CHAPTER HFS 94

PATIENT RIGHTS AND RESOLUTION OF PATIENT GRIEVANCES

This Department of Health and Family Services chapter is promulgated to implement Statute 51.61 concerning the rights of patients receiving treatment for mental illness, a developmental disability, alcohol abuse or dependency or other drug abuse or dependency.

HFS 94.03 Informed Consent.
(1) Any informed consent document required under this chapter shall declare that the patient or person acting on the patient’s behalf has been provided with specific, complete and accurate information and time to study the information or to seek additional information concerning the proposed treatment or services made necessary by and directly related to the person’s mental illness, developmental disability, alcoholism or drug dependency, including:
   (a) The benefits of the proposed treatment and services;
   (b) The way the treatment is to be administered and the services are to be provided;
   (c) The expected treatment side effects or risks of side effects which are a reasonable possibility, including side effects or risks of side effects from medications;
   (d) Alternative treatment modes and services;
   (e) The probable consequences of not receiving the proposed treatment and services;
   (f) The time period for which the informed consent is effective, which shall be no longer that 15 months from the time the consent is given; and
   (g) The right to withdraw informed consent at any time, in writing.
(2) An informed consent document is not valid unless the subject patient who has signed it is competent, that is, is substantially able to understand all significant information which has been explained in easily understandable language, or the consent form has been signed by the legal guardian of an incompetent patient or the parent of a minor, except that the patient’s informed consent is always required for the patient’s participation in experimental research, subjection to drastic treatment procedures or receipt of electroconvulsive therapy.
(3) The patient, or the person acting on the patient’s behalf shall be given a copy of the completed informed consent form, upon request.
(4) When informed consent is refused or withdrawn, no retaliation may be threatened or carried out.
CHAPTER HFS 124

HOSPITALS

HFS 124.05 (3) Policies. (a) Patient rights and responsibilities.
(1) Every hospital shall have written policies established by the governing board on patient rights and responsibilities which shall provide that:
   (k) The patient or the patient’s legally authorized representative shall give prior informed consent for the patient’s participation in any form of research.

CHAPTER 448

MEDICAL PRACTICES

448.30 Information on alternate models of treatment.
Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician’s duty to inform the patient under this section does not require disclosure of:
(1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.
(2) Detailed technical information that in all probability a patient would not understand.
(3) Risks apparent or known to the patient.
(4) Extremely remote possibilities that might falsely or detriment ally alarm the patient.
(5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
(6) Information in cases where the patient is incapable of consenting.

NOTE: Under Wisconsin Administrative Code MED 10.02(2)(a), “violating or attempting to violate any provision or term of ch. 448, Stats., or any valid rule of the board” is defined as “unprofessional conduct” and exposes the physician to discipline.

Legal precedent:
Martin v. Richards, 192 Wis.2d 156 (1955): A one to three in 100 chance of a condition’s existence is not an “extremely remote possibility” under 448.30(4) when very serious consequences could result if the condition was present. The failure to disclose a 1% chance of intracranial bleeding prior to a decision whether to perform additional tests was found to be a breach of duty to obtain informed consent.

CHAPTER 155

POWER OF ATTORNEY FOR HEALTH CARE

155.01 Definitions.
(8) “Incapacity” means the inability to receive and evaluate information effectively or to communicate decisions to such an extent that the individual lacks the capacity to manage his or her health care decisions.
(10) “Power of attorney for health care” means the designation, by an individual, of another as his or her health care agent for the purpose of making health care decisions on his or her behalf if the individual cannot due to incapacity.

155.05 Power of attorney for health care.
(1) An individual who is of sound mind and has attained the age 18 may voluntarily execute a power of attorney for health care.
(2) Unless otherwise specified in the power of attorney for health care instrument, an individual’s power of attorney for health care takes effect upon finding of incapacity by 2 physicians, as defined by s. 448.01 (5), or one physician and one licensed psychologist, as defined in s. 455.01 (4), who personally examine the principal and sign a statement specifying that the principal has incapacity. Mere old age, eccentricity or physical disability, either singly or together, are insufficient to make a finding of incapacity. Neither of the individuals who make a finding of incapacity may be a relative of the principal or have knowledge the he or she is entitled to or has a claim on any portion of the principal’s capital estate.

NOTE: This statute presumes the principal had capacity to consent to health care before becoming unable to communicate his or her wishes and so is not effective in situations where the principal lacked capacity (e.g., minor, incompetent).

NOTE: Duress is a common law requirement, so its limits are established by courts. A patient under duress may claim lack of capacity and therefore the informed consent is invalid. A patient must be given time to consider options and not be subject to undue influence from health care providers.

155.10 Power of attorney for health care instrument; execution; witnesses.
(1) A valid power of attorney for health care instrument shall be all of the following:
   (a) In writing.
   (b) Dated and signed by the principal or by an individual who has attained the age 18, at the express direction and in the presence of the principal.
   (c) Signed in the presence of 2 witnesses who meet the requirements of sub. (2).
   (d) Voluntarily executed.
(2) A witness to the execution of a valid power of attorney for health care instrument shall be an individual who has attained age 18. No witness to the execution of the power of attorney for health care instrument may, at any time of the execution, be any of the following:
   (a) Related to the principal by blood, marriage or adoption.
   (b) Have knowledge that he or she is entitled to or has a claim on any portion of the principal’s estate.
   (c) Directly financially responsible for the principal’s health care.
   (d) An individual who is a health care provider who is serving the principal at the time of execution, an employee, other than a chaplain or social worker, of the health care provider or an employee, other that a chaplain or social worker, of an inpatient health care facility in which the principal is a patient.
   (e) The principal’s health care agent.

155.20 Health care agent; powers; limitations.
(3) A health care agent may not consent to experimental mental health research or to psychosurgery, electroconvulsive treatment or drastic mental health treatment for the principal.
NOTE: There are no other state law limitations on the ability of an agent to give consent to participation in research. However, Federal regulations still need to be considered.

155.40 Revocation of power of attorney for health care.
(1) A principal may revoke his power of attorney for health care and invalidate the power of attorney for health care instrument at any time by doing any of the following:
   (a) Canceling, defacing, obliterating, burning, tearing or otherwise destroying the power of attorney for health care instrument or directing another in the presence of the principal to so destroy the power of attorney for health care instrument.
   (b) Executing a statement, in writing, that is signed and dated by the principal, expressing the principal’s intent to revoke the power of attorney for health care.
   (c) Verbally expressing the principal’s intent to revoke the power of attorney for health care, in the presence of 2 witnesses.
   (d) Executing a subsequent power of attorney for health care instrument.

155.60 Safeguards.
(3) Upon receipt of a power of attorney for health care instrument or a statement of incapacity under s. 155.05 (2), a health care facility or health care provider shall acknowledge this receipt in writing and, if the principal is a patient of the health care provider, the health care provider shall include the instrument or the statement in the medical record of the principal.

INFORMED CONSENT- MINORS

The Department of Veterans Affairs disapproves research involving minors unless a waiver is granted by the Chief R&D Officer. Wisconsin statutes that define a minor are summarized below. Anyone under the age of 18 is a minor and is incapable as a matter of law of giving informed consent, with limited exceptions as follows:

- A minor of any age can consent to diagnosis and treatment of sexually transmitted diseases except for HIV, under §252.11, Wis. Stats.
- A minor 12 and older can consent to treatment for alcohol or other drug dependency, under §51.47, Wis. Stats.
- A minor 17 and older may donate blood, under §146.33, Wis. Stats.
- A minor 12 and older may donate blood marrow to a sibling if a psychologist confirms that the minor is capable of giving informed consent, under §146.34(4), Wis. Stat.
- A minor emancipated by marriage has capacity to give informed consent.

No exception is give for the treatment of pregnancy or for contraception or abortion, under §48.375, Wis. Stats. Such treatment requires consent from specified family members or the courts.

Informed consent for minors is typically given by the parents. When parental consent is required, only one parent is required to give valid consent, even if the other parent of the minor objects. The only exception is that a parent and minor age 14 and older both must consent to outpatient mental health treatment.
FINAL NOTES:
Under HFS 94.11 (2), the patient shall be informed that he or she has a right to consult with legal
counsel, legal guardian, if any, and independent specialists prior to giving informed consent for
electroconvulsive therapy.

A general understanding exists that family members have the right to make decisions for other family
members. In fact, family members generally have no standing to make health care decisions for other
family members under Wisconsin law, except as described above.

Legal precedent:
Martin v. Richards, 192 Wis.2d 156 (1955): A doctor has a duty under 448.30 to advise of alternative
modes of treatment for diagnosed conditions.

Schreiber v. Physicians Insurance Co., 222 Wis2d 417 (1999): The onset of a procedure does not
categorically foreclose withdrawal of a patient’s consent. Withdrawal of consent removes the doctor’s
authority to continue and obligates the doctor to conduct another informed consent discussion. If the
patient’s choice of treatment, based on disclosure of all pertinent information to the patient, is known,
the objective test of what a reasonable person would have chosen is not relevant. Once consent is
withdrawn, the informed consent process must start again from the beginning in order to be valid.

Wisconsin Statutes
Patient Health Care Records

The basic principle is that physical records are the property of the entity that creates them, but that the
subject of the records both has a right to control the information in them and has an expectation of
privacy concerning their use and disclosure. Wisconsin law applies where it is “more stringent” than
HIPAA’s Privacy Rule per 45 CFR §160.202. Wisconsin State Statutes pertaining to patient health care
records are summarized below.

CHAPTER 146
MISCELLANEOUS HEALTH PROVISIONS

146.81 Health care records; definitions.
“Patient health care records” means “all records related to the health of the patient prepared by or under
the supervision of a health care provider”. In general, this applies to anything upon which a health care
provider relies or would expect to rely upon to provide health care to a patient. “Health care provider” is
declared at §48.981(2m)(b) as a physician, an physician assistant or a licensed nurse. Chapter 146 defines
20 additional categories that meet the definition of “health care provider”. The “patient” is the person
receiving health care services from a health care provider.

146.82 Confidentiality of patient health care records.
Under §146.82, “patient health care records” must remain confidential and may only be released with
the patient’s “written informed consent” unless an exception applies. In this case, the elements of
“written informed consent” under §146.81(2) are the name of the patient, type of health information to
be disclosed, persons to whom health care records may be disclosed, the purpose of the disclosure, the
signature by an authorized person and the relationship to the patient if not the patient, the date of
signature and the period during which the consent remains effective. The “written informed consent”
must be “well documented” in the medical record under Wis. Admin. Code MED 18.03.

Under §146.82(1), consent to the release of patient health care records may only be given by the
“patient” or a “person authorized by the patient” unless an exception applies. “Person authorized by the
patient” that can consent to the release includes parent or custodian of a minor, legal guardian, personal
representative or spouse of deceased, an agent under a health care power of attorney or any person
authorized in writing by the patient.

Under §146.82(2)(a), release of patient health care records may be made without patient consent “for
research purposes if the researcher is affiliated with the health care provider and provides the records
custodian with written assurances” that further disclosure will not be made. The research exception does
not apply for patient health care records of private pay patients if they file written notice with the
custodian of the records at least once each year objecting to such release.

Under §146.82(2)(a)(20), release of patient health care records is permitted if the records do not contain
information that identifies the patient and the circumstances of the release do not provide information
that would permit the identification of the patient.

NOTE: Research records that meet the definition under §146.81 must be included in the patient health
care records. Research records that do not meet the above definition but are nevertheless included in the
patient health care records, must be disclosed. To avoid the need to disclose research records,
researchers must make sure that information that does not meet the above definition is not included in
the patient health care records. Information in the research records that meets the above definition but is
not included in the patient health care records is still subject to disclosure.

Wisconsin Statutes
Alcohol, Drug Abuse, Developmental Disabilities, Mental Health

CHAPTER 51

STATE ALCOHOL, DRUG ABUSE DEVELOPMENTAL DISABILITIES AND MENTAL
HEALTH ACT

Under §51.30, records of individuals who are receiving or who at any time have received services for
mental illness, developmental disabilities, alcoholism or drug dependency may be released without
informed written consent for purposes of research if the research project has been approved by the
department and the researcher has provided assurances that the information will be used only for
purposes for which it was provided to the researcher, the information will not be released to a person not
connected with the study under consideration, and the final product of the research will not reveal
information that may serve to identify the individual whose treatment records are being released under
this subsection without the informed consent of the individual. Such information shall remain
confidential. In approving research projects under this subsection, the department shall impose any additional safeguards needed to prevent unwarranted disclosure of information.

Under §51.61, each patient shall have a right not to be subjected to experimental research without the express and informed consent of the patient and of the patient’s guardian after consultation with independent specialists and the patient’s legal counsel. Such proposed research shall first be reviewed and approved by the institution’s research and human rights committee and by the department before any such consent may be sought. Prior to such approval, the committee and the department shall determine that research complies with the principles of the statement on the use of human subjects research adopted by the American Association on Mental Health Deficiency, and with the regulations for research involving human subjects required by the U.S. department of health and human services for projects supported by that agency.

Wisconsin Statutes
Genetic Testing

CHAPTER 631
INSURANCE CONTRACTS GENERALLY

Section 631.89 defines “genetic test” as “a test using deoxyribonucleic acid extracted from an individual’s cells in order to determine the presence of a genetic disease or disorder or the individual’s predisposition for a particular genetic disease or disorder”. Paternity and forensic testing are excluded from the definition. This section provides that insurers may not require or request that a health care provider reveal whether or not an individual has had a genetic test or the results of that test. It includes employers who provide insurance as part of an employee benefit. Other than that, there are no current limits under Wisconsin law on genetic testing or disclosure of test results. It is anticipated that additional legislation will be drafted in the future to control the use of such information.

Wisconsin Statutes
HIV Testing

CHAPTER 252
COMMUNICABLE DISEASES

252.15 Restrictions on use of a test for HIV.
NOTE: This section governs HIV testing and release of testing results. Treatment of HIV is not covered. Under 252.15(2)(a)(2), results of required HIV testing at blood banks may be disclosed for purposes of managing blood donations or a person making such a donation. Participation in HIV testing and HIV test results for a patient may otherwise only be disclosed within the organization to the extent that the person to whom it is disclosed is actually providing health care to a patient, unless an exception applies.
HIV testing and test results may be disclosed if the subject consents or an exception applies as follows:

- Testing for organ donation.
- Testing for research if the subject’s identity is not known and cannot be retrieved by the researcher.
- Testing for research if the researcher is affiliated with the health care provider, has permission from the IRB and provides a written assurance to the disclosure of the information that it will only be used for research purposes and will not be released outside the study with any personally identifiable information without the subject’s consent.

If the release of HIV test results is based on consent, the party releasing the information must have a signed consent that lists the statutorily permitted exceptions to release without consent or states in the consent that the list is available on request. A record of the consent and the HIV test results reported must be maintained by the discloser.

---

**Wisconsin Statutes**

**Required Reporting**

Under Wisconsin statutes:

- Under §979.0, death must be reported to the sheriff or Chief Medical Examiner
- Under §254.13(1), lead poisoning diagnosis must be reported to the Department of Health and Family Services (DHFS) within 48 hours of detection.
- Under Wis. Admin. Code HFS Chapter 145, communicable disease diagnoses must be reported.
- Under §48.981, reasonable cause to suspect child abuse or neglect must be reported. A fetus is not a child for purposes of this reporting requirement.
- Under §255.04, cancer diagnosis, except for squamous cell carcinoma or basal cell carcinoma arising in the skin, must be reported to DHFS.
- Under §146.0255, positive results of controlled substances tests on infants must be reported to DHFS.
- Under §146.955, gunshot wound or other wound likely the result of a crime or second or third degree burn to more than 5% of the body must be reported to the sheriff.
- There is a common law duty to warn third parties of the dangerousness of a patient. In Schuster v. Altenberg, 144 Wis.2d 223 (1988), the Wisconsin Supreme Court said that the failure to warn others of a patient’s dangerousness is professional negligence because “the duty to others to exercise reasonable care includes the duty to warn potential victims.”

---

**Wisconsin Statutes**

**Miscellaneous**

Under §450.07, sale or distribution of prescription drugs or medical devices may be made at wholesale “for purposes of lawful research”.

Under §255.055(1), state funds are authorized for breast cancer research at the Medical College of Wisconsin, subject to appropriations.
CHAPTER HFS 94

PATIENT RIGHTS AND RESOLUTION OF PATIENT GRIEVANCES
This Department of Health and Family Services chapter is promulgated to implement Statute 51.61 concerning the rights of patients receiving treatment for mental illness, a developmental disability, alcohol abuse or dependency or other drug abuse or dependency.

HFS 94.02 Definitions.
(38) “Research” means a systematic investigation designed to develop or contribute to generalizable knowledge, except that it does not include and investigation involving only treatment records or routine follow-up questionnaires.

HFS 94.14 Research.
(1) All proposed research involving patients shall meet the requirements of s. 51.61 (1)(j), Stats., 45 CFR 46, and this section.
(2) No patient may be subject to any experimental diagnostic or treatment technique or to any other experimental intervention unless the patient gives informed consent, the patient’s informed consent is confirmed by the consent monitor and the research and human rights committee has determined that adequate provisions are made to:
   (a) Protect the privacy of the patient;
   (b) Protect the confidentiality of treatment records in accordance with s. 51.30, Stats., and ch. HFS 92;
   (c) Ensure that no patient may be approached to participate in the research unless the patient’s participation is approved by the person who is responsible for the treatment plan of the patient; and
   (d) Ensure that the conditions of this section and other requirements under this chapter are met.

HFS 94.13 Research and human rights committee.
(1) An inpatient or residential treatment facility conducting or permitting research or drastic treatment procedures involving human subjects shall establish a research and human rights committee in accordance with 45 CFR 46, s. 51.61 (4), Stats, and this section.
(2) The committee shall include 2 members who are consumers or who represent either an agency or organization which advocates rights of patients covered by this chapter.
(3) The inpatient or residential treatment facility research and human rights committee shall designate a person to act as consent monitor who shall be authorized to validate informed consent and terminate a patient’s participation in a research project or drastic treatment procedure immediately upon violation of any requirement under this chapter or upon the patient’s withdrawal of consent.
51.61 Patients Rights

(a) Each facility that conducts human subjects research shall establish a research and human rights committee consisting of not less than 5 persons with varying backgrounds to assure complete and adequate review of research activities commonly conducted at the facility. The committee shall be sufficiently qualified through maturity, experience and expertise of its members and diversity of its membership to ensure respect for its advice and counsel for safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the committee shall be able to ascertain the acceptability of proposals in terms of commitments of the facility and federal regulations, applicable law, standards of professional conduct and practice, and community attitudes.

(b) No member of a committee may be directly involved in the research activity or involved in either the initial or continuing review of an activity in which he or she has a conflicting interest, except to provide information requested by the committee.

(c) No committee may consist entirely of persons who are officers, employees or agents of or are otherwise associated with the facility, apart from their membership on the committee.

(d) No committee may consist entirely of members of a single professional group.

(e) A majority of the membership of the committee constitutes a quorum to do business.