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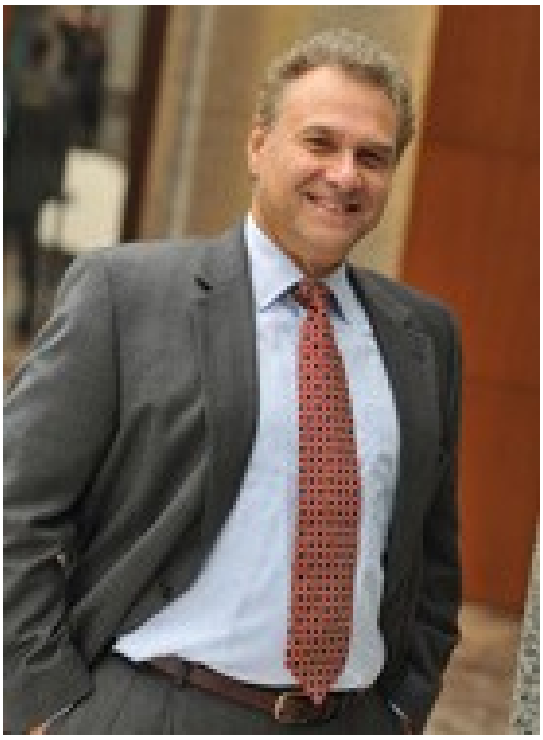
Maryland Bar Association
Health Care Section
– Developments in Informed Consent –



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INFORMED CONSENT

ORIGINS of INFORMED CONSENT

The Common Law

Civil and Criminal Battery

Since all established English law as it existed in 1776 was incorporated into Maryland law, it has been a tort for a doctor to perform a procedure, including any examination procedure, without first obtaining the patient's permission. Battery is an intentional tort and liability for battery subjects a physician to both punitive and compensatory damages and may be excluded from coverage under insurance.

Failure to obtain ***informed*** consent is negligence not battery.

Civil Negligence

Breach of the standard of care compared to breach of the duty to obtain informed consent.

Breach of the Standard of Care

Failure to provide care consistent with the standard of care that would be provided by a similarly qualified reasonable and prudent provider and resulting injury to the patient.

The standard of care is established by testimony of similarly qualified experts stating their opinion of what a reasonable and prudent doctor would have done or the care that would have been provided given the conditions presented by the patient.
The standard of care may also be established by reference to authoritative treatises, studies, and professional society publications.

Breach of the Duty to Obtain Informed Consent

Maryland, through the development of its common law, imposes a separate and substantial obligation on doctors to obtain informed consent prior to providing any care to patients.

Sard v. Hardy

The seminal, and still most fundamental, exposition of the law of informed consent was developed in *Sard v. Hardy* (1977). This case was brought by a patient when she became pregnant despite having received a well performed tubal ligation to which she had consented.

The patient claimed that the doctor was negligent in failing to advise her that the procedure had a 2% failure rate and that there were alternative methods of sterilization and birth control.

The Court of Appeals agreed, and clearly established the doctor's duty to obtain a patient's ***informed*** consent prior to providing any particular treatment.

This duty was held to be separate and distinct from the tort of battery (an unpermitted touching or act upon a patient) and from negligence in the selection and rendering of a particular treatment.

There was no breach of the standard of care provided Sard. The recommendation was reasonable and the ligation was carefully performed and met all elements of the standard of care. However, there was a breach of the separate duty to obtain her ***informed*** consent to the procedure because she was not provided

The Court stated that this duty is founded on the patient's right to make an informed choice about a particular therapy, so that a physician does not substitute his judgment, no matter how appropriate, for that of the patient.

Meeting the duty of informed consent, the Court held, required providing the patient with information and advice regarding: (1) the nature of the patients ailment or diagnosis; (2) the nature of the proposed treatment; (3) the probability of success and material risks, complications and outcomes and; (3) alternatives.

Material risks are those "which a physician knows or ought to know would be significant to a reasonable person in the patient's position" in making a decision about whether to submit to a particular treatment. Maryland's Civil Pattern Jury Instructions adopted this exposition of informed consent, but made clear that whether the patient would have consented to the procedure if informed of the risk, is a relevant factor, but is not conclusive and that only information regarding those risks which would be material to an intelligent decision by a ***reasonably prudent patient*** need be provided."

McQuitty v. Spangler

In *McQuitty v Spangler* (2009) the Court of Appeals revisited the law of informed consent as stated in Sard and both reaffirmed and amplified it.

This case was brought by a patient who gave birth to a child who sustained substantial neurological damage during gestation. The patient claimed that she was not given sufficient information to permit her to give her informed consent as to whether to continue carrying her child closer to term or have had a sooner Cesarean delivery. The physician's defense was that since he had the patient's initial consent to continue to carry the child and never proposed a sooner Cesarean delivery, he had no duty to obtain her informed consent to that procedure.

The Court disagreed and in deciding this case amplified the law of informed consent. Under the holding in *McQuitty* it now appears that a doctor has a duty to inform a patient of risks and available alternative treatments related to all *material changes* in her condition. Informed consent is no longer limited to those circumstances where a patient is asked to decide whether to submit to a specifically proposed procedure. Informed consent now requires provision of all information material to a patient in determining his course of care ("what shall be done with his own body and when"). The information must be sufficient to permit the patient involvement in the healthcare choices and treatment alternatives pertinent to his condition. In general determinations of which course of treatment to follow are for the patient to decide,

assisted by as much information and advice the doctor may reasonably be able to furnish.

Summary

Informed consent requires advising the patient of:

1. The patient's condition or diagnosis

2. The nature of the proposed treatment

3. All reasonable alternative treatments, including, if appropriate, no treatment and lifestyle changes

4. The probability of success and the risks of the proposed treatment and all reasonable alternatives.

5. All material changes in the patient's condition, all reasonable changes treatment options implicated by the change in condition.

6. All material information needed for a reasonably prudent patient to make decisions determining his course of care.

But there is no stated requirement as to how the patient is to be informed. Information may be provided through written, oral or any combination of communications. A written acknowledgement is not required.

Statutes, Regulations and Administrative Rulings

Health Occupations Article

The Maryland legislature has, with but one exception, declined over the years to set standards or create guidelines regarding informed consent.

However, for social workers the legislature did enact Sec 19-318 of the Health Occupations Article. It requires social workers to inform their patients of the services which may be provided, the cost for each service, and "sufficient information for a patient to give informed

consent regarding the service to be provided." The informed consent requirements must be documented by notation in the patient record or a form signed by the patient.

Code of Maryland Regulations (COMAR)

Only the Board of Chiropractic Examiners has undertaken to promulgate specific rules for providing informed to consent to patients by its licensed doctors. COMAR 10.43.14.06 sets out, in more detail than the standards of any other healthcare profession, the informed consent obligations imposed on chiropractors.

Summary of the Chiropractic Regulatory Requirements:

Patient to be provided:

Sufficient information to give an informed consent to treatment

Reason and description of each proposed procedure

Benefits, side effects, complications and alternatives

Estimated cost of treatment and cost of alternative treatments

Right to withdraw at any time and possible risks

To decline any observation, recording or non-therapeutic use of treatment

Patient's signed consent

Maryland Professional Board Pronouncements and Rulings

Rulings requiring more detailed and signed informed consents

1. Maryland Board of Physicians, as a condition of probation or corrective action may require specific items in a written informed consent document. *Board of Physicians v Barbara Solomon,*
2. Board of Chiropractic Examiners, in disciplinary actions has indicated specific limitations and information in extended course of care contracts with patients

Professional Associations, Specialty Boards and Hospitals

In General

The standard of care and a determination of that "which a physician knows or ought to know would be significant to a reasonable person in the patient's position" will likely find an evidentiary foundation in the standards of professional associations.

The AMA Guidelines

The American Medical Association guidelines recommend a doctor-***not*** a delegated associate:

1. discuss the diagnosis, if known
2. nature and purpose of treatment or procedure
3. risks and benefits of proposed procedure and of alternatives, including no treatment.
4. provide opportunity to ask questions to ensure understanding
5. document discussion and agreement in the ***patient record.***

The American Chiropractic Association

The American Chiropractic Association guidelines on Informed Consent recommend a doctor:

1. As in *McQuitty,* treat informed consent as an "ongoing discussion throughout the patient's course of care.
2. Advise and describe the recommended course of action and discuss the benefits, risks and reasonable and alternatives
3. Determine that the patient reasonably understands the discussion
4. Provide and opportunity to ask questions
5. Note any refusal to follow recommendations
6. Document the elements of informed consent in the patient record.

CMS Interpretive Hospital Guidelines (Sec 842.24)

CMS states hospital medical record must contain a document recording the patient's informed consent for procedures and treatments specified in the hospital by-laws and federal and state laws. The consent form must contain:

1. The name of the patient
2. The name of the facility
3. The specific procedure

4. The name of the responsible doctor for the procedure and the practitioner who conducted the informed consent discussion.
5. The signature of the patient
6. Date and time executed
7. Indication or listing of the material risks
7. Identification of physicians or other non-physician practitioners who may participate in procedure
8. Statement that the procedure, its benefits, material risks and alternatives was explained to the patient.

Note: CMS states that "Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity."

INFORMED CONSENT IN OTHER STATES

A. Connecticut

Like Maryland, Connecticut has adopted the "material risk" or "reasonable patient" standard of informed consent.[1] Under this approach, informed consent requires disclosure of the nature of the procedure, the risks, alternatives, and the anticipated benefits.[2] However, the full scope of the required disclosure is determined by what information would be material to a reasonable person in the patient's position faced with the decision of whether to embark upon a contemplated course of therapy.[3]

The Connecticut Board of Chiropractic Examiners recently issued a Declaratory Ruling in which it discusses which risks are considered to be material in the practice of chiropractic.[4] The Board stated that the materiality of a risk is determined by weighing the benefits of a procedure against the frequency and severity of the potential harm. Under this standard, the Board held that the scientific evidence is sufficient to establish that a stroke or cervical dissection is ***not*** a risk or side effect of a joint mobilization, manipulation, or adjustment of the cervical spine performed by a chiropractor.

B. Georgia

Georgia does not recognize the common law doctrine of informed consent.[5] Instead, informed consent is governed by statute in Georgia.[6] The informed consent statute does not impose a general requirement of disclosure upon physicians.[7] It enumerates a limited number of specific factors that must be disclosed by a physician prior to performing surgery or a diagnostic procedure.[8] Significantly, chiropractic treatment is not included among the matters for which informed consent is required by statute.[9] Thus, chiropractors in Georgia do not have a common law or statutory duty to

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[1] Logan v. Greenwich Hospital Association, 191 Conn. 282, 292-93 (1983); Duffy v. Flagg, 279 Conn. 682, 687-88 (2006).
[2] Id.
[3] Duffy v. Flagg, 279 Conn. at 692.
[4] Available at http://www.ct.gov/dph/lib/dph/phho/chiropractors/declaratory_rulings/declaratory_ruling_regarding_informed_consent_6_10_2010.pdf
[5] Blotner v. Dorieka, 285 Ga. 481 (2009).
[6] Informed Consent Doctrine, OCGA § 31-9-6.1
[7] Id.
[8] Id.
[9] Blotner v. Dorieka, 285 Ga. 481 (2009) (citing OCGA § 31-9-6.1).

inform patients of the material risks of a proposed treatment or procedure.[10] Physicians merely have a duty to truthfully answer questions from a patient regarding the risks associated with a treatment or procedure.[11]

C. Florida

Informed consent in Florida is governed by the Florida Medical Consent Law.[12] Unlike Maryland, Florida has adopted the professional community standard of informed consent, providing that an action for lack of informed consent is barred if

> "1. The action of the [physician] in obtaining the consent of the patient…was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community; and
> 2. A reasonable individual, from the information provided by the physician…would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures."[13]

The statute also provides that an action for lack of informed consent must fail if the jury determines that the patient would reasonably have undergone a treatment or procedure had she been fully advised by the physician.

Courts applying Florida's Medical Consent Law have held that a physician has a duty to advise his patient of the material risks of undergoing a medical procedure[14] and that consent is informed when the patient knows the dangers and degree of danger of the procedure to be performed.[15]

D. New Jersey

Like Maryland, New Jersey has adopted the "material risk" or "reasonable patient" standard of informed consent.[16] Under this approach, both case law

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[10] Blotner v. Dorieka, 285 Ga. 481 (2009); Albany Urology Clinic v. Cleveland, 272 Ga. 296, 528 S.E.2d 777 (2000).
[11] Id.
[12] § 766.103(3), Fla. Stat. (2005).
[13] Id.
[14] Thomas v. Berrios, 348 So.2d 905, 907 (Fla. 2d DCA 1977).
[15] Valcin v. Pub. Health Trust of Dade County, 473 So.2d 1297, 1302 (Fla. 3d DCA 1984).
[16] Largey v. Rothman, 110 N.J. 204, 211-12, 540 A.2d 504 (1988).

and statute indicate that informed consent requires disclosure of the available medical options, the medically significant risks associated with those options, the nature of the proposed treatment, and the significance of giving informed consent.[17] However, the full scope of the required disclosure is determined by what information would be material to a reasonable person in the patient's position faced with the decision of whether to submit to the medical treatment at issue.[18]

E. California

Like Maryland, California applies the "material risk" or "reasonable patient" standard of informed consent.[19] Under this approach, informed consent requires disclosure of the available alternatives to the proposed therapy and the dangers inherently or potentially involved in each treatment.[20] However, the full scope of the required disclosure is determined by what information would be material to a reasonable person in the patient's position faced with the decision of whether to submit to the medical treatment at issue.[21]

F. Virginia

Unlike Maryland, Virginia employs the professional community standard of informed consent.[22] Accordingly, a physician's duty to disclose is defined with reference to the degree of skill and diligence exercised by a reasonably prudent practitioner in the same specialty in Virginia.[23] This generally entails a disclosure of the dangers of, possible negative consequences of, and alternatives to the proposed treatment or procedure.[24] To recover against a physician for lack of informed consent, the patient must establish by expert testimony whether and to what extent any information should have been disclosed.[25]

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[17] Howard v. Univ. of Med. & Dentistry of N.J., 172 N.J. 537, 548, 800 A.2d 73 (2002); N.J. Stat. Ann. § 26:2H-12.8 (2000).
[18] Largey v. Rothman, 110 N.J. 204, 211-12, 540 A.2d 504 (1988).
[19] Cobbs v. Grant, 8 Cal. 3d 224, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).
[20] Id.
[21] Id.; Wilson v. Merritt, 142 Cal.App.4th 1125, 1133-34, 48 Cal.Rptr.3d 630, 637 (2006).
[22] Tashman v. Gibbs, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002).
[23] Bryan v. Burt, 254 Va. 28, 34, 486 S.E.2d 536, 539 (1997); Pierce v. Caday, 244 Va. 285, 291, 422 S.E.2d 371, 374 (1992).
[24] Rizzo v. Schiller, 248 Va. 155, 158, 445 S.E.2d 153, 155 (1994).
[25] Moates v. Hyslop, 253 Va. 45, 48, 480 S.E.2d 109, 111 (1997); Tashman v. Gibbs, 263 Va. 65, 73, 556 S.E.2d 772, 777 (2002).

MALPRACTICE INSURANCE REQUIREMENTS

Suggested Forms may be available from a doctor's malpractice carrier and should be reviewed and considered. Additional terms should be incorporated, but terms required by Maryland law should not be deleted.

WHAT TO SAY AND HOW TO INFORM

Too much, too little, video, materials, Q&A

SENSITIVE ISSUES

Diagnosis

Alternatives

Care plans

Costs

Complications

INFORMED UNDER HIPAA

Notice of Privacy Practices

Right to health care information

A STANDARDIZED FORM

Attached for discussion

CONSENT TO CHIROPRACTIC EXAMINATION AND CARE

I hereby authorize _____ ("the Practice") and its licensed doctors and assistants, based on my complaints and the history I have provided, to undertake an examination and provide an evaluation and treatment plan which may include chiropractic adjustments and other tests and procedures considered therapeutically appropriate. I also wish to rely on the Practice doctors to make those decisions about my care, based on the facts then known, that they believe are in my best interest.

The nature and purpose of the chiropractic examination and evaluation, the chiropractic adjustments and the other procedures that may be recommended during the course of my care have been explained and described to my satisfaction.*

By signing below I acknowledge my consent to be examined:

_____
Patient's Printed Name

_____
Patient's Signature

The specifics of the doctor's recommendation will be further explained during a Report of Findings following your examination and any subsequent examinations and significant changes in your diagnosis or treatment plan.

Based on current findings, Practice doctors have discussed my diagnosis and treatment plan, the benefits and expected improvement with the proposed treatment and the reasonable alternatives to the proposed treatment.** They have also explained the cost of my proposed care (or provided me with a current fee schedule) and to the extent practicable the costs of reasonable alternatives to the proposed treatment.*

To aid the understanding of my condition and the reasons for the proposed course of care, the Practice has provided me with specific pamphlets and other literature (and videos) and Practice doctors have answered my questions regarding the planned treatments and course of care that I will receive.* Practice doctors have also explained that my diagnosis and treatments may change during the course of care and that they will advise me of material changes in my diagnosis and treatment options and answer any additional questions that I may have at any time.**

I have also been advised that although the incidence of complications associated with chiropractic services is very low, anyone undergoing adjusting or manipulative procedures should know of rare possible hazards and complications which may be encountered or result during the course of care. These include, but are not limited to, fractures, disk injuries, strokes, dislocations, sprains, and those which relate to physical

aberrations unknown or reasonably undetectable by the doctor.* [Note: per published study in *Spine*, the Connecticut Board decision on non-materiality of stroke and other data, chiropractors may consider deleting the reference to stroke in this sentence or with proper evidence-based references any other complications that will not be material to a patients care.]

I understand and accept that:

1. I have the right to withdraw from or discontinue treatment at any time and that the Practice doctors will advise me of any material risks in this regard.*
2. That neither the practice of chiropractic nor medicine is an exact science and that my care may involve the making of judgments based upon the facts known to the doctor during the course of my care.
3. That it is not reasonable to expect the doctor to be able to anticipate or explain all risks and complications or an undesirable result does not necessarily indicate an error in judgment or treatment.
4. The Practice does not guarantee as to results with respect any course of care or treatment.
5. My care and treatment will not be observed or recorded for any non-therapeutic purpose without my consent.*

I have read this Consent (or have had it read to me) and have also had an opportunity to ask questions about the Consent and understand to my satisfaction the care and treatment I may receive. My signature below acknowledges my consent to the examination, evaluation and proposed course of care and treatments by the Practice.

_____
Patient's Printed Name

_____
Patient's Signature

Doctor's Notes:
Patient counseled by:
Discussion _____
Provision of chiropractic pamphlet _____
Viewing video _____

_____
Signature of doctor

*** Denotes Maryland Board of Chiropractic Examiners regulatory requirements.**

**** Denotes additional requirements of Maryland common law as discussed and amplified in *McQuitty v. Spangler***

Note: Inclusion of the above consent elements, except in unusual circumstances, will concurrently meet those standards published by the American Chiropractic Association and the International Chiropractic Association. The patient record should also indicate all significant changes in the diagnosis or treatment plan and that the changes were discussed with patient. The elements related to obtaining a patient's informed consent to new developments and changes in care should be documented and as detailed as appropriate.