

## **Informed Consent: Patient Safety and Standard of Care**

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### **The Statute:**

446.08 Informed consent. Any chiropractor who treats a patient shall inform the patient about the availability of reasonable alternate modes of treatment and about the benefits and risks of these treatments.

The reasonable chiropractor standard is the standard for informing a patient under this section.

The reasonable chiropractor standard requires disclosure only of information that a reasonable chiropractor would know and disclose under the circumstances.

The chiropractor's duty to inform the patient under this section does not require disclosure of any of the following:

- (1) Detailed technical information that in all probability a patient would not understand.
- (2) Risks apparent or known to the patient.
- (3) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
- (4) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
- (5) Information in cases where the patient is incapable of consenting.
- (6) Information about alternate modes of treatment for any condition the chiropractor has not included in his or her diagnosis at the time the chiropractor informs the patient.

### **The Rule:**

#### **Chir 11.02 Patient record contents .**

- (1) Complete and comprehensive patient records shall be created and maintained by a chiropractor for every patient with whom the chiropractor consults, examines or treats.
- (2) Patient records shall be maintained for a minimum period of 7 years as specified in s. Chir 6.02 (27).
- (3) Patient records shall be prepared in substantial compliance with the requirements of this chapter.
- (4) Patient records shall be complete and sufficiently legible to be understandable to health care professionals generally familiar with chiropractic practice, procedures and nomenclature.
- (5) **Patient records shall include documentation of informed consent of the patient, or the parent or guardian of any patient under the age of 18, for examination, diagnostic testing and treatment.**
- (6) Rationale for diagnostic testing, treatment or other ancillary services shall be documented in or readily inferred from the patient record.
- (7) Significant, relevant patient health risk factors shall be identified and documented in the patient record.
- (8) Each entry in the patient record shall be dated and shall identify the chiropractor, chiropractic assistant or other person making the entry.

**Note:** Chiropractors should be aware that federal requirements, especially in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), may have an impact on record-keeping requirements.

**The six elements of informed consent:**

- The patient's diagnosis, if known.
- The nature and purpose of the proposed treatment or procedure.
- The risks and benefits of the proposed treatment or procedure.
- Alternatives.
- Risks and benefits of the alternative treatment or procedure.
- Risks and benefits of not receiving or undergoing the treatment or procedure.

**Types of Stroke:**

*Ischemic:* [88% of strokes] brain damage due to occlusion of blood vessels

- Thrombotic strokes [~60% of all strokes] are caused by a blood clot (thrombus) in an artery going to the brain. The clot blocks blood flow to part of the brain. Blood clots usually form in arteries damaged by plaque.
- Embolic strokes [~20% of all strokes] are caused by a wandering clot (embolus) that's formed elsewhere (usually in the heart or neck arteries). Clots are carried in the bloodstream and block a blood vessel in or leading to the brain.

*Hemorrhagic:* [12% of strokes] brain damage due to a rupture of blood vessel

- Subarachnoid hemorrhage [SAH]: This occurs when a blood vessel on the surface of the brain ruptures and bleeds into the space between the brain and skull. The most common cause is a ruptured aneurysm caused by high blood pressure. Other causes are: rupture of an AVM (arteriovenous malformation), bleeding from an injury due to a blow to the head, or venous or capillary problems.
- Intracerebral hemorrhage [ICH]: This is bleeding into the tissue deep within the brain. High blood pressure is often the cause of this type of stroke. Injury and rupture due to problem vessels can also be the cause.

**Duration of stroke symptoms:**

TIA: Transient ischemic attack    Stroke-like symptoms for < 24 hours.    Will precede an actual stroke in 10-15% of cases

RIND: Reversible ischemic neurological deficit lasting up to six weeks.

Stroke: neurological deficit lasting up > six weeks.

**Risk factors for stroke:**

*Generally nonmodifiable risk factors:*

Age, gender, race, low birth weight, genetic factors

*Well documented and modifiable risk factors:*

Smoking, hypertension, diabetes, dyslipidemia, atrial fibrillation, other cardiac conditions, asymptomatic carotid stenosis, sickle cell disease, post-menopausal hormone therapy, oral contraceptives, diet and nutrition, physical inactivity, obesity and body fat distribution, history of prior TIA, RIND or stroke, infection [especially URI],

prescription medications, illegal drug abuse, weather: large daily temperature changes and higher average dew points.

*Less well-documented or potentially modifiable risk factors:*

Migraine, metabolic syndrome, alcohol consumption, drug abuse, sleep-disordered breathing, hyperhomocystenemia, elevated Lp[a], hypercoaguability, inflammation and infection, the use of aspirin for primary stroke prevention, elongated styloid processes, calcification of ICA or VA or abdominal aorta.

*Anecdotal or temporal relationships:*

Situps, beauty parlor, spinal manipulation, soda, diet soda, extended sleep

Posterior ponticles are not likely related

Under Sec. 51.61, Wisconsin Statutes, **The patient's written, "informed consent" is required:**

To perform **labor** which is of financial benefit to the facility. (ss. 51.61(1)(b)1c)

For all **medication and treatment** (unless court-ordered). (ss. 51.61(1)(f)-(g))

To be subjected to **experimental research**. (ss. 51.61(1)(j))

To be subjected to **psychosurgery**, or other **drastic treatment** procedures. (ss. 51.61(1)(k))

For **release of treatment records** (with 27 exceptions - refer to ss. 51.61(1)(n) and ss. 51.30 for list)

To be **filmed or taped**. (ss. 51.61(1)(o))

For **customary and usual treatment** techniques and procedures, "...unless the person has been found not competent to refuse medication and treatment under ss. 51.61(1)(g). In the case of a minor, the written, informed consent of the **parent or guardian** is required.

Except as provided under an order issued under ss. 51.14 (3) (h) or (4) (g), **if the minor is 14 years of age** or older, the written, informed **consent** of the minor and the **minor's parent or guardian** is required..." (ss. 51.61(6))

**DHS 94.03, Wisconsin Administrative Code - "INFORMED CONSENT.** (1) Any informed consent document required under this chapter shall declare that the patient or the 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:

(2) An informed consent document is not valid unless the subject patient who signed it is **competent**, that 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.

## Highlights of Wisconsin Case Law:

### **Kerkman v. Hintz, 142 Wis. 2d 404, 418 N.W.2d 795 (1988).**

We conclude that a chiropractor must exercise that degree of care, diligence, judgment, and skill which is exercised by a reasonable chiropractor under like or similar circumstances.

A chiropractor has no duty to refer to a physician a patient who is not treatable through chiropractic means. Chiropractors aren't held to medical standard of care.

### **McGeshick v. Choucair 9 F.3d 1229 (1993)**

The doctrine of informed consent is limited to apprising the patient of risks that inhere to proposed treatments. It does not impose a duty to apprise a patient of any knowledge the doctor may have regarding the condition of the patient or of all possible methods of diagnosis.

### **Johnson v. Kokemoor, 199 Wis. 2d 615, 545 N.W.2d 495 (1996), 93-3099.**

What a physician must disclose is contingent on what a reasonable person would need to know to make an informed decision. When different physicians have substantially different success rates with a procedure and a reasonable person would consider that information material, a court may admit statistical evidence of the relative risk.

### **Kuklinski v. Rodriguez, 203 Wis. 2d 324, 329, 552 N.W.2d 869 (Ct. App. 1996)**

Under the **reasonable patient standard**, "Wisconsin law requires that a physician disclose information necessary for a reasonable person to make an intelligent decision with respect to the choices of treatment or diagnosis."

### **Goldstein v Janusz 1998 WI**

First, the supreme court in Kerkman implicitly determined that chiropractors do not have a duty to "recognize medical problems" because to do so would require chiropractors to make medical determinations which, under Wisconsin law, they are not licensed to make.

Second, as a matter of law, recognition of an abnormal mass in the lung area which was revealed by an x-ray is not within the practice of chiropractic because it concerns a body organ which is not a part of the "spinal column, skeletal articulation or adjacent tissue." Thus, detection or recognition of the mass as an "abnormality" would have amounted to a "recognition of a medical problem."

### **Murphy v Nordhagen 1998 WI**

Acknowledging that its holding rejected the rule, operable in several other states, that a chiropractor has a "duty to refer" patients to medical doctors, the Kerkman court **rejected the notion of any such duty with respect to chiropractors.**

In holding that **a chiropractor does not have a duty to refer**, we recognize that a number of states have imposed such a requirement. However, because implicit in a requirement that a chiropractor refer a patient to a medical doctor is the imposition on the

chiropractor to make a medical determination that the patient needs medical care, such a determination could not be made without employing medical knowledge.

Because a chiropractor is not licensed to make such a determination, we hold that a chiropractor does not have a duty to refer a patient who is not treatable through chiropractic means to a medical doctor.

**Hannemann v. Boyson, 2005 WI 94, 282 Wis. 2d 664, 698 N.W.2d 714, 03-1527**

The chiropractic rule does not impose any parameters on a chiropractor's duty to obtain informed consent, unlike Wis. Stat. § 448.30, which imposes specific requirements upon physicians.

“We conclude that although the practice of chiropractic and the practice of medicine are distinct health care professions, the obligation of the practitioners of both to disclose the risks of the treatment and care they provide should be the same.”

“As such, we hold that the scope of a chiropractor's duty to obtain informed consent is the same as that of a medical doctor.”

### **Jandre 2012 WI**

Specifically, the statute previously required “a physician to disclose information necessary for a reasonable person to make an intelligent decision with respect to the choices of treatment or diagnosis.”

In Jandre, the law required physicians to inform patients about “the availability of **all alternate, viable medical modes of treatment and about the benefits and risks of these treatments.**”

However, if Jandre is followed, physicians will be required to disclose all possible thought processes and potential diagnostic procedures with patients before any diagnosis is made.

The Jandre decision led to swift legislative reforms that changed from a ‘reasonable patient standard’ for informed consent to a ‘reasonable physician’ and later to a ‘reasonable chiropractor’;

### **Current law: Duty to evaluate**

446.02 (7d)(a) A chiropractor shall evaluate each patient before commencing treatment of the patient to determine whether the patient has a condition that is treatable by the practice of chiropractic. The evaluation shall be based upon an examination that is appropriate to the patient. To conduct the evaluation, the chiropractor shall utilize chiropractic science, as defined by the examining board by rule, and the principles of education and training of the chiropractic profession.

**Current law: Duty to assess**

(b) A chiropractor shall discontinue the practice of chiropractic on a patient if, at any time after the evaluation under par. (a) or during or following treatment of the patient, the chiropractor determines or reasonably believes that the patient's condition is not treatable by the practice of chiropractic, or will not respond to further practice of chiropractic by the chiropractor, except that a chiropractor may provide maintenance, supportive, and wellness care to the patient if the patient is being treated by another health care professional.

(c) A chiropractor who discontinues the practice of chiropractic as required in par. (b) shall inform the patient of the reason for discontinuing the practice of chiropractic and shall refer the patient to a physician licensed under subch. II of ch. 448. A chiropractor may continue to provide maintenance, supportive, and wellness care to a patient referred under this paragraph who requests these services from the chiropractor.

**Current law: Duty to refer**

A referral under this paragraph shall describe the chiropractor's findings. If the referral is written, the chiropractor shall provide the patient with a copy and shall maintain a copy in the patient's records. If the referral is oral, the chiropractor shall communicate the referral directly to the physician, shall notify the patient about the referral, and shall make a written record of the oral referral.

The written record of the oral referral shall include the name of the physician to whom the patient was referred and the date of the referral. The chiropractor shall maintain a copy of the written record of the oral referral in the patient's records.

**Summary of current law [2015]**

1. Informed consent to the reasonable chiropractor standard is required on each patient and must be documented.
2. If for developmental disability, IC may be valid for only 14 months.
3. DC has duty to assess, inform and refer.
4. "I'm sorry" is not admissible in a malpractice action.

**Standard of care:**

- the level at which an ordinary, prudent professional with the same training and experience in good standing in a same or similar community would practice under the same or similar circumstances.
- An "average" standard would not apply because in that case at least half of any group of practitioners would not qualify.

ACA, ICA, ACC, AMA all have positions on informed consent