symptoms and that specifies the circumstances under which bed rails are to be used. For purposes of this subsection, "medical symptoms" includes the following:

- (a) A concern for the physical safety of the resident.
- (b) Physical or psychological need expressed by a resident. A resident's fear of falling may be the basis of a medical symptom.

(2) A nursing home that provides bed rails under subsection (1) shall do all of the following:

- (a) Document that the requirements of subsection (1) have been met.
- (b) Monitor the resident's use of the bed rails.
- (c) In consultation with the resident, resident's family, resident's attending physician, and individual who consented to the bed rails, periodically reevaluate the resident's need for the bed rails.

Michigan Administrative Code- Michigan Department of Community Health (R 330.7001 through R 330.7260)- Bureau of Mental Health & Substance Abuse Services- Rights of Recipients- Part 7. Rights of Recipients- Subpart 1. General Provisions- Mich. Admin. Code R. 330.7003- Informed consent⁴⁹

⁴⁸ Accessed at

<http://www.legislature.mi.gov/%28S%285p0qtc55q34yvy45yfchxj55%29%29/mileg.aspx?page=getobject&objectname=mcl-333-21734&query=on&highlight=consent>.

⁴⁹ Accessed on page 3 at http://www7.dleg.state.mi.us/WebORRGSA/969_2011-007CH_AdminCode.pdf.

(1) All of the following are elements of informed consent:

(a) Legal competency. An individual shall be presumed to be legally competent. This presumption may be rebutted only by a court appointment of a guardian or exercise by a court of guardianship powers and only to the extent of the scope and duration of the guardianship. An individual shall be presumed legally competent regarding matters that are not within the scope and authority of the guardianship.

(b) Knowledge. To consent, a recipient or legal representative must have basic information about the procedure, risks, other related consequences, and other relevant information. The standard governing required disclosure by a doctor is what a reasonable patient needs to know in order to make an informed decision. Other relevant information includes all of the following:

(i) The purpose of the procedures.

(ii) A description of the attendant discomforts, risks, and benefits that can reasonably be expected.

(iii) A disclosure of appropriate alternatives advantageous to the recipient.

(iv) An offer to answer further inquiries.

(c) Comprehension. An individual must be able to understand what the personal implications of providing consent will be based upon the information provided under subdivision (b) of this subrule.

(d) Voluntariness. There shall be free power of choice without the intervention of an element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion, including promises or assurances of privileges or freedom. There shall be an instruction that an individual is free to withdraw consent and to discontinue participation or activity at any time without prejudice to the recipient.

(2) A provider shall establish written policies that include procedures for evaluating comprehension and for assuring disclosure of relevant information and measures to ensure voluntariness before obtaining consent. The policies and procedures shall specify for specific circumstances the types of information that shall be disclosed and steps that may be taken to protect voluntariness. The procedures shall include a mechanism for determining whether guardianship proceedings should be considered.

(3) Informed consent shall be reobtained if changes in circumstances substantially change the risks, other consequences, or benefits that were previously expected.

(4) A written agreement documenting an informed consent shall not include any exculpatory language through which the recipient, or a person consenting on the recipient's behalf, waives or appears to waive, a legal right, including a release of a provider or its agents from liability for negligence. The agreement shall embody the basic elements of informed consent in the

particular context. The individual, guardian, or parent consenting shall be given adequate opportunity to read the document before signing it. The requirement of a written consent shall not eliminate, where essential to the individual's understanding or otherwise deemed advisable, a reading of the document to the individual or an oral explanation in a language the individual understands. A note of the explanation and by whom made shall be placed in the record along with the written consent.

(5) A consent is executed when it is signed by the appropriate individual.

Summary and Analysis:

- Michigan's public health law relating to nursing home care (Article 17, Part 217, MCL 333.21701 to 333.21799e) only provides for informed consent in regard to the use of bed rails. In this context, nursing home residents are provided the option of using bedrails by the facility and, upon receiving a request to use bedrails by the resident or his/her representatives, the facility is obliged to inform them of the risks of bed rail use and alternatives. As detailed in the excerpted text, above, there are substantial requirements for facility documentation, periodic reevaluation by the facility and the development by the state agency of guidelines. Interestingly, in light of the FDA "Black Box Warning" against using antipsychotic with an elderly population, the Michigan law calls on the state agency to consider recommendation by the FDA on bedrails in establishing guidelines.
- The informed consent provision in Michigan's administrative code are robust but pertain specifically to individuals receiving psychiatric care, not nursing home residents. Following are some of the key provisions of the administrative code, included here because they might be constructive in the development of strong informed consent protections for nursing home residents in federal or state law.
 - Section (1B) provides requirements for information that must be given to a patient in order to consider the patient informed. These provisions include the purpose of the treatment, the risks and benefits, alternatives to treatment and require the facility to answer any questions the patient may have.
 - Informed consent must be obtained every time circumstances change substantially. This offers a high level of protection for the patient by ensuring that the patient or the patient's representative is able to participate in the treatment plan at all times.
 - The statute requires that informed consent be made in written form.
- Because Michigan law only provides for nursing home informed consent in the context of bed rail use the federal bill would likely provide stronger protections.

Minnesota

Minnesota Statutes – Chapter 144 - Department of Health, 144.651 HEALTH CARE BILL OF RIGHTS, Subd. 33. Restraints.⁵⁰

(a) Competent nursing home residents, family members of residents who are not competent, and legally appointed conservators, guardians, and health care agents as defined under section [145C.01](#), have the right to request and consent to the use of a physical restraint in order to treat the medical symptoms of the resident.

(b) Upon receiving a request for a physical restraint, a nursing home shall inform the resident, family member, or legal representative of alternatives to and the risks involved with physical restraint use. The nursing home shall provide a physical restraint to a resident only upon receipt of a signed consent form authorizing restraint use and a written order from the attending physician that contains statements and determinations regarding medical symptoms and specifies the circumstances under which restraints are to be used.

(c) A nursing home providing a restraint under paragraph (b) must:

- (1) document that the procedures outlined in that paragraph have been followed;
- (2) monitor the use of the restraint by the resident; and
- (3) periodically, in consultation with the resident, the family, and the attending physician, reevaluate the resident's need for the restraint.

(d) A nursing home shall not be subject to fines, civil money penalties, or other state or federal survey enforcement remedies solely as the result of allowing the use of a physical restraint as authorized in this subdivision. Nothing in this subdivision shall preclude the commissioner from taking action to protect the health and safety of a resident if:

- (1) the use of the restraint has jeopardized the health and safety of the resident; and
- (2) the nursing home failed to take reasonable measures to protect the health and safety of the resident.

(e) For purposes of this subdivision, "medical symptoms" include:

- (1) a concern for the physical safety of the resident; and
- (2) physical or psychological needs expressed by a resident. A resident's fear of falling may be the basis of a medical symptom.

A written order from the attending physician that contains statements and determinations regarding medical symptoms is sufficient evidence of the medical necessity of the physical restraint.

(f) When determining nursing facility compliance with state and federal standards for the use of physical restraints, the commissioner of health is bound by the statements and determinations contained in the attending physician's order regarding medical symptoms. For purposes of this

⁵⁰ Accessed at <https://www.revisor.mn.gov/statutes/?id=144.651&year=2012>.

order, "medical symptoms" include the request by a competent resident, family member of a resident who is not competent, or legally appointed conservator, guardian, or health care agent as defined under section [145C.01](#), that the facility provide a physical restraint in order to enhance the physical safety of the resident.

Minnesota Statutes – Public Welfare and Related Activities, Chapter 253B – Civil Commitment, 253B.03 – Rights of Patients, Subdivision 6 – Consent for medical procedure⁵¹

A patient has the right to prior consent to any medical or surgical treatment, other than treatment for chemical dependency or noninvasive treatment for mental illness.

The following procedures shall be used to obtain consent for any treatment necessary to preserve the life or health of any committed patient:

- (a) The written, informed consent of a competent adult patient for the treatment is sufficient.
- (b) If the patient is subject to guardianship which includes the provision of medical care, the written, informed consent of the guardian for the treatment is sufficient.
- (c) If the head of the treatment facility determines that the patient is not competent to consent to the treatment and the patient has not been adjudicated incompetent, written, informed consent for the surgery or medical treatment shall be obtained from the nearest proper relative. For this purpose, the following persons are proper relatives, in the order listed: the patient's spouse, parent, adult child, or adult sibling. If the nearest proper relatives cannot be located, refuse to consent to the procedure, or are unable to consent, the head of the treatment facility or an interested person may petition the committing court for approval for the treatment or may petition a court of competent jurisdiction for the appointment of a guardian. The determination that the patient is not competent, and the reasons for the determination, shall be documented in the patient's clinical record.

Summary and Analysis:

- Minnesota's resident's rights law (Chapter 144) does not confer a right to informed consent. The only informed consent provisions identified relate to care of individuals who have been committed to an institution (Chapter 253B).
- Chapter 253B is excerpted above because it sets very explicit standards for obtaining consent from a resident with capacity, a resident's guardian, an incapacitated resident's close family member, or, if necessary, obtaining consent in an emergency. This multi-tiered approach to obtaining consent is protective in the sense that it helps ensure that an institutionalized patient (or his/her surrogate) is always involved in the medical decision-making process, even in an emergency situation.

⁵¹ Accessed at http://statutes.laws.com/minnesota/245-267/253B/253B_03.

- Subdivision 33 of the health care bill of rights law is included here because it addresses, in depth, consent requirements for the use of physical restraints. It is noteworthy, however, that these requirements are predicated on a request for the use of restraints by resident, or his/her family or other representatives.
- Because Minnesota law does not explicitly provide for informed consent for nursing home resident care, the federal law would likely provide stronger protections.

Missouri

Rules of Department of Health and Senior Services, Division 30—Division of Regulation and Licensure Chapter 88—Resident’s Rights and Handling, Resident Funds and Property in Long-Term Care Facilities⁵²

(13) Each resident shall be afforded the opportunity to participate in the planning of his or her total care and medical treatment, to refuse treatment and to participate in experimental research only upon his or her informed written consent. If a resident refuses treatment, this refusal shall be documented in the resident’s record and the resident, his or her legally authorized representatives or designees, or both, shall be informed of possible consequences of not receiving treatment.

Summary and Analysis:

- Missouri’s resident’s rights law does not provide for informed consent except in the case of a resident’s participation in experimental treatment.
- Thus, the federal bill would likely provide stronger protections for nursing home residents in this state.

Montana

Montana Ann. Code – Title 50 – Health and Safety, Chapter 5 – Hospitals and Related Facilities, Part 11 – Long-Term Health Care Facilities, section 50-5-1104 – Rights of Long-Term Care Facility Residents⁵³

(1) The state adopts by reference for all long-term care facilities the rights for long-term care facility residents applied by the federal government to facilities that provide skilled nursing care

⁵² Accessed at www.sos.mo.gov/adrules/csr/current/19csr/19c30-88.pdf.

⁵³ Accessed at <http://law.justia.com/codes/montana/2005/50/50-5-1104.html>.

or intermediate nursing care and participate in a Medicaid or Medicare program (42 U.S.C. 1395i-3(a) and 1396r(a), as implemented by regulation).

(2) In addition to the rights adopted under subsection (1), the state adopts for all residents of long-term care facilities the following rights:

(f) During a resident's stay in a long-term care facility, the resident retains the prerogative to exercise decision-making rights in all aspects of the resident's health care, including placement and treatment issues such as medication, special diets, or other medical regimens.

Montana Code Annotated- Title 53. Social Services and Institutions- Ch. 21 Mentally Ill- Part 13. Mental Health Care Advance Directives- 01. Purpose⁵⁴

The purpose of this part is to:

(2) recognize the right of any person who has capacity to give or withhold informed consent for mental health services.

Summary and Analysis:

- Montana's nursing home law (Title 50) provides for a resident's right to make decisions about his or her care, but does not provide for a specific right to informed consent.
- Montana's mental health care law (Title 53) states that a mental health patient has the right to informed consent for a mental health service. This indicates that Montana recognizes an individual's right to informed consent in the context of mental health care. However, we were unable to identify language indicating whether or not this right is limited to mental health care in certain settings and/or among certain populations. Based upon its placement in this chapter of the law it likely pertains only to individuals being treated for "serious" mental illness (as the title of part one of this chapter implies).
- Because the informed consent law for mental health care is vague and a general informed consent law does not exist, the federal bill would likely provide stronger protections for residents in this state.

⁵⁴ Accessed at <http://leg.mt.gov/bills/mca/53/21/53-21-1301.htm>.

Nebraska

Nebraska Revised Statutes – Chapter 44 – Insurance, Article 28 – Nebraska Hospital-Medical Liability Act.

Section 44-2816. Definition of Informed Consent.⁵⁵

Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities. Failure to obtain informed consent shall include failure to obtain any express or implied consent for any operation, treatment, or procedure in a case in which a reasonably prudent health care provider in the community or similar communities would have obtained an express or implied consent for such operation, treatment, or procedure under similar circumstances.

Section 44-2820. Action based on failure to obtain informed consent; burden of proof.⁵⁶

Before the plaintiff may recover any damages in any action based on failure to obtain informed consent, it shall be established by a preponderance of the evidence that a reasonably prudent person in the plaintiff's position would not have undergone the treatment had he or she been properly informed and that the lack of informed consent was the proximate cause of the injury and damages claimed.

Summary and Analysis:

- Nebraska's definition of informed consent requires healthcare providers to provide information to a resident that would "ordinarily" be communicated in a similar practice or locality. This requirement closely resembles a reasonable person standard.
- The law does not specify who must provide information, how it is to be provided or the manner in which consent must be given.
- Section 44-2820 undermines the right to informed consent in its requirement that a cause of action (lawsuit) for failure to obtain informed consent will only succeed if a "reasonably prudent person in the plaintiff's position" would not have undergone the treatment. Since, under federal law, a nursing home resident may refuse any treatment, even if doing so would be detrimental, this sets a significantly higher bar.
- Because of these limitations, the proposed federal bill would likely provide stronger protections to Nebraska nursing home residents than those that exist under state law.

⁵⁵ Accessed at <http://nebraskalegislature.gov/laws/statutes.php?statute=44-2816>.

⁵⁶ Accessed at <http://nebraskalegislature.gov/laws/statutes.php?statute=44-2820>.

Nevada

Nevada Revised Statutes – Title 40 – Public Health and Safety, Chapter 449 – Medical and Other Related Facilities, Patient’s Rights, 449.710 – Specific Rights: Information concerning facility; treatment; billing.⁵⁷

Every patient of a medical facility or facility for the dependent has the right to:

5. Receive from his or her physician a complete and current description of the patient's diagnosis, plan for treatment and prognosis in terms which the patient is able to understand. If it is not medically advisable to give this information to the patient, the physician shall:
 - (a) Provide the information to an appropriate person responsible for the patient; and
 - (b) Inform that person that he or she shall not disclose the information to the patient.

6. Receive from his or her physician the information necessary for the patient to give his or her informed consent to a procedure or treatment. Except in an emergency, this information must not be limited to a specific procedure or treatment and must include:
 - (a) A description of the significant medical risks involved;
 - (b) Any information on alternatives to the treatment or procedure if the patient requests that information;
 - (c) The name of the person responsible for the procedure or treatment; and
 - (d) The costs likely to be incurred for the treatment or procedure and any alternative treatment or procedure.

Summary and Analysis:

- Nevada’s informed consent law is a part of the patients’ rights section of the state’s public health code.
- The state’s informed consent law is stronger than the federal bill in regard to the state’s requirement that a physician provide the information necessary for the resident to provide informed consent. Since the federal bill only requires the prescriber of medication to be involved in the information process, the state’s law is more protective in this respect.
- However, the state statute does not specify when the facility must obtain informed consent or in what manner informed consent should be obtained. In regard to these issues, the federal bill would offer more protection for patients.

⁵⁷ Accessed at <http://statutes.laws.com/nevada/title-40/chapter-449/patient-s-rights/449-710>.

New Hampshire

New Hampshire Revised Statutes – Title XI – Hospitals and Sanitaria, Chapter 151 – Residential Care and Health-Facility Licensing, Patients’ Bill of Rights, 151:21 – Patients’ Bill of Rights.⁵⁸

The policy describing the rights and responsibilities of each patient admitted to the facility shall include, as a minimum, the following:

IV. The patient shall be fully informed by a health care provider of his or her medical condition, health care needs, and diagnostic test results, including the manner by which such results will be provided and the expected time interval between testing and receiving results, unless medically inadvisable and so documented in the medical record, and shall be given the opportunity to participate in the planning of his or her total care and medical treatment, to refuse treatment, and to be involved in experimental research upon the patient's written consent only. For the purposes of this paragraph "health care provider" means any person, corporation, facility, or institution either licensed by this state or otherwise lawfully providing health care services, including, but not limited to, a physician, hospital or other health care facility, dentist, nurse, optometrist, podiatrist, physical therapist, or psychologist, and any officer, employee, or agent of such provider acting in the course and scope of employment or agency related to or supportive of health care services.

Summary and Analysis:

- New Hampshire law does not explicitly provide for informed consent, except in the case of participation in experimental research.
- The proposed federal bill would likely provide stronger protections for nursing home residents in this state.

New Jersey

2013 New Jersey Revised Statutes, Title 30 - INSTITUTIONS AND AGENCIES, Section 30:13-3 - Responsibilities of nursing homes.⁵⁹

⁵⁸ Accessed at <http://www.gencourt.state.nh.us/rsa/html/xi/151/151-21.htm>.

⁵⁹ Accessed at <http://law.justia.com/codes/new-jersey/2013/title-30/section-30-13-3/>.

3. Every nursing home shall have the responsibility for:

d. Ensuring that an applicant for admission or a resident is treated without discrimination as to age, race, religion, sex or national origin. However, the participation of a resident in recreational activities, meals or other social functions may be restricted or prohibited if recommended by a resident's attending physician in writing and consented to by the resident.

e. Ensuring that no resident shall be subjected to physical restraints except upon written orders of an attending physician for a specific period of time when necessary to protect such resident from injury to himself or others. Restraints shall not be employed for purposes of punishment or the convenience of any nursing home staff personnel. The confinement of a resident in a locked room shall be prohibited.

f. Ensuring that drugs and other medications shall not be employed for purposes of punishment, for convenience of any nursing home staff personnel or in such quantities so as to interfere with a resident's rehabilitation or his normal living activities.

**2013 New Jersey Revised Statutes, Title 26 - HEALTH AND VITAL STATISTICS,
26:14-4 Informed consent defined; use.⁶⁰**

4. As used in this act, "informed consent" means the authorization given pursuant to this act to participate in medical research performed on a subject after each of the following conditions has been satisfied:

a. The subject or his guardian, or authorized representative as provided in section 5 of this act, as applicable, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's guardian or authorized representative is fluent, of the following facts that include:

(1) an explanation of the procedures to be followed in the research and any drugs or devices to be utilized, including the purposes of the procedures, drugs, or devices and, when applicable, the use of placebo controls and the process by which persons will be assigned to control groups;

(2) a description of any attendant discomfort and reasonably foreseeable risks to the subject;

(3) an explanation of any potential direct benefits to the subject. If no such direct benefits are reasonably expected, that fact should be made clear;

(4) a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits;

(5) an estimate of the expected duration of the research procedure or study;

(6) an offer to answer any inquiries concerning the research or the procedures involved and an explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury;

⁶⁰ Accessed at <http://law.justia.com/codes/new-jersey/2013/title-26/section-26-14-4/>.

- (7)an instruction to the subject or his guardian or authorized representative, as applicable, that he is free to withdraw his prior consent to the medical experiment and discontinue participation in the research at any time, without prejudice to the subject;
- (8)the name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the research;
- (9)the name of the sponsor or funding source, if any, or manufacturer if the research involves a drug or device, and the organization, if any, under whose general aegis the research is being conducted;
- (10) the name, address, and phone number of an impartial third party, not associated with the research, to whom the subject may address complaints about the research and the contact information for the institutional review board connected with the research; and
- (11) the material financial stake or interest, if any, that the investigator or research institution has in the research. For purposes of this section, "material" means \$10,000 or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned or as otherwise determined by the research institution.
- b. The subject or his guardian or authorized representative, as applicable, has signed and dated a written consent form.
- c. The written consent form is signed and dated by a person, who is not the subject, his guardian or authorized representative, or the researcher, and who can attest that the requirements for informed consent to the medical research have been satisfied.
- d. Consent is given voluntarily and freely by the subject or his guardian or authorized representative without the intervention of force, fraud, deceit, duress, coercion or undue influence.

Summary and Analysis:

- New Jersey's nursing home law has a provision on resident's rights that largely follows federal requirements. It does not provide for a specific right to informed consent.
- The state law has a section (30:13-3) on nursing home requirements which likewise does not specify a general right to informed consent but which does include parameters for obtaining consent from a resident and for the use of physical restraints and drugs.
- New Jersey's law providing informed consent (26:14-4) relates only to participation in research. It is included here because it has numerous provisions that would be useful in the development of informed consent requirements with broader applicability.
- Because New Jersey law does not provide specific patient or resident informed consent rights the federal bill would likely provide stronger protections for residents in this state.

New Mexico

New Mexico Administrative Code – Title 7 – Health, Chapter 9 – Nursing Homes and Intermediate Care Facilities, Part 2 – Requirements for Long Term Care Facilities. 7.9.2.38 – Removals From the Facility⁶¹

The provisions of this section shall apply to all resident removals.

A. CONDITIONS: No resident may be temporarily or permanently removed from this facility except:

(1) Voluntary removal: Upon the request or with the informed consent of the resident or guardian.

New Mexico Statutes- Ch. 43 Commitment Procedures- Art. 1 Mental Health and Developmental Disabilities- .15 Consent to treatment; adult clients⁶²

A) No psychotropic medication, psychosurgery, convulsive therapy, experimental treatment or behavior modification program involving aversive stimuli or substantial deprivations shall be administered to a client without proper consent. If the client is capable of understanding the proposed nature of treatment and its consequences and is capable of informed consent, the client's consent shall be obtained before the treatment is performed. A client shall not be presumed to be incapable of giving consent for administration of psychotropic medications solely because the client has been involuntarily committed to a treatment facility or is awaiting a hearing on whether the client should be involuntarily committed to a treatment facility.

Summary and Analysis:

- New Mexico's nursing home code only provides for informed consent in the cases of voluntary transfer, with numerous condition under which residents may be involuntarily transferred.
- Section (43-1-15) of the law provides for consent to treatment in the context of care for people with serious mental health and developmental disabilities. It does not apply to the general population or nursing home residents. In (A) the statute states that no patient shall be administered psychotropic medication without the patient's consent.

⁶¹ Accessed at <http://dhi.health.state.nm.us/>.

⁶² Accessed at <http://statutes.laws.com/new-mexico/chapter-43/article-1/section-43-1-15>.

Parts B through M (not included here) describe protocol for obtaining consent when a patient is deemed unable to provide consent.

- The federal bill would likely provide greater protection for New Mexico nursing home residents.

New York

New York Public Health Law, Article 28 – Hospitals, Section 2803(c) – Rights of patients in certain medical facilities⁶³

2. The commissioner shall require that every nursing home and facility providing health related service, as defined in subdivision two and paragraph (b) of subdivision four of section twenty-eight hundred one of this article, shall adopt and make public a statement of the rights and responsibilities of the patients who are receiving care in such facilities, and shall treat such patients in accordance with the provisions of such statement.

3. Said statement of rights and responsibilities shall include, but not be limited to the following:

a. Every patient's civil and religious liberties, including the right to independent personal decisions and knowledge of available choices, shall not be infringed and the facility shall encourage and assist in the fullest possible exercise of these rights.

e. Every patient shall have the right to receive adequate and appropriate medical care, to be fully informed of his or her medical condition and proposed treatment unless medically contraindicated, and to refuse medication and treatment after being fully informed of and understanding the consequences of such actions.

f. Every patient shall have the right to have privacy in treatment and in caring for personal needs, confidentiality in the treatment of personal and medical records, and security in storing personal possessions.

h. Every patient shall be free from mental and physical abuse and from physical and chemical restraints, except those restraints authorized in writing by a physician for a specified and limited period of time or as are necessitated by an emergency in which case the restraint may only be applied by a qualified licensed nurse who shall set forth in writing the circumstances requiring the use of restraint and in the case of use of a chemical restraint a physician shall be consulted within twenty-four hours.

Summary and Analysis:

- New York's public health law contains a provision on patients' rights. It follows the

⁶³ Accessed at <http://public.leginfo.state.ny.us>. Note that while the title specifies hospitals this section applies to "every nursing home and facility providing health related service."

rights iterated in current federal law and, likewise, does not provide for a right to informed consent.

- Importantly, as regards the right to be free from chemical (and physical) restraints, these patient rights do include a provision explicitly prohibiting the use of physical and chemical restraints, except when “authorized in **writing** by a physician for a specified and limited period of time or as are necessitated by an emergency in which case the restraint may only be applied by a qualified licensed nurse who shall set forth in **writing** the circumstances requiring the use of restraint and in the case of use of a chemical restraint a physician shall be consulted within twenty-four hours.” [Paragraph “h” above, emphases added here.]
- New York law does provide for informed consent in certain limited circumstances, such as for participation in experimental research ([Public Health Law §2442](#)), a “do not resuscitate” order (Public Health Law §2964), a hysterectomy (Public Health Law §2495) and, in the case of insurance companies, for HIV or genetic testing (Public Health Law [§2781](#) and §2611, respectively).
- Public Health Law §2805-d refers to informed consent in the context of medical, dental or podiatric malpractice claims. However, this section focuses on defenses to such claims and limitations thereto. It does not speak to how consent is to be given or by whom and it provides significant leeway for the medical professional’s discretion as a defense against culpability.
- Given the lack of a specific right to informed consent in a nursing home or other institutional setting, and the significant limitations on the rights to informed consent where they are provided for in the law (as described above), the proposed federal bill would likely provide stronger protections than those that exist in New York State law.

North Carolina

North Carolina General Statutes - Chapter 131E - Health Care Facilities and Services, Part 2. Nursing Home Patients' Bill of Rights.⁶⁴

115. Legislative intent.

It is the intent of the General Assembly to promote the interests and well-being of the patients in nursing homes and adult care homes licensed pursuant to G.S. 131E-102, and

⁶⁴ Accessed on page 47 at http://www.ncga.state.nc.us/EnactedLegislation/Statutes/pdf/ByChapter/Chapter_131E.pdf.

patients in a nursing home operated by a hospital which is licensed under Article 5 of Chapter 131E of the General Statutes. It is the intent of the General Assembly that every patient's civil and religious liberties, including the right to independent personal decisions and knowledge of available choices, shall not be infringed and that the facility shall encourage and assist the patient in the fullest possible exercise of these rights.

117. Declaration of patient's rights.

(4) To have on file in the patient's record a written or verbal order of the attending physician containing any information as the attending physician deems appropriate or necessary, together with the proposed schedule of medical treatment. The patient shall give prior informed consent to participation in experimental research. Written evidence of compliance with this subdivision, including signed acknowledgements by the patient, shall be retained by the facility in the patient's file....

North Carolina General Statutes - Chapter 90 — Medicine and Allied Occupations. 21.13. Informed consent to health care treatment or procedure.⁶⁵

(a) No recovery shall be allowed against any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient or the patient's spouse, parent, guardian, nearest relative or other person authorized to give consent for the patient where:

(1) The action of the health care provider in obtaining the consent of the patient or other person authorized to give consent for the patient was in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities; and

(2) A reasonable person, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities; or

(3) A reasonable person, under all the surrounding circumstances, would have undergone such treatment or procedure had he been advised by the health care provider in accordance with the provisions of subdivisions (1) and (2) of this subsection.

(b) A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be a valid consent....

⁶⁵ Accessed at http://law.justia.com/codes/north-carolina/2005/chapter_90/gs_90-21.13.html.

North Carolina General Statutes- Ch. 122C Mental Health, Developmental Disabilities and Substance Abuse Act of 1985- Art. 3 Clients Rights and Advance Instruction- Part 1 Client's Rights- § 122C-57. Right to treatment and consent to treatment⁶⁶

(a) Each client who is admitted to and is receiving services from a facility has the right to receive age-appropriate treatment for mental health, mental retardation, and substance abuse illness or disability. Each client within 30 days of admission to a facility shall have an individual written treatment or habilitation plan implemented by the facility. The client and the client's legally responsible person shall be informed in advance of the potential risks and alleged benefits of the treatment choices.

(b) Each client has the right to be free from unnecessary or excessive medication. Medication shall not be used for punishment, discipline, or staff convenience.

(c) Medication shall be administered in accordance with accepted medical standards and only upon the order of a physician as documented in the client's record.

(d) Each voluntarily admitted client or the client's legally responsible person (including a health care agent named pursuant to a valid health care power of attorney) has the right to consent to or refuse any treatment offered by the facility. Consent may be withdrawn at any time by the person who gave the consent. If treatment is refused, the qualified professional shall determine whether treatment in some other modality is possible. If all appropriate treatment modalities are refused, the voluntarily admitted client may be discharged. In an emergency, a voluntarily admitted client may be administered treatment or medication, other than those specified in subsection (f) of this section, despite the refusal of the client or the client's legally responsible person, even if the client's refusal is expressed in a valid advance instruction for mental health treatment. The Commission may adopt rules to provide a procedure to be followed when a voluntarily admitted client refuses treatment.

(e) In the case of an involuntarily committed client, treatment measures other than those requiring express written consent as specified in subsection (f) of this section may be given despite the refusal of the client, the client's legally responsible person, a health care agent named pursuant to a valid health care power of attorney, or the client's refusal expressed in a valid advance instruction for mental health treatment....

(f) Treatment involving electroshock therapy, the use of experimental drugs or procedures, or surgery other than emergency surgery may not be given without the express and informed written consent of the client, the client's legally responsible person, a health care agent named pursuant to a valid health care power of attorney, or the client's consent expressed in a valid advance instruction for mental health treatment.

This consent may be withdrawn at any time by the person who gave the consent. The Commission may adopt rules specifying other therapeutic and diagnostic procedures that

⁶⁶ Accessed at

http://www.ncleg.net/EnactedLegislation/Statutes/PDF/ByArticle/Chapter_122C/Article_3.pdf.

require the express and informed written consent of the client, the client's legally responsible person, or a health care agent named pursuant to a valid health care power of attorney.

Summary and Analysis:

- The legislative intent provided at the beginning of North Carolina's Nursing Home Patient's Bill of Rights (Chapter 131E) states that "the right to independent personal decisions and knowledge of available choices, shall not be infringed and that the facility shall encourage and assist the patient in the fullest possible exercise of these rights." However, informed consent is only addressed in one provision (4), relating solely to participation in experimental research.
- The state's malpractice law (Chapter 90) provides for informed consent, predicated on a reasonable person standard. The statute also states that "consent evidenced in writing" has a presumption of validity.
- Chapter 122C in the Mental Health, Developmental Disabilities and Substance Abuse Act of 1985 describes the rights to treatment and to consent to treatment for individuals receiving mental health care or treatment. It provides for an individuals right to consent or refuse treatment, and to withdraw consent at any time, within specific parameters.
- Section (a) of (122C-57) also states that the patient or the patient's representative must be informed of risks and benefits of treatments which is part of informed consent and section (d) adds that consent may be withdrawn at any time. It also provides that "electroshock therapy, the use of experimental drugs or procedures, or surgery other than emergency surgery may not be given without the express and informed written consent of the client..."
- While the explicit informed consent protections in North Carolina law do not apply in the context of the provision of nursing home care, they may be instructive in the development of state or federal protections in the future. However, because they do not provide protections for nursing home resident care (except as a safeguard for participation in experimental research), the federal bill would likely provide stronger protections for residents in this state.

North Dakota

North Dakota Code – Title 50 – Public Welfare, Chapter 50.10-2 – Rights of Health Care Facility Residents, section 50.10.2-02 – Residents’ Rights – Implementation⁶⁷

1. All facilities shall, upon a resident's admission, provide in hand to the resident and a member of the resident's immediate family or any existing legal guardian of the resident a statement of the resident's rights while living in the facility...the statement must include provisions ensuring each resident the following minimum rights:

h. The right to be adequately informed of one's medical condition and proposed treatment and to participate in the planning of all medical treatment, including the right to refuse medication and treatment, to be discharged from the facility upon written request, and to be notified by the resident's attending physician of the medical consequences of any such actions.

Summary and Analysis:

- North Dakota has a bill of rights for residents of health care facilities, including nursing home residents. There is no language in this bill of rights providing for an explicit right to informed consent, though the phrasing of the rights to be informed, participate in planning and refuse medical treatment can be read as providing an implicit right to informed consent.
- North Dakota law does explicitly provide for informed consent under certain circumstances, including the performance of an abortion and testing for blood-borne pathogens.
- Because of its specificity, the federal bill would likely provide greater protections for residents in North Dakota nursing homes.

Ohio

Ohio Code – Title 37 – Health—Safety—Morals, Chapter 3721 – Nursing Homes; Residential Care Facilities, Residents’ Rights, Section 3721.13 – Residents’ Rights; Sponsor May Protect

⁶⁷ Accessed at http://www.lawserver.com/law/state/north-dakota/nd-code/north_dakota_code_50_10-2_02.

Rights⁶⁸

(A) The rights of residents of a home shall include, but are not limited to, the following:

(8) The right to participate in decisions that affect the resident's life, including the right to communicate with the physician and employees of the home in planning the resident's treatment or care and to obtain from the attending physician complete and current information concerning medical condition, prognosis, and treatment plan, in terms the resident can reasonably be expected to understand; the right of access to all information in the resident's medical record; and the right to give or withhold informed consent for treatment after the consequences of that choice have been carefully explained. When the attending physician finds that it is not medically advisable to give the information to the resident, the information shall be made available to the resident's sponsor on the resident's behalf, if the sponsor has a legal interest or is authorized by the resident to receive the information. The home is not liable for a violation of this division if the violation is found to be the result of an act or omission on the part of a physician selected by the resident who is not otherwise affiliated with the home.

2317.54 Informed consent; health care facility liability precluded, when; form for written consent, OH ST § 2317.54⁶⁹

(A) The consent sets forth in general terms the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks, and, except in emergency situations, sets forth the names of the physicians who shall perform the intended surgical procedures.

(B) The person making the consent acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.

(C) The consent is signed by the patient for whom the procedure is to be performed, or, if the patient for any reason including, but not limited to, competence, minority, or the fact that, at the latest time that the consent is needed, the patient is under the influence of alcohol, hallucinogens, or drugs, lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances, including either of the following:

⁶⁸ Accessed at <http://codes.ohio.gov/orc/3721.13>.

⁶⁹ Sources: (1) Law accessed at <http://codes.ohio.gov/orc/2317.54>. (2) *Informed Consent in Ohio* by Ted Kurt, Esq., Health Living News (February 2003). Available at <http://members.buckeye-express.com/tedkurt/Formatted%20Informed%20Consent%20in%20Ohio.pdf>.

Summary and Analysis:

- Ohio's nursing home resident's rights law specifically sets forth the right of a resident to give or withhold consent after the consequences of making that choice is explained to the resident. There is no distinction concerning whether the consent must be in writing, or can be oral, which implies that consent can be provided orally.
- In order for consent to be informed, the consent requirement sets forth in general terms the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks, and, except in emergency situations, sets forth the names of the physicians who will provide care. In addition, the benefits and alternatives must also be communicated to the resident.
- Because it sets forth a specific protocol for informed consent in the context of antipsychotic drug use on people with dementia, the federal bill would provide stronger protections for residents in this state.

Oklahoma

Oklahoma Statutes – Title 63 – Public Health and Safety, Chapter 1 – Public Health and Code, Article 19 – Nursing Home Care Act, Section 1-1918 – Rights and Responsibilities – Violations—Penalties⁷⁰

5. Every resident shall have the right to receive adequate and appropriate medical care consistent with established and recognized medical practice standards within the community. Every resident, unless adjudged to be mentally incapacitated, shall be fully informed by the resident's attending physician of the resident's medical condition and advised in advance of proposed treatment or changes in treatment in terms and language that the resident can understand, unless medically contraindicated, and to participate in the planning of care and treatment or changes in care and treatment. Every resident shall have the right to refuse medication and treatment after being fully informed of and understanding the consequences of such actions unless adjudged to be mentally incapacitated....

Oklahoma Statutes - Title 43A-11-110. Informed consent - Examination and certification of incapacity - Conflicting instructions - Transfer when unable to comply with directive.⁷¹

A. The attending physician or psychologist shall continue to obtain the declarant's informed

⁷⁰ Accessed at <http://law.justia.com/codes/oklahoma/2006/os43a.html>.

⁷¹ Accessed at <http://law.justia.com/codes/oklahoma/2006/os43a.html>.

consent to all mental health treatment decisions when the declarant is capable of providing informed consent or refusal.

Summary and Analysis:

- Oklahoma's Nursing Home Care Act provides for a resident's right to be fully informed, participate in treatment planning and refuse treatment. These rights reflect those which already exist in federal law and do not specify a right to informed consent.
- The only references to informed consent identified were in Oklahoma law relating to mental health treatment, such as the one above, which appeared to be focused on providing consent to allow someone else to make decisions for the individual, rather than enabling the individual to be more empowered in their healthcare.
- Because Oklahoma law does not provide for informed consent in the nursing home setting, the federal bill would likely provide stronger protections to Oklahoma nursing home residents.

Oregon

Oregon Revised Statutes- Title 52. Occupations and Professions- Ch. 677 Regulations of Medicine, Podiatry and Acupuncture, Physicians and Surgeons- 677.097 Obtaining informed consent of patient⁷²

(1) In order to obtain the informed consent of a patient, a physician or physician assistant shall explain the following:

- (a) In general terms the procedure or treatment to be undertaken;
- (b) That there may be alternative procedures or methods of treatment, if any; and
- (c) That there are risks, if any, to the procedure or treatment.

(2) After giving the explanation specified in subsection (1) of this section, the physician or physician assistant shall ask the patient if the patient wants a more detailed explanation. If the patient requests further explanation, the physician or physician assistant shall disclose in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. In determining that further explanation would be materially detrimental the physician or physician assistant shall give due consideration to the standards of practice of reasonable medical or podiatric practitioners in the same or a similar community under the same or similar circumstances.

⁷² Accessed at <http://www.oregonlaws.org/ors/677.097>.

Summary and Analysis:

- Oregon’s nursing home resident’s rights law⁷³ does not set forth a specific informed consent right.
- Oregon’s law for regulation of medical practitioners provides informed consent. In some respects it is more protective than the proposed federal bill. For instance, it includes the requirement that a physician or physician’s assistant inform the resident personally. This is more protective than the federal bill’s requirement that the prescriber of medication simply be “involved” in the information process.
- Section (2) of the law also mandates that the physician or physician’s assistant ask if the resident would like a more detailed explanation of the general terms, alternative procedures, and risks of the procedure or treatment. This requirement is not present in the proposed federal bill, and is an additional safeguard to ensure that every resident completely understands the treatment to which he or she is consenting to.
- While Oregon law contains a general informed consent provision in terms of medical practice, the specific focus of the federal bill on nursing home residents rights makes it likely that the federal bill would provide greater protections to residents in this state.

Pennsylvania

Pennsylvania Statutes Title 28 – Health and Safety, Chapter 201 – Applicability, Definitions, Ownership and General Operation of Long-Term Care Nursing Facilities, § 201.29. Resident rights⁷⁴

(o) Experimental research or treatment in a nursing home may not be carried out without the approval of the Department and without the written approval of the resident after full disclosure. For the purposes of this subsection, “experimental research” means an experimental treatment or procedure that is one of the following:

- (1) Not a generally accepted practice in the medical community.
- (2) Exposes the resident to pain, injury, invasion of privacy or asks the resident to surrender autonomy, such as a drug study.

Pennsylvania Statutes – Title 40 – Insurance, Chapter 5C – Medical Care Availability and Reduction of Error (MCARE) Act, Chapter 5 – Medical Professional Liability, Section 1303.504

⁷³ 2011 ORS, Vol. 11 , Chapter 441, § 441.605. Legislative declaration of rights intended for residents. Accessed at <http://www.oregonlaws.org/ors/441.605>.

⁷⁴ Accessed at <http://www.pacode.com/secure/data/028/chapter201/chap201toc.html>.

– Informed Consent.⁷⁵

(a) Duty of Physicians.-- Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

- (1) Performing surgery, including the related administration of anesthesia.
- (2) Administering radiation or chemotherapy.
- (3) Administering a blood transfusion.
- (4) Inserting a surgical device or appliance.
- (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) Description of Procedure. -- Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.

Summary and Analysis:

- Pennsylvania's nursing home resident rights provision only addresses informed consent in respect to the right not to participate in experimental research or treatment. The term itself is not used, rather the law requires written approval by the resident. Interestingly, experimental treatment is defined as one that is "[n]ot a generally accepted practice in the medical community... or... [e]xposes the resident to pain, injury, invasion of privacy or asks the resident to surrender autonomy...." The inappropriate use of antipsychotics on nursing home residents may be considered as falling into one or both of these categories.
- This informed consent requirement provided for in Title 40 only applies to five distinct scenarios, set forth in sections (a)(1-5) above. If a resident does not undergo one of the five listed procedures, informed consent protections would presumably be inapplicable.
- Given that Pennsylvania does not provide specific rights to informed consent for nursing home care, the federal bill would likely provide stronger protections.

⁷⁵ Accessed at

http://patientsafetyauthority.org/PatientSafetyAuthority/Governance/Documents/act_13.pdf.

Rhode Island

Rhode Island General Laws - Title 23 – Health and Safety

Chapter 17.5 – Rights of Nursing Home Patients, § 23-17.5-6 – Care by physician -- Disclosure of patient's medical condition.⁷⁶

(b) Each patient shall be informed by a physician of his or her medical condition unless medically contraindicated, as documented by a physician in his or her medical record, and shall be afforded the opportunity to participate in the planning of his or her medical treatment.

Chapter 23-17 – Licensing of Health Care Facilities, § 23-17-19.1 – Rights of patients.⁷⁷

Every health care facility licensed under this chapter shall observe the following standards and any other standards that may be prescribed in rules and regulations promulgated by the licensing agency with respect to each patient who utilizes the facility:

(4) The patient shall have the right to refuse any treatment by the health care facility to the extent permitted by law.

(10) Except as otherwise provided in this subparagraph, if the health care facility proposes to use the patient in any human subjects research, it shall first thoroughly inform the patient of the proposal and offer the patient the right to refuse to participate in the project.

(b) No facility shall be required to inform prospectively the patient of the proposal and the patient's right to refuse to participate when: (i) the facility's human subjects research involves the investigation of potentially lifesaving devices, medications and/or treatments and the patient is unable to grant consent due to a life-threatening situation and consent is not available from the agent pursuant to chapter 23-4.10 of the general laws or the patient's decision maker if an agent has not been designated or an applicable advanced directive has not been executed by the patient; and (ii) the facility's institutional review board approves the human subjects research pursuant to the requirements of 21 CFR Part 50 and/or 45 CFR Part 46 (relating to the informed consent of human subjects). Any health care facility engaging in research pursuant to the requirements of subparagraph (b) herein shall file a copy of the relevant research protocol with the department of health, which filing shall be publicly available.

Summary and Analysis:

⁷⁶ Accessed at <http://webserver.rilin.state.ri.us/Statutes/title23/23-17.5/23-17.5-6.HTM>.

⁷⁷ Accessed at <http://webserver.rilin.state.ri.us/Statutes/title23/23-17/23-17-19.1.HTM>.

- Rhode Island’s nursing home resident’s rights law does not provide for informed consent. However, in line with federal requirements, it provides for the right to be informed, the right to participate in planning and the right to refuse. If the individual is not informed, because it is medically contraindicated, the physician has a duty to record this in the individual’s medical record.
- Like many other states, Rhode Island law [23-17-19.1] has specific provisions for informing and getting a resident’s consent to participation in research. However, Rhode Island’s law explicitly provides for a number of circumstances in which a facility can *avoid* these requirements (and neither inform the resident nor gain his or her consent).
- Given the weaknesses in Rhode Island law, the federal bill would likely provide stronger protections to nursing home residents in this state.

South Carolina

South Carolina – Title 44 – Health, Chapter 81 – Bill of Rights for Residents of Long-Term Care Facilities, Section 44-81-40 – Rights of Residents⁷⁸

- (C) Each resident or the resident's legal guardian has the right to:
- (2) participate in planning care and treatment or changes in care and treatment;
 - (3) be fully informed in advance about changes in care and treatment that may affect the resident's well-being;
 - (4) receive from the resident's physician a complete and current description of the resident's diagnosis and prognosis in terms that the resident is able to understand;
 - (5) refuse to participate in experimental research.

Summary and Analysis:

- South Carolina’s health code contains a bill of rights for residents of long-term care facilities. The resident’s rights laid out in the South Carolina law are similar to longstanding federal requirements. They do not specifically provide for a resident’s right to informed consent.
- South Carolina’s Rights of Mental Health Patients (§ 44-22-140) includes a provision for a patient’s right to informed consent for treatments and medications. However, it appears to be limited in scope to individuals undergoing significant psychiatric treatment and thus is not relevant here.

⁷⁸ Accessed at <http://scstatehouse.gov/code/t44c081.php>.

- The federal bill would likely provide stronger informed consent protections for South Carolina nursing home residents.

South Dakota

South Dakota Statutes- Title 34 - Public Health and Safety -12c. Health Care Consent Procedures. 34-12C-6. Rights of authorized person as incapacitated person.⁷⁹

The informed consent of the person authorized under this chapter to make a health care decision shall, for all purposes, be deemed the informed consent of the incapacitated person. The person has the same right as does the incapacitated person to receive information relevant to the proposed health care, and to receive, review, and consent to the disclosure of medical records. Disclosure of information regarding contemplated health care to a person authorized to make a health care decision for an incapacitated person is not a waiver of any evidentiary privilege or of a right to assert confidentiality.

South Dakota Statutes - Title 27A- Mentally Ill Persons, Chapter 27A-15 – Treatment of Minors. 27A-15-47. Oral and written informed consent of minor and parent required for use of psychotropic medication on minor sixteen or older.⁸⁰

Except as otherwise provided by this title, psychotropic medication and other treatment may be administered to a minor sixteen years of age or older only with the oral and written informed consent of the minor and the minor's parent, legal guardian, or custodian. If oral and written consent are unable to be obtained by the facility within a reasonable time, efforts to obtain such consent shall be documented in the minor's record and either oral or written consent shall then be sufficient for this purpose.

Psychotropic medication may be administered only if prescribed by the minor's treating psychiatrist upon the psychiatrist's written determination that the medication is the least restrictive treatment alternative medically necessary for improvement of the minor's serious emotional disturbance. The informed consent of the minor and the minor's parent, legal guardian, or custodian and the treating psychiatrist's determination shall become part of the

⁷⁹ Accessed at <http://legis.state.sd.us/statutes/DisplayStatute.aspx?Type=Statute&Statute=34-12C>.

⁸⁰ Accessed at <http://legis.state.sd.us/statutes/DisplayStatute.aspx?Type=Statute&Statute=27A-15-47>.

minor's medical records. The failure to obtain the informed consent of the minor shall be treated as a refusal of treatment pursuant to § 27A-15-48.

Summary and Analysis:

- South Dakota's health care consent law references informed consent in several places but does not specifically provide for a right to informed consent in decision-making about care.
- The health care consent procedures (34-12c) pertain to informed consent of incapacitated persons who requires a representative or guardian.
- The informed consent requirements for prescribing psychotropic medications to minors (under 27A-15-47, relating to "mentally ill persons"), though inapplicable to the general nursing home population, contains worthwhile provisions, including a requirement that consent be both oral and in writing and that the psychiatrist must make a written determination "...that the medication is the least restrictive treatment alternative medically necessary for improvement of the minor's serious emotional disturbance."
- Other South Dakota laws identified that provide informed consent relate to genetic testing (34-12-22) and abortions (34-23A-3).
- Due to the lack of specific informed consent protections for nursing home residents, the federal bill would likely provide stronger protections for nursing home residents of this state.

Tennessee

Tennessee Code – Title 68 – Health, Safety and Environmental Protection, Health, Chapter 11 – Health Facilities and Resources, Part 9 – Rights of Nursing Home Residents and Patients, and Members of the Public Regarding Nursing Homes, Section 68-11-901 – Enumeration of Minimum Rights⁸¹

Every nursing home resident/patient has the following minimum rights:

(10) To choose, with the help of their authorized family member or guardian, a personal

⁸¹ Accessed at <http://www.lexisnexis.com/hottopics/tncode/> (Note: The Tennessee Code is freely accessible on the LexisNexis website).

physician. Further, to be fully informed of the resident's medical condition, unless medically contraindicated and documented by the physician in the resident's medical record. The facility shall give the patient and authorized family member the opportunity to participate in the planning of the patient's total care plan and medical treatment;

(11) To refuse treatment:

(A) The resident must be informed of the consequences of that decision;

(B) The refusal and its reason must be documented in the resident's medical record and reported to the physician; and

(C) The right to refuse treatment may not be abridged, restricted, limited or amended by medical contraindication as provided below....

State of Tennessee - Department of Children's Services, Administrative Policies and Procedures: 20.24 - Informed Consent⁸²

Purpose: Informed consent is based on the fundamental principle that every person has the right to control his/her own bodily integrity. The individual has a right to receive sufficient information to enable the individual to make an informed decision about whether to consent to or refuse the tests or treatments.

A. Introduction to informed consent

1. Every individual has the right to receive information regarding prescribed tests or treatments, including risks and benefits of taking the tests or treatments and risks/benefits of not taking the tests or treatments.

2. The healthcare provider should provide a verbal and/or written explanation about the prescribed treatment or test, explained in a way the patient fully understands, which generally includes the following:

- a) Diagnosis for which the treatment/medication is prescribed;
- b) Nature of the medication, treatment, test, or procedure;
- c) Name of the medication, including both generic and brand names;
- d) Dosage and frequency of medication;
- e) Expected benefits;
- f) Possible risks and side effects;
- g) Availability of alternatives; and
- h) Prognosis without proposed intervention.

3. Informed consent is the consent to treatment given after the individual, legal custodian, and/or legal guardian has received sufficient information about the risks and benefits of taking and not taking a prescribed or recommended treatment.

⁸² Accessed at www.state.tn.us/youth/dcsguide/policies/chap20/20.24.pdf.

4. In deciding whether or not to consent to treatment, youth, parents, or DCS staff/representatives should ask questions as appropriate or needed, and may seek assistance from the DCS regional nurse or psychologist. Furthermore, DCS staff/representatives should seek guidance from supervisory staff or local DCS attorney if they have further questions.

5. Depending upon the setting and the healthcare provider, the individual or their guardian may be asked to sign a form documenting their consent to or refusal of treatment. Should the consent be provided verbally, DCS will require a written copy of the consent documentation from the healthcare provider.

B. Engaging families in informed consent

1. Parents should be engaged in the informed consent process unless their rights are terminated.
2. In addition to the parent(s), the child's DCS Caregiver (FSW, resource parent, or private provider staff) should also participate in healthcare appointments.

[Further details on engaging families omitted.]

H. Consent for psychotropic medication

1. When the need for psychotropic medication arises, the parent(s) should be engaged in all medication decisions and appointments for the child, unless parental rights have been terminated or the youth is 16 years of age or older.

[Further details omitted.]

Summary and Analysis:

- Tennessee's nursing home resident's rights law closely follows the federal minimum standards. It does not provide a specific right to informed consent.
- Tennessee does have significantly detailed informed consent requirements for care of children in custody, with provisions for the use of psychotropic medication.
- Tennessee also has specified guidelines to consent for mental health patients for psychotropic medications.⁸³
- Because it does not provide for a general patient right to informed consent or a nursing home resident's right to informed consent the federal bill would likely provide stronger protections for residents in this state.

⁸³ Source: *Rules of the Tennessee Department of Mental Health and Mental Retardation*. Office of the Commissioner. Available at <http://www.tn.gov/sos/rules/0940/0940-01/0940-01-03.pdf>.

Texas

Texas Code – Health and Safety Code, Title 4 – Health Facilities, Subtitle B – Licensing of Health Facilities, Chapter 242 – Convalescent and Nursing Homes and Related Institutions, Subchapter L – Rights of Residents, Section - 242.501 – Resident’s Rights⁸⁴

(a)(9) to retain the services of a physician the resident chooses, at the resident's own expense or through a health care plan, and to have a physician explain to the resident, in language that the resident understands, the resident's complete medical condition, the recommended treatment, and the expected results of the treatment, including reasonably expected effects, side effects, and risks associated with psychoactive medications;

(10) to participate in developing a plan of care, to refuse treatment, and to refuse to participate in experimental research.

Summary and Analysis:

- Texas has a nursing home resident’s rights law which follows federal minimum standards with an important addition: it specifically addresses the right to be informed about psychoactive medications. However, the law (including this provision) does not specifically provide for a right to informed consent.
- Thus, the federal bill would likely provide stronger protections for residents in this state.

Utah

UT ST § 78B-3-406. Failure to obtain informed consent--Proof required of patient--Defenses--Consent to health care⁸⁵

(1) When a person submits to health care rendered by a health care provider, it shall be

⁸⁴ Source: *Resident’s Bill of Rights*. Texas Department of Aging and Disability Services. Available at http://www.dads.state.tx.us/news_info/publications/brochures/DADS141_ALResidents_Bill_of_Rights.pdf.

⁸⁵ Accessed at http://le.utah.gov/code/TITLE78B/htm/78B03_040600.htm.

presumed that what the health care provider did was either expressly or impliedly authorized to be done. For a patient to recover damages from a health care provider in an action based upon the provider's failure to obtain informed consent, the patient must prove the following:

- (a) that a provider-patient relationship existed between the patient and health care provider;
- (b) the health care provider rendered health care to the patient;
- (c) the patient suffered personal injuries arising out of the health care rendered;
- (d) the health care rendered carried with it a substantial and significant risk of causing the patient serious harm;
- (e) the patient was not informed of the substantial and significant risk;
- (f) a reasonable, prudent person in the patient's position would not have consented to the health care rendered after having been fully informed as to all facts relevant to the decision to give consent. In determining what a reasonable, prudent person in the patient's position would do under the circumstances, the finder of fact shall use the viewpoint of the patient before health care was provided and before the occurrence of any personal injuries alleged to have arisen from said health care; and
- (g) the unauthorized part of the health care rendered was the proximate cause of personal injuries suffered by the patient.

Utah Administrative Code - R432. Health, Family Health and Preparedness, Licensing. Rule R432-150. Nursing Care Facility, R432-150-12. Resident Rights⁸⁶

- (1) The facility shall establish written residents' rights.
- (2) The facility shall post resident rights in areas accessible to residents. A copy of the residents' rights document shall be available to the residents, the residents' guardian or responsible person, and to the public and the Department upon request.
- (3) The facility shall ensure that each resident admitted to the facility has the right to:
 - (a) be informed, prior to or at the time of admission and for the duration of stay, of resident rights and of all rules and regulations governing resident conduct.
 - (b) be informed, prior to or at the time of admission and for the duration of stay, of services available in the facility and of related charges, including any charges for services not covered by the facility's basic per diem rate or not covered under Titles XVIII or XIX of the Social Security Act.
 - (c) be informed by a licensed practitioner of current total health status, including current medical condition, unless medically contraindicated, the right to refuse treatment, and the right to formulate an advance directive in accordance with UCA Section 75-2-1101;

⁸⁶ Accessed at <http://www.rules.utah.gov/publicat/code/r432/r432-150.htm#T12>.

(e) be encouraged and assisted throughout the period of stay to exercise all rights as a resident and as a citizen, and to voice grievances and recommend changes in policies and services to facility staff and outside representatives of personal choice, free from restraint, interference, coercion, discrimination, or reprisal....

R432-150-14. Restraint Policy.⁸⁷

(1) Each resident has the right to be free from physical restraints imposed for purposes of discipline or convenience, or not required to treat the resident's medical symptoms.

(2) The facility must have written policies and procedures regarding the proper use of restraints.

(a) Physical and chemical restraints may only be used to assist residents to attain and maintain optimum levels of physical and emotional functioning.

(b) Physical and chemical restraints must not be used as substitutes for direct resident care, activities, or other services.

(c) Restraints must not unduly hinder evacuation of the resident in the event of fire or other emergency.

(d) If use of a physical or a chemical restraint is implemented, the facility must inform the resident, next of kin, and the legally designated representative of the reasons for the restraint, the circumstances under which the restraint shall be discontinued, and the hazards of the restraint, including potential physical side effects.

(3) The facility must develop and implement policies and procedures that govern the use of physical and chemical restraints. These policies shall promote optimal resident function in a safe, therapeutic manner and minimize adverse consequences of restraint use.

(4) Physical and chemical restraint policies must incorporate and address at least the following:

(a) resident assessment criteria which includes:

(i) appropriateness of use;

(ii) procedures for use;

(iii) purpose and nature of the restraint;

(iv) less restrictive alternatives prior to the use of more restrictive measures; and

(v) behavior management and modification protocols including possible alterations to the physical environment;

(b) examples of the types of restraints and safety devices that are acceptable for the use indicated and possible resident conditions for which the restraint may be used; and

(c) physical restraint guidelines for periodic release and position change or exercise, with instructions for documentation of this action.

(5) Emergency use of physical and chemical restraints must comply with the following:

⁸⁷ Accessed at <http://www.rules.utah.gov/publicat/code/r432/r432-150.htm#T14>.

- (a) A physician, a licensed health practitioner, the director of nursing, or the health services supervisor must authorize the emergency use of restraints.
- (b) The facility must notify the attending physician as soon as possible, but at least within 24 hours of the application of the restraints.
- (c) The facility must notify the director of nursing or health services supervisor no later than the beginning of the next day shift of the application of the restraints.
- (d) The facility must document in the resident's record the circumstances necessitating emergency use of the restraint and the resident's response.
- (6) Physical restraints must be authorized in writing by a licensed practitioner and incorporated into the resident's plan of care.
- (a) The interdisciplinary team must review and document the use of physical restraints, including simple safety devices, during each resident care conference, and upon receipt of renewal orders from the licensed practitioner.
- (b) The resident care plan must indicate the type of physical restraint or safety device, the length of time to be used, the frequency of release, and the type of exercise or ambulation to be provided.
- (c) Staff application of physical restraints must ensure minimal discomfort to the resident and allow sufficient body movement for proper circulation.
- (d) Staff application of physical restraints must not cause injury or allow a potential for injury.
- (e) Leather restraints, straight jackets, or locked restraints are prohibited.
- (7) Chemical restraints must be authorized in writing by a licensed practitioner and incorporated into the resident's plan of care in conjunction with an individualized behavior management program.
- (a) The interdisciplinary team must review and document the use of chemical restraints during each resident care conference and upon receipt of renewal orders from the licensed practitioner.
- (b) The facility must monitor each resident receiving chemical restraints for adverse effects that significantly hinder verbal, emotional, or physical abilities.
- (c) Any medication given to a resident must be administered according to the requirements of professional and ethical practice and according to the policies and procedures of the facility.
- (d) The facility must initiate drug holidays in accordance with R432-150-15(13)(b).
- (8) Facility policy must include criteria for admission and retention of residents who require behavior management programs.

Summary and Analysis:

- Utah law has nursing home resident's rights provisions that follow the federal minimum requirements. They do not provide for a specific right to informed consent.

- Utah law does provide for significant criteria around the use of physical and chemical restraints. They do not, however, include informed consent.
- Thus, the federal bill would likely provide stronger protections to residents in this state.

Vermont

Vermont Statutes– Title 33 – Human Services, Part 5 – Programs and Services for Vulnerable Adults, Chapter 73 – Nursing Home Residents’ Bill of Rights, Section 7301 – Nursing Home Residents’ Bill of Rights⁸⁸

(2) The staff of the facility shall ensure that, at least, each individual admitted to the facility:
 (C) is fully informed, by a physician, of the medical condition, and is afforded the opportunity to participate in the planning of the medical treatment and to refuse to participate in experimental research;

(G) is free from mental and physical abuse, and free from chemical and (except in emergencies) physical restraints except as authorized in writing by a physician for a specified and limited period of time, or when necessary to protect the resident from self-injury or injury to others. The facility shall inform residents of its restraint policy and appeal rights under the facility's grievance procedure. The policy must include the release of the restraints no less than every two hours for 10 minutes for exercise or repositioning. The resident has the right to be free from any physical restraints imposed or psychoactive drugs administered for purposes of discipline or convenience;

(P) to the extent permitted by law, has the right to refuse care or treatment, including the right to discharge himself or herself from the facility, and to be informed of the consequences of that action and the nursing home shall be relieved of any further responsibility for that refusal.

Title 12: Court Procedure, Chapter 81: CONDUCT OF TRIAL, 12 V.S.A. § 1909. Limitation of medical malpractice action based on lack of informed consent⁸⁹

(a) For the purpose of this section "lack of informed consent" means:

(1) The failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical practitioner under similar circumstances would have disclosed, in a

⁸⁸ Accessed at <http://www.leg.state.vt.us/statutes/fullchapter.cfm?Title=33&Chapter=073>.

⁸⁹ Accessed at <http://www.leg.state.vt.us/statutes/fullsection.cfm?Title=12&Chapter=081&Section=01909>.

manner permitting the patient to make a knowledgeable evaluation; or

(2) The failure to disclose the information required by subsection (d) of this section.

(b) The right of action to recover for medical malpractice based on a lack of informed consent shall not apply in the case of an emergency.

(c) It shall be a defense to any action for medical malpractice based upon an alleged failure to obtain such an informed consent that:

(1) The risk not disclosed is too commonly known to require disclosure and that the risk is not substantial; or

(2) The patient assured the medical practitioner he or she would undergo the treatment, procedure or diagnosis regardless of the risk involved, or the patient indicated to the medical practitioner that he or she did not want to be informed of the matters to which he or she would be entitled to be informed; or

(3) Consent by or on behalf of the patient was not reasonably possible; or

(4) A reasonably prudent person in the patient's position would have undergone the treatment or diagnosis if he or she had been fully informed.

(d) A patient shall be entitled to a reasonable answer to any specific question about foreseeable risks and benefits, and a medical practitioner shall not withhold any requested information.

(e) A motion for judgment for the defendant at the end of plaintiff's case must be granted as to any cause of action for medical malpractice based solely on lack of informed consent if the plaintiff has failed to adduce expert medical testimony in support of the allegation that he or she was not provided sufficient information as required by subsection (a)(1) of this section.

(Added 1975, No. 250 (Adj. Sess.), § 3, eff. April 7, 1976; 2009, No. 25, § 5.)

Summary and Analysis:

- Vermont's human services law includes a bill of rights for nursing home residents. It does not provide for informed consent.
- The bill of rights includes some provisions related to the use of chemical and physical restraints.
- Vermont's medical malpractice law provide provisions around informed consent but the law does not state the scope of situations in which informed consent is required. Other sections of Vermont law do specifically require informed consent in certain situations, such as emergency contraception, abortion and use of a midwife.
- Given the absence of specific informed consent requirements for patients in general or nursing home residents in particular, the federal bill would likely provide stronger protections to residents in this state.

Virginia

Code of Virginia – Title 32.1 – Health, Chapter 5 – Regulation of Medical Care Facilities and Services, Article 2 – Rights and Responsibilities of Patients in Nursing Homes, Section 32.1-138 – Enumeration; Posting of Policies; Staff Training; Responsibilities Devolving on Guardians, etc.; Exceptions; Certification of Compliance⁹⁰

A. The governing body of a nursing home facility required to be licensed under the provisions of Article 1 (§ 32.1-123 et seq.) of this chapter, through the administrator of such facility, shall cause to be promulgated policies and procedures to ensure that, at the minimum, each patient admitted to such facility:

1. Is fully informed, as evidenced by the patient's written acknowledgment, prior to or at the time of admission and during his stay, of his rights and of all rules and regulations governing patient conduct and responsibilities;
2. Is fully informed, as evidenced by the patient's written acknowledgment, prior to or at the time of admission and during his stay, of services available in the facility, the terms of such services, and related charges, including any charges for services not covered under Titles XVIII or XIX of the United States Social Security Act or not covered by the facility's basic per diem rate;
3. Is fully informed in summary form of the findings concerning the facility in federal Centers for Medicare & Medicaid Services surveys and investigations, if any;
4. Is fully informed by a physician, physician assistant, or nurse practitioner of his medical condition unless medically contraindicated as documented by a physician, physician assistant, or nurse practitioner in his medical record and is afforded the opportunity to participate in the planning of his medical treatment and to refuse to participate in experimental research;
6. Is encouraged and assisted, throughout the period of his stay, to exercise his rights as a patient and as a citizen and to this end may voice grievances and recommend changes in policies and services to facility staff and to outside representatives of his choice, free from restraint, interference, coercion, discrimination, or reprisal;
8. Is free from mental and physical abuse and free from chemical and, except in emergencies, physical restraints except as authorized in writing by a physician for a specified and limited period of time or when necessary to protect the patient from injury to himself or to others;
16. Is fully informed, as evidenced by the written acknowledgment of the resident or his legal representative, prior to or at the time of admission and during his stay, that he should exercise whatever due diligence he deems necessary with respect to information on any sexual offenders registered pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1, including how to

⁹⁰ Accessed at <http://lis.virginia.gov/cgi-bin/legp604.exe?000+cod+32.1-138>.

obtain such information. Upon request, the nursing home facility shall assist the resident, prospective resident, or the legal representative of the resident or prospective resident in accessing this information and provide the resident, prospective resident, or the legal representative of the resident or prospective resident with printed copies of the requested information.

B. All established policies and procedures regarding the rights and responsibilities of patients shall be printed in at least 12-point type and posted conspicuously in a public place in all nursing home facilities required to be licensed under the provisions of Article 1 (§ 32.1-123 et seq.) of this chapter. These policies and procedures shall include the name and telephone number of the complaint coordinator in the Division of Licensure and Certification of the Virginia Department of Health, the Adult Protective Services' toll-free telephone number, as well as the toll-free telephone number for the Virginia Long-Term Care Ombudsman Program and any substate ombudsman program serving the area. Copies of such policies and procedures shall be given to patients upon admittance to the facility and made available to patients currently in residence, to any guardians, responsible party as defined in regulation, next of kin, or sponsoring agency or agencies, and to the public.

C. The provisions of this section shall not be construed to restrict any right that any patient in residence has under law.

D. Each facility shall provide appropriate staff training to implement each patient's rights included in subsection A hereof.

Title 18.2 - CRIMES AND OFFENSES GENERALLY, Chapter 8 - Crimes Involving Morals and Decency, § 18.2-369. Abuse and neglect of incapacitated adults; penalty.⁹¹

A. It shall be unlawful for any responsible person to abuse or neglect any incapacitated adult as defined in this section. Any responsible person who abuses or neglects an incapacitated adult in violation of this section and the abuse or neglect does not result in serious bodily injury or disease to the incapacitated adult is guilty of a Class 1 misdemeanor. Any responsible person who is convicted of a second or subsequent offense under this subsection is guilty of a Class 6 felony.

B. Any responsible person who abuses or neglects an incapacitated adult in violation of this section and the abuse or neglect results in serious bodily injury or disease to the incapacitated adult is guilty of a Class 4 felony. Any responsible person who abuses or neglects an incapacitated adult in violation of this section and the abuse or neglect results in the death of the incapacitated adult is guilty of a Class 3 felony.

C. For purposes of this section:

⁹¹ Accessed at <http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+18.2-369>.

"Abuse" means (i) knowing and willful conduct that causes physical injury or pain or (ii) knowing and willful use of physical restraint, including confinement, as punishment, for convenience or as a substitute for treatment, except where such conduct or physical restraint, including confinement, is a part of care or treatment and is in furtherance of the health and safety of the incapacitated person.

"Incapacitated adult" means any person 18 years of age or older who is impaired by reason of mental illness, intellectual disability, physical illness or disability, advanced age or other causes to the extent the adult lacks sufficient understanding or capacity to make, communicate or carry out reasonable decisions concerning his well-being.

"Neglect" means the knowing and willful failure by a responsible person to provide treatment, care, goods or services which results in injury to the health or endangers the safety of an incapacitated adult.

"Responsible person" means a person who has responsibility for the care, custody or control of an incapacitated person by operation of law or who has assumed such responsibility voluntarily, by contract or in fact.

"Serious bodily injury or disease" shall include but not be limited to (i) disfigurement, (ii) a fracture, (iii) a severe burn or laceration, (iv) mutilation, (v) maiming, or (vi) life-threatening internal injuries or conditions, whether or not caused by trauma.

D. No responsible person shall be in violation of this section whose conduct was (i) in accordance with the informed consent of the incapacitated person or a person authorized to consent on his behalf; (ii) in accordance with a declaration by the incapacitated person under the Natural Death Act of Virginia (§ [54.1-2981](#) et seq.) or with the provisions of a valid medical power of attorney; (iii) in accordance with the wishes of the incapacitated person or a person authorized to consent on behalf of the incapacitated person and in accord with the tenets and practices of a church or religious denomination; (iv) incident to necessary movement of, placement of or protection from harm to the incapacitated person; or (v) a bona fide, recognized or approved practice to provide medical care.

Summary and Analysis:

- Virginia's nursing home residents' rights law (32.1-138) does not provide for a specific right to informed consent for resident care. However, it does provide for a resident's written informed consent regarding information on sex offenders.
- Virginia's criminal law relating to abuse or neglect of incapacitated individuals (which includes a wide range of people, from those with mental illness to frail elderly) references informed consent, not as a right of the individual but rather as a reason for excusing the abuse or neglect (if it was conducted "in accordance with the informed consent of the incapacitated person..."). In addition, another basis for excusing the abuse or neglect is if it is "a bona fide, recognized or approved practice to provide

medical care....” This potentially conflicts with the right that individuals have under federal standards to reject treatment, even if doing so is to their detriment. Thus, Virginia law may actually undermine the longstanding consent requirements that every nursing home resident in the U.S. has.

- As a result, the federal bill would likely provide stronger protections for nursing home residents in this state.

Washington

Washington Administrative Code – Title 388 – Department of Social and Health Services - 388-97-0260 - Informed consent.⁹²

(1) The nursing home must ensure that the informed consent process is followed with:

(a) The resident to the maximum extent possible, taking into consideration his or her ability to understand and respond; and

(b) The surrogate decision maker when the resident is determined to be incapacitated as established through the provision of a legal document such as durable power of attorney for health care, a court proceeding, or as authorized by state law, including RCW 7.70.065. The surrogate decision maker must:

(i) First determine if the resident would consent or refuse the proposed or alternative treatment;

(ii) Discuss determination of consent or refusal with the resident whenever possible; and

(iii) When a determination of the resident's consent or refusal of treatment cannot be made, make the decision in the best interest of the resident.

(2) The informed consent process must include, in words and language that the resident, or if applicable the resident's surrogate decision maker, understands, a description of:

(a) The nature and character of the proposed treatment;

(b) The anticipated results of the proposed treatment;

(c) The recognized possible alternative forms of treatment;

(d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment including nontreatment; and

(e) The right of the resident to choose not to be informed.

⁹² Source: WAC 388-97-0260. Accessed at <http://apps.leg.wa.gov/wac/default.aspx?cite=388-97-0260>.

(3) To ensure informed consent or refusal by a resident, or if applicable the resident's surrogate decision maker, regarding plan or care options, the nursing home must:

- (a) Provide the informed consent process to the resident in a neutral manner and in a language, words, and manner the resident can understand;
- (b) Inform the resident of the right to consent to or refuse care and service options at the time of resident assessment and plan of care development (see WAC 388-97-1000 and 388-97-1020[]) and with condition changes, as necessary to ensure that the resident's wishes are known;
- (c) Inform the resident at the time of initial plan of care decisions and periodically of the right to change his or her mind about an earlier consent or refusal decision;
- (d) Ensure that evidence of informed consent or refusal is consistent with WAC 388-97-1000 and 388-97-1020; and
- (e) Where appropriate, include evidence of resident's choice not to be informed as required in subsections (2) and (3) of this section.

Revised Code of Washington – Title 74 – Public Assistance, Chapter 74.42 – Nursing Homes – Resident Care, Operating Standards, § 74.42.040. Resident's rights regarding medical condition, care, and treatment.⁹³

The facility shall insure that each resident and guardian, if any:

- (1) Is fully informed by a physician about his or her health and medical condition unless the physician decides that informing the resident is medically contraindicated and the physician documents this decision in the resident's record;
- (2) Has the opportunity to participate in his or her total care and treatment;
- (3) Has the opportunity to refuse treatment; and
- (4) Gives informed, written consent before participating in experimental research.

Summary and Analysis:

- Two sections of Washington law that address informed consent were identified. Title 388 provides explicit requirements for informed consent (as noted below). Title 74 has been included because, though its informed consent provision is limited to consent to participate in experimental research, it explicitly requires *written* consent (whereas Title 388 is silent as to the forms in which information should be presented and consent provided).
- Further comments regarding WAC 388-97-0260:
 - Nursing homes are responsible for determining the extent of a resident's capacity.

⁹³ Source: RCW 74.42.040. Accessed at <http://apps.leg.wa.gov/rcw/default.aspx?cite=74.42.040>.

- Steps are outlined for how a surrogate decision maker, when necessary, is to determine a resident's wishes.
- It requires that information is presented in language appropriate to the resident or surrogate.
- It requires that informed consent processes are consistent with statutory requirement for resident assessment and resident decision making. The resident assessment requirements (WAC 388-97-1000) include a requirement for documentation of the process, including documentation of a resident's participation therein.
- Given the strong standards set forth in Washington law, the proposed federal bill would likely not provide greater protections for residents in this state.

West Virginia

CHAPTER 16. PUBLIC HEALTH, ARTICLE 30. WEST VIRGINIA HEALTH CARE DECISIONS ACT, §16-30-2. Legislative findings and purpose.⁹⁴

(a) *Purpose.* -- The purpose of this article is to ensure that a patient's right to self-determination in health care decisions be communicated and protected; and to set forth a process for private health care decision making for incapacitated adults, including the use of advance directives, which reduces the need for judicial involvement and defines the circumstances under which immunity shall be available for health care providers and surrogate decision makers who make health care decisions.

The intent of the Legislature is to establish an effective method for private health care decision making for incapacitated adults, and to provide that the courts should not be the usual venue for making decisions. It is not the intent of the Legislature to legalize, condone, authorize or approve mercy killing or assisted suicide.

(b) *Findings.* -- The Legislature hereby finds that:

(1) Common law tradition and the medical profession in general have traditionally recognized the right of a capable adult to accept or reject medical or surgical intervention affecting one's own medical condition;

(5) The right to make medical treatment decisions extends to a person who is incapacitated at the moment of decision. An incapacitated person who has not made his or her wishes known in advance through an applicable living will, medical power of attorney or through some other means has the right to have health care decisions made on his or her behalf by a person who

⁹⁴ Accessed at <http://www.legis.state.wv.us/WVCODE/Code.cfm?chap=16&art=30#30>.

will act in accordance with the incapacitated person's expressed values and wishes, or, if those values and wishes are unknown, in the incapacitated person's best interests.

(i) "Health care decision" means a decision to give, withhold or withdraw informed consent to any type of health care, including, but not limited to, medical and surgical treatments, including life-prolonging interventions, psychiatric treatment, nursing care, hospitalization, treatment in a nursing home or other facility, home health care and organ or tissue donation.

**TITLE 64 LEGISLATIVE RULES, WEST VIRGINIA DIVISION OF HEALTH, SERIES 13
NURSING HOME LICENSURE RULE, § 64-13-4. Residents' Rights., WV ADC § 64-13-4⁹⁵**

4.6. Refusal of Treatment and Experimental Research.

4.6.a.1. As provided under State law, a resident who has the capacity to make a health care decision and who either withholds consent to treatment or makes an explicit refusal of treatment, either directly or through an advance directive, shall not be treated against his or her wishes.

4.6.a.1.B. When a refusal of treatment occurs, the nursing home shall assess the reasons for the resident's refusal, clarify and educate the resident, and in the case of incapacity, the legal representative, as to the consequences of the refusal, and offer alternative treatments, and continue to provide all other services.

8.15.e.4. Recognizing that the resident has the right to refuse medical treatment, all residents have the right to request substitute foods even when this violates the physician's orders.

8.15.e.4.1. A nursing home shall provide education to the resident regarding the benefits of the prescribed diet and consequences of his or her refusal to eat the prescribed diet.

8.15.e.4.2. A nursing home shall document the informed decision in the resident's clinical record.

Summary and Analysis:

- West Virginia's public health law (16-30-3) provides for a general patient's right to informed consent. It defines decision making as being predicated on informed consent, which is in line with the contention that informed consent, though not specifically mentioned in federal requirements, is implicit therein.
- West Virginia's nursing home resident's rights law (64-13-4) also refers to informed decision making. While the excerpted sections above pertain to food choices, it is

⁹⁵ Accessed at http://www.hpm.umn.edu/nhregsplus/NHRegs_by_State/West%20Virginia/West%20Virginia.html.

explicitly related in the law to the right to refuse medical treatment. The documentation of the resident's informed decision is also required.

- Because of its specificity, in particular its detailed protocol for using antipsychotic medication on people with dementia, the federal bill would likely provide stronger protections for residents in this state.

Wisconsin

Wisconsin Code – Charitable, Curative, Reformatory, and Penal Institutions and Agencies – Subchapter I – Care and Service Residential Facilities⁹⁶

Section 50.09 – Rights of Residents in Certain Facilities.

(1) RESIDENTS' RIGHTS. Every resident in a nursing home or community-based residential facility shall, except as provided in sub. (5), have the right to:

(n) Be fully informed of the resident's treatment and care and participate in the planning of the resident's treatment and care.

50.08 - Informed consent for psychotropic medications.

(1) In this section:

(a) "Degenerative brain disorder" has the meaning given in s. [55.01 \(1v\)](#).

(b) "Incapacitated" has the meaning given in s. [50.06 \(1\)](#).

(c) "Person acting on behalf of the resident" means a guardian of the person, as defined in s. [54.01 \(12\)](#), or a health care agent, as defined in s. [155.01 \(4\)](#).

(d) "Psychotropic medication" means an antipsychotic, an antidepressant, lithium carbonate, or a tranquilizer.

(2) A physician, an advanced practice nurse prescriber certified under s. [441.16 \(2\)](#), or a physician assistant licensed under ch. [448](#), who prescribes a psychotropic medication to a nursing home resident who has degenerative brain disorder shall notify the nursing home if the prescribed medication has a boxed warning under [21 CFR 201.57](#).

(3)

(a) Except as provided in sub. [\(3m\)](#) or [\(4\)](#), before administering a psychotropic medication that has a boxed warning under [21 CFR 201.57](#) to a resident who has degenerative brain disorder, a nursing home shall obtain written informed consent from the resident or, if the resident is

⁹⁶ Accessed at <http://docs.legis.wisconsin.gov/statutes/statutes/50/1/09>.

incapacitated, a person acting on behalf of the resident, on a form provided by the department under par. [\(b\)](#) or on a form that contains the same information as the form under par. [\(b\)](#).

(b) The department shall make available on its Web site or by mail multiple, drug-specific forms for obtaining informed consent under par. [\(a\)](#) for the administration of psychotropic medication that contain all of the following:

1. A space for a description of the benefits of the proposed treatment and the way the medication will be administered.
2. A description, using the most recently issued information from the federal food and drug administration, of the side effects or risks of side effects of the medication and any warnings about the medication.
3. A space for a description of any alternative treatment modes or medications.
4. A space for a description of the probable consequences of not receiving the medication.
5. A space for indicating the period for which the informed consent is effective, which shall be no longer than 15 months from the time the consent is given.
6. A statement that the resident or a person acting on behalf of the resident may withdraw informed consent, in writing, at any time.
7. A declaration that the resident or the person acting on behalf of the resident has been provided with specific, complete, and accurate information, and time to study the information or to seek additional information concerning the medication.
8. A space for the signature of the resident or the person acting on behalf of the resident.

(c) Written informed consent provided by a guardian is subject to s. [54.25 \(2\) \(d\) 2. ab.](#) and [ac.](#)

(cm) If a health care agent is acting on behalf of a resident, the health care agent shall give informed consent in accordance with the desires of the resident as expressed in the power of attorney for health care instrument under ch. [155](#) or, if the resident's desires are unknown, in accordance with s. [155.20 \(5\)](#).

(d) Upon request, the nursing home shall give the resident, or a person acting on behalf of the resident, a copy of the completed informed consent form.

(e) Unless consent is withdrawn sooner, written informed consent obtained under this subsection is valid for the period specified on the informed consent form but not for longer than 15 months from the date the resident, or a person acting on behalf of the resident, signed the form.

(f) A resident, or a person acting on behalf of the resident, may withdraw consent, in writing, at any time.

(fm) At the time a resident, or a person acting on behalf of the resident, signs the informed consent form, the nursing home shall orally inform the resident, or the person acting on behalf of the resident, of all of the following:

1. That the resident, or the person on behalf of the resident, may withdraw consent, in writing, at any time.

2. That, unless consent is withdrawn sooner, the informed consent is valid for the period specified on the informed consent form or for 15 months from the date on which the resident, or the person acting on behalf of the resident, signs the form, whichever is shorter.

(g) No person may retaliate against or threaten to retaliate against a resident or person acting on behalf of a resident for refusing to provide or withdrawing consent.

(h) The nursing home shall use the most current written informed consent forms available from the department or shall update its own forms with the most current information about the medications available from the department.

(3m) A nursing home is not required to obtain written informed consent before administering a psychotropic medication to a resident under sub. (3) if the prescription for the psychotropic medication is written or reauthorized while the resident is off of the nursing home's premises.

(4)

(a) A nursing home is not required to obtain written informed consent before administering a psychotropic medication to a resident under sub. (3) if all of the following apply:

1. The resident is not the subject of a court order to administer psychotropic medications under s. 55.14.

2. There is an emergency in which a resident is at significant risk of physical or emotional harm or the resident puts others at significant risk of physical harm and in which time and distance preclude obtaining written informed consent before administering psychotropic medication.

3. A physician has determined that the resident or others will be harmed if the psychotropic medication is not administered before written informed consent is obtained.

(b) If par. (a) applies, the nursing home shall obtain oral consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, before administering the psychotropic medication, except as provided in par. (c). The oral consent shall be entered in the resident's medical record. The oral consent shall be valid for 10 days, after which time the nursing home may not continue to administer the psychotropic medication unless it has obtained written informed consent under sub. (3).

(c) If par. (a) applies, the resident is incapacitated, and the nursing home has made a good faith effort to obtain oral consent, under par. (b), of a person acting on behalf of the resident but has been unable to contact such a person, the nursing home may administer the psychotropic medication to the resident for up to 24 hours before obtaining consent under par. (a) or sub. (3).

(5) This section does not abridge any rights that a resident has under s. 51.61 (1) (g).

Summary and Analysis:

- Wisconsin requires informed consent for the use of psychotropic drugs. Consent must be in writing, except under certain circumstances.
- Because of its specificity, including the requirement for informed consent to be in

writing, it is unlikely that the federal bill would provide greater protections for nursing home residents in this state.

Wyoming

Wyoming Medical Malpractice Act, TITLE 33 - PROFESSIONS AND OCCUPATIONS, CHAPTER 26 - PHYSICIANS AND SURGEONS, ARTICLE 1 - GENERAL PROVISIONS⁹⁷

R) Utilization of experimental forms of therapy without proper informed consent from the patient, without conforming to generally-accepted criteria or standard protocols, without keeping detailed, legible records or without having periodic analysis of the study and results reviewed by a committee of peers;

(S) Except in emergency situations where the consent of the patient or the patient's legally designated representative cannot be reasonably obtained, assisting in the care or treatment of a patient without the consent of the patient, the attending physician or the patient's legal representative....

Wyoming Statutes Annotated, TITLE 35 - PUBLIC HEALTH AND SAFETY, ARTICLE 9 - LICENSING AND OPERATIONS⁹⁸

Summary and Analysis:

- Other than the medical malpractice law (Title 33), we were unable to identify a relevant informed consent law for Wyoming or a resident's rights or patient's rights law or rules that referenced more than federal minimum standards.
- Thus, the federal bill would likely provide stronger informed consent protections for Wyoming nursing home residents.

⁹⁷ Accessed at

<http://legisweb.state.wy.us/statutes/statutes.aspx?file=titles/Title33/T33CH26.htm>.

⁹⁸ Accessed at

<http://legisweb.state.wy.us/statutes/statutes.aspx?file=titles/Title35/Title35.htm>.

Appendix 1: The Improving Dementia Care Treatment for Older Adults Act (Section 5)

Following is Section 5 of the Improving Dementia Care Treatment for Older Adults Act. This section is included here because it contains the bill's language relating to protocols for informed consent.⁹⁹

SEC. 5. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC.

(a) Standardized Protocol-

(1) SKILLED NURSING FACILITIES- Section 1819(b) of the Social Security Act (42 U.S.C. 1395i-3(b)), as amended by section 4, is amended by adding at the end the following new paragraph: '(10) STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION-

(A) PROTOCOL- Not later than 180 days after the date on which the Comptroller General submits the report on State informed consent laws under section 5(a)(3) of the Improving Dementia Care Treatment for Older Adults Act of 2012, the Secretary shall develop a standardized protocol for skilled nursing facilities to obtain informed consent from an older adult with dementia (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) prior to prescribing an antipsychotic to the older adult for a use not approved by the Food and Drug Administration. '(B) REQUIREMENTS- The standardized protocol developed under subparagraph (A) shall include the following:

(i) A requirement, with respect to an older adult with dementia, that--

'(I) the facility, with the involvement of the prescriber, inform the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) of--

(aa) possible side effects and risks associated with the antipsychotic, including the mention of any 'black box warning';

(bb) treatment modalities that were attempted prior to the use of the antipsychotic; and

(cc) any other information the Secretary determines appropriate;

(II) the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) provide consent to the administration of the antipsychotic; and '(III) the administration of the antipsychotic is in accordance with any plan of care that the older adult has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.

(ii) An alternative protocol for obtaining such informed consent--

⁹⁹ SS. 3604 (112th): Improving Dementia Care Treatment for Older Adults Act of 2012. Accessed at <http://www.govtrack.us/congress/bills/112/s3604/text>.

(I) in the case of emergencies; and ‘(II) in the absence of a clearly identified designated health care agent or other surrogate under State law or regulation.

(iii) Other items determined appropriate by the Secretary.

(C) TIMING OF INFORMED CONSENT- Under the standardized protocol, a skilled nursing facility shall obtain informed consent--

(i) prior to the initial prescribing of antipsychotics; or ‘(ii) in the case of an individual already prescribed antipsychotics when admitted to a facility, the facility shall obtain informed consent if the facility maintains antipsychotic treatment after the first drug regimen review conducted with respect to the individual.

(D) COMPLIANCE- Effective beginning on the date that is 18 months after the date of enactment of the Improving Dementia Care Treatment for Older Adults Act of 2012, a skilled nursing facility shall comply with the standardized protocol developed under subparagraph (A).

(E) NO PREEMPTION- Nothing in this paragraph shall preempt any provision of State or Federal law that provides broader rights with respect to informed consent for residents of facilities.’.

(2) NURSING FACILITIES- Section 1919(b) of the Social Security Act (42 U.S.C. 1396r(b)), as amended by section 4, is amended by adding at the end the following new paragraph: ‘(10) STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION-

(A) PROTOCOL- Not later than 180 days after the date on which the Comptroller General submits the report on State informed consent laws under section 5(a)(3) of the Improving Dementia Care Treatment for Older Adults Act of 2012, the Secretary shall develop a standardized protocol for nursing facilities to obtain informed consent from an older adult with dementia (or, if applicable, the older adult’s designated health care agent or other surrogate under State law or regulation) prior to prescribing an antipsychotic to the older adult for a use not approved by the Food and Drug Administration. ‘(B) REQUIREMENTS- The standardized protocol developed under subparagraph (A) shall include the following:

(i) A requirement, with respect to an older adult with dementia, that--

(I) the facility, with the involvement of the prescriber, inform the older adult (or, if applicable, the older adult’s designated health care agent or other surrogate under State law or regulation) of--

(aa) possible side effects and risks associated with the antipsychotic, including the mention of any ‘black box warning’;

(bb) treatment modalities that were attempted prior to the use of the antipsychotic; and

(cc) any other information the Secretary determines appropriate;

(II) the older adult (or, if applicable, the older adult’s designated health care agent or other surrogate under State law or regulation) provide consent to the administration of the antipsychotic; and ‘(III) the administration of the antipsychotic is in accordance with any plan of care that the older adult has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.

(ii) An alternative protocol for obtaining such informed consent--

(I) in the case of emergencies; and ‘(II) in the absence of a clearly identified designated health care agent or other surrogate under State law or regulation.

(iii) Other items determined appropriate by the Secretary.

(C) TIMING OF INFORMED CONSENT- Under the standardized protocol, a nursing facility shall obtain informed consent--

(i) prior to the initial prescribing of antipsychotics; or (ii) in the case of an individual already prescribed antipsychotics when admitted to a facility, the facility shall obtain informed consent if the facility maintains antipsychotic treatment after the first drug regimen review conducted with respect to the individual.

(D) COMPLIANCE- Effective beginning on the date that is 18 months after the date of enactment of the Improving Dementia Care Treatment for Older Adults Act of 2012, a nursing facility shall comply with the standardized protocol developed under subparagraph (A).

(E) NO PREEMPTION- Nothing in this paragraph shall preempt any provision of State or Federal law that provides broader rights with respect to informed consent for residents of facilities.’.

(3) GAO STUDY AND REPORT ON INFORMED CONSENT LAWS WITH RESPECT TO PRESCRIBING OF AN ANTIPSYCHOTIC-

(A) STUDY- The Comptroller General of the United States (in this paragraph referred to as the ‘Comptroller General’) shall conduct a study of State laws and regulations concerning informed consent with respect to the administration of an antipsychotic (or other psychoactive medication) with regard to the effectiveness of such laws and practices in changing the frequency of prescribing of antipsychotics (or other psychoactive medications) to older adults with dementia. The study shall include an analysis as to whether in the case of States that have not enacted such informed consent laws, such States have developed other mechanisms to guide appropriate prescribing of antipsychotics in older adults with dementia. (B) REPORT- Not later than 180 days after the date of enactment of this Act, the Comptroller General shall submit to the Secretary and to Congress a report containing the results of the study conducted under subparagraph (A), together with such recommendations as the Comptroller General determines appropriate.

(b) Development of Measure of Utilization of Antipsychotics for Inclusion on Nursing Home Compare Website-

(1) MEDICARE- Section 1819(i) of the Social Security Act (42 U.S.C. 1395i-3(i)) is amended by adding at the end the following new paragraph: ‘(3) DEVELOPMENT OF MEASURE OF UTILIZATION OF ANTIPSYCHOTICS-

(A) IN GENERAL- The Secretary shall include a measure of the utilization of antipsychotics for each facility for inclusion on such website (or a successor website) as part of the quality measures or health inspection measures, or both such measures, under the Five-Star Quality Rating System. ‘(B) CONSIDERATIONS- In developing the measure under subparagraph (A), the Secretary shall take into account special patient populations, special care units, appropriate diagnoses, and other factors, as determined appropriate by the Secretary.’.

(2) MEDICAID- Section 1919(i) of the Social Security Act (42 U.S.C. 1396r(i)) is amended by adding at the end the following new paragraph: ‘(3) DEVELOPMENT OF MEASURE OF UTILIZATION OF ANTIPSYCHOTICS-

(A) IN GENERAL- The Secretary shall include a measure of the utilization of antipsychotics for each facility for inclusion on such website (or a successor website) as part of the quality measures or health inspection measures, or both such measures, under the Five-Star Quality Rating System. ‘(B) CONSIDERATIONS- In developing the measure under subparagraph (A), the

Secretary shall take into account special patient populations, special care units, appropriate diagnoses, and other factors, as determined appropriate by the Secretary.’

Appendix 2: Federal Informed Consent Requirements for Experimental Research

Code of Federal Regulations, TITLE 45 - PUBLIC WELFARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46 - PROTECTION OF HUMAN SUBJECTS¹⁰⁰

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

¹⁰⁰ Accessed at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>.

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)
[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

Summary and Analysis:

- These requirements for informed consent pertain only to a resident's potential participation in experimental research.
- They are included here because they provide numerous provisions relevant to the development and implementation of informed consent policies.
- Requirements include basic elements such as information on the risks and benefits of the proposed treatment (including, importantly, potential discomfort that the treatment might cause the resident) and alternative treatment options.
- Additional important requirements in this law include:
 - Consent must be sought and given only "under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."
 - "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights...."

Appendix 3: Chart Showing Status of State Informed Consent Laws (Based on Study Findings)

State	Strong Informed Consent Provisions	Weak or No Informed Consent Provisions
Alabama		X
Alaska	X	
Arizona		X
Arkansas		X
California	X	
Colorado		X
Connecticut		X
Delaware		X
District of Columbia		X
Florida		X
Georgia		X
Hawaii		X
Idaho		X
Illinois	X	
Indiana		X
Iowa	X	
Kansas		X
Kentucky		X
Louisiana		X
Maine		X
Maryland		X
Massachusetts		X
Michigan		X
Minnesota		X
Missouri		X
Montana		X
Nebraska		X
Nevada	X	
New Hampshire		X
New Jersey		X
New Mexico		X
New York		X
North Carolina		X
North Dakota		X
Ohio		X
Oklahoma		X
Oregon		X
Pennsylvania		X
Rhode Island		X
South Carolina		X
South Dakota		X
Tennessee		X
Texas		X
Utah		X
Vermont		X
Virginia		X
Washington	X	
West Virginia		X
Wisconsin	X	
Wyoming		X