

Chapter 2A:

Consent to

Healthcare—General

Rules

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For reference purposes, this chapter was prepared from laws, cases, and materials selected by the authors, which were available as of April 30, 2016.

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2A.1 Part A Summary

This part of the chapter provides a general overview of the issues which pertain to consent to medical treatment.¹ It provides a foundation for the special consent rules set forth in Part B, and the decision making for incompetent patients set forth in Part C. This Part A should be read in conjunction with those other Parts.

Part A explains the basis for the requirement to obtain informed consent to treatment, who must obtain the consent, and types of consent. The elements of informed consent are described, as well as who may give consent, refusal or withdrawal of consent, and when obtaining consent is not necessary. Various aspects of consent litigation are also explained.

2A.2 Why is Consent Required?

Hospitals and other health care providers have a responsibility to patients to provide competent health care. Inherent in that responsibility is an obligation not to violate the substantial personal and property rights of the patient that might be affected by health care. Fundamental among these rights is the right of persons to decide what happens to their bodies. The concept is that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body...”² This premise has been recognized by courts in Washington since 1970.³ It has been acknowledged by the legislature since its adoption of RCW 7.70.050 in 1975.

Consent is required to give function to this right to self-decision. The failure to obtain consent is an abrogation of the patient’s right to self-decision and can lead to liability in tort. Tort liability can arise under two theories: the intentional tort of battery and negligence.

2A.2.1 What is Consent?

Consent is a process inherent in the relationship between the health care provider (usually a physician) and a patient. It involves a dialogue between them in which information is exchanged concerning the patient and the health care services or treatment being recommended. The patient relies on the health care provider to explain what the patient needs to know about the patient’s body, the treatment proposed, the risks of the proposed treatment, and alternatives. The health care provider relies on the patient to ask questions if the information provided is unclear or incomplete. Additionally, the health care provider relies on the patient to provide accurate and complete information about his or her history and symptoms.

The consent process includes elements of capacity, information, understanding and voluntariness. The patient must have the legal and mental capacity to make health care decisions. The patient must be provided with adequate information to enable the effective exercise of the patient’s right of self-decision. The information provided by the health care provider must be in terms and language the patient can comprehend, taking into consideration the patient’s education and language capabilities. Additionally, the patient must understand that the decision is the patient’s to make and must understand what that decision entails. The discussion between the health care provider and the patient must take place in an environment free from coercion, duress, or undue influence.

¹ This chapter draws heavily on the information set forth in the *Washington State Hospital Association Consent Manual*. The *Consent Manual* provides a convenient tool for ready retrieval by hospital administrators and personnel of the consents and releases with which they must deal in their day-to-day operations. It includes general information regarding consents and releases with sample forms.

² Justice Cardozo in *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129, 105 N.E. 92 (1914), *overruled on other grounds in Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1957).

³ *Watkins v. Parpala*, 2 Wn. App. 484, 490-91, 469 P.2d 974, *rev. denied*, 78 Wn.2d 995 (1970).

Informed consent is, however, more than the signing of the form. Frequently the consent process is documented through the use of a consent form. The form, which is signed by the patient, should set forth the elements of the dialogue between the health care provider and the patient to the extent necessary to demonstrate that the patient has received adequate information to effectively exercise the right to self-decision.

2A.2.2 Battery

In light of a patient’s right to determine what should be done to his or her body, medical treatment undertaken without obtaining consent may result in a battery—the touching of another person without implied or express consent. “The performance of an operation without first obtaining any consent thereto may fall within the concepts of assault and battery as an intentional tort. . . .”⁴ This theory is valid in Washington now only where treatment is performed in the absence of any consent at all.⁵ If the issue is the adequacy of the consent process rather than the absence of any consent at all, negligence theory applies.⁶

2A.2.2.1 Negligence Theory

A health care provider has a duty to disclose information to the patient about the proposed treatment. Breach of that duty constitutes negligence. A health care provider “breaches his duty when he fails to disclose a fact material to the exercise of the patient’s power either to consent to or veto a proposed medical procedure.”⁷ For a lawsuit to be successful on the negligence theory of lack of informed consent, the plaintiff must show that the health care provider breached a duty of care by failing to disclose a material fact, that the patient agreed to a procedure based upon the inadequate disclosure, that as a reasonably foreseeable consequence of the inadequate information, the patient was harmed, and that had a reasonably prudent patient been given the material information, a reasonable patient would not have undergone that procedure.

2A.3 Responsibility to Obtain Consent

Obtaining a patient’s informed consent prior to treatment is a fiduciary duty.⁸ That duty arises when the health care provider “is in the process of diagnosing, has made a diagnosis, or has pursued a course of treatment.”⁹ It is a nondelegable duty owed by the health care provider to the patient or the patient’s representative. To the extent that a health care provider relies upon ancillary health care personnel to take responsibility for obtaining the patient’s signature on a consent form, the provider will be responsible for what the ancillary personnel do or fail to do as a part of the consent process. Thus, the health care provider has the primary responsibility for obtaining consent. Hospitals and other health care facilities, while having regulatory obligations to assure that consent has been obtained, do not have the same level of responsibility for obtaining consent as the individual actually providing the health care.

⁴ *Miller v. Kennedy*, 11 Wn. App. 272, 281-82, 522 P.2d 852 (1974), *aff’d per curiam*, 85 Wn.2d 151(1975) (hereinafter cited as *Miller*).

⁵ *Miller*, 11 Wn. App. at 290, n.11. See discussion at Section 2A.9 of Part A for circumstances in which a health care provider may provide treatment without obtaining a patient’s informed consent.

⁶ *But see* R. Clary, *Physicians and Surgeons: Informed Consent*, 17 Gonz. L. Rev. 193, 197 (1981) (stating that battery arises also if the physician, by his conduct, misleads the patient) (hereinafter cited as *Informed Consent*).

⁷ Edwin Rauzi, *Informed Consent in Washington: Expanded Scope of Material Facts That The Physician Must Disclose to His Patient*, 55 Wash. L. Rev. 655, 660 (1980) (hereinafter cited as *Informed Consent in Washington*).

⁸ *Miller*, 11 Wn. App. at 282.

⁹ *Informed Consent*, at 193.

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2A.3.1 Health Care Provider

The basis for the health care provider's fiduciary duty to obtain a patient's informed consent is the unequal information status of the provider and the patient.¹⁰ The trust relationship between physician and patient requires that the physician recognize the patient's lack of material information about the patient's medical condition and supply that information to the patient. "The patient has the right to chart his own destiny, and the doctor must supply the patient with the material facts the patient will need in order to intelligently chart that destiny with dignity."¹¹ Therefore, it is most often the treating physician who is responsible for explaining medical treatment and procedures to a patient. It is also the treating physician who should obtain the patient's informed consent to the procedure or treatment and should document that consent with a properly filled out and executed consent form, as well as a notation in the medical record as to the discussion with the patient and the information provided.

2A.3.2 Hospital or Other Health Care Facility

A hospital or other health care facility has an obligation to oversee the welfare of its patients.¹² It must take reasonable steps to assure that the necessary consents have in fact been obtained by the responsible health care provider. While RCW 7.70.020(3) includes hospitals as health care providers, Washington courts have "refused to interpret [RCW 7.70.050] as demanding equal informed consent obligations for all entities and individuals encompassed within the definition of health care provider."¹³ Unless there are extraordinary circumstances, a hospital and its staff are not under a duty to obtain informed consent from a patient.¹⁴ Nonetheless, there are regulatory and accreditation requirements which demand the involvement of hospitals and other health care facilities in the consent process.

2A.3.2.1 Washington Department of Health (DOH) Regulations

Hospitals are required to play a policing role in the informed consent process. They must ensure the patient's right to be involved in all aspects of their care including obtaining informed consent.¹⁵ Hospital medical records must contain, among other things, "consent documents."¹⁶ The Department's hospital regulations do not further define consent documents. These requirements are conditions of licensure for hospitals in Washington. Medical records are reviewed for compliance with these requirements as a part of licensure surveys.

2A.3.2.2 Washington Department of Social and Health Services (DSHS) Regulations

Nursing homes are subject to detailed informed consent requirements found in WAC 388-97-0260. This regulation requires that nursing homes comply with the informed consent process outlined in RCW 7.70 in the development of the nursing home resident's comprehensive care plan. In order to ensure informed consent or refusal by a resident regarding care plan options, the nursing home must provide the information to the resident in a neutral manner, and in a language and manner the resident can understand. The resident must be informed that he or she has the right to change his or her mind about an earlier consent or refusal decision. The regulations require that evidence of informed consent or refusal be consistent with the

¹⁰ *Informed Consent in Washington*, at 657.

¹¹ *Miller*, 11 Wn. App. at 282.

¹² *See, e.g., Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984) (hospitals).

¹³ *Howell v. Spokane & Inland Empire Blood Bank*, 114 Wn.2d 42, 55, 785 P.2d 815 (1990) (*citing Alexander v. Gonser*, 42 Wn. App. 234, 711 P.2d 347 (1985), *rev. denied*, 105 Wn.2d 1017 (1986)).

¹⁴ *Howell*, 114 Wn.2d at 55-56; *Alexander*, 42 Wn. App. at 239.

¹⁵ WAC 246-320-141(4)(b).

¹⁶ WAC 246-320-166(4)(c).

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resident assessment and with comprehensive care planning. When surrogate decision makers are exercising the resident's rights, the surrogate decision maker must first determine if the resident would consent or refuse the proposed or alternative treatment, attempt to discuss the consent or refusal with the resident whenever possible, try to determine the wishes of the resident, and if the resident's decision cannot be determined, make the decision in the best interest of the resident.

2A.3.2.3 The Joint Commission's Requirements

The Joint Commission establishes informed consent standards for hospitals and other organizations which they accredit. The Joint Commission's 2016 Hospital Accreditation Standards requires that "[t]he hospital honors the patient's right to give or withhold informed consent." RI.01.03.01. The rationale for the RI.01.03.01 is as follows:

Obtaining informed consent presents an opportunity to establish a mutual understanding between the patient and the licensed independent practitioner or other licensed practitioners with privileges about the care, treatment, and services that the patient will receive. Informed consent is not merely a signed document. It is a process that considers patient needs and preferences, compliance with law and regulation, and patient education. Utilizing the informed consent process helps the patient to participate fully in decisions about his or her care, treatment, and services.¹⁷

Hospitals must have a written policy on informed consent which identifies the specific care, treatment, and services that require informed consent, how informed consent is documented, and when treatment may be given without informed consent or with consent from a surrogate decision-maker. The standards also describe the necessary components of the informed consent process, which include the following:

- A discussion about the patient's proposed care, treatment, and services;
- The potential benefits, risks, and side effects of the proposed care, treatment and services, as well as reasonable alternatives;
- The likelihood of the patient achieving his or her goals, and any potential problems that might occur during recuperation; and
- Any circumstances under which information about the patient must be disclosed or reported.

Informed consent is required to be obtained in accordance with the hospital's policies and processes. A patient's medical record includes any informed consent when required by hospital policy. RC.02.01.01.

In addition, the 2016 Standards require that the hospital honor the patient's right to give or withhold informed consent to the production or use of recordings, films or other images of the patient for purposes other than the patient's care. RI.01.03.03. If the recordings, films, or other images are for external use, the consent must include an explanation of how they will be used.

¹⁷ *Rationale for RI.01.03.01*, The Joint Commission (2016).

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2A.3.2.4 Medicare and Medicaid Conditions of Participation

Medicare and Medicaid Conditions of Participation provide that patients have the right to make informed decisions about their care:

The patient or his representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.¹⁸

To fulfill the requirements for a patient's right to make informed decisions, hospitals must establish processes to assure that the patient or the patient's representative receives information about the patient's medical status, diagnosis and prognosis. Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures necessary to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. Informed decisions related to care planning also extend to discharge planning for a patient's post-acute care. Hospitals also are required to have policies and procedures to assure a patient's right to request or refuse treatment, which should indicate how a patient's request will be addressed, although hospitals are not required to fulfill a patient's request if it is deemed medically unnecessary or inappropriate.¹⁹

Medicare and Medicaid Conditions of Participation also require hospitals to assure that documentation of informed consent be included in a patient's medical record. The relevant regulations governing hospital Conditions of Participation for Medical Record Services require that hospital medical records include "properly executed informed consent forms" for procedures and treatments which either the medical staff or state or federal law specify require written patient consent.²⁰ Hospitals that allow surgeries to be performed must assure that "[a] properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies."²¹ Although the regulations do not include more specificity regarding the informed consent form, CMS has adopted, as a part of the State Operations Manual, Interpretive Guidelines that spell out the precise requirements for the informed consent form:

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner; (Significant surgical tasks include: opening and closing, harvesting

¹⁸ 42 C.F.R. § 482.13(b)(2).

¹⁹ Centers for Medicare and Medicaid Services, State Operations Manual, Appendix A (Rev. 151, November 20, 2015); https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

²⁰ 42 C.F.R. § 482.24(c)(4)(v).

²¹ 42 C.F.R. § 482.51(b)(2). The Interpretive Guidelines also outline requirements for a hospital's informed consent policy.

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- grafts, dissecting tissue, implanting devices, altering tissues, administering anesthesia, and placing invasive lines.)
- Benefits;
 - Risks;
 - Alternative procedures and treatments;
 - Signature of patient or legal guardians;
 - Date and time consent is obtained;
 - Statement that procedure was explained to patient or guardian;
 - Signature of professional person witnessing the consent; and
 - Name/signature of person who explained the procedure to the patient or guardian.

The interpretive guidelines go on to explain the view of CMS with respect to obtaining informed consent.²²

Conditions of Participation for critical access hospitals²³ and Ambulatory Surgery Centers²⁴ require clinical records to include consent forms. Conditions of Participation for long-term care facilities also implicitly refer to informed consent. The rubric of “Free Choice” for long-term care facility residents requires that residents be fully informed in advance about care and treatment, and participate in planning, care, and treatment or changes in care and treatment, unless the resident is adjudged incompetent or otherwise found to be incapacitated.²⁵

2A.4 Types of Consent

Consent to treatment may be either implied or express. Consent may be implied by the facts and circumstances surrounding the treatment, and also may arise as a result of common law or statutes that deem implied consent to treatment as a result of certain circumstances. Express consent may be given either verbally or in writing. Generally, it is not the form of expression that gives rise to litigation. Rather, problems or litigation arises from inadequate disclosure.

2A.4.1 Implied Consent

Entering a physician’s office for treatment or voluntarily entering a hospital and submitting to treatment are facts and circumstances which may imply the patient’s consent to treatment. But, reliance upon the patient’s presence and acquiescence in treatment alone is hazardous, and should not be depended upon, particularly

²² This explanation includes the requirement that informed consent provide that the patient is informed as to who will actually perform surgical interventions that are planned, and that when practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon’s supervision, the patient must be informed of who those other practitioners are, as well as, what important tasks each will carry out. For surgeries where residents will perform important parts of the surgery, the guidelines also encourage the informed consent discussion to include specific information regarding the circumstances and scope of a resident’s participation. In addition, the surgical informed consent process should identify whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer anesthesia, and if so, the types of tasks that each type of practitioner will carry out; and that such practitioners will only be performing tasks within their scope of practice for which they have been granted privileges by the hospital. This has created some controversy from the practical standpoint of achieving compliance in that surgeons do not always know who will be involved at the time that the informed consent form is signed.

²³ 42 C.F.R. § 485.638(a)(4)(i).

²⁴ 42 C.F.R. § 416.47(b)(7).

²⁵ 42 C.F.R. § 483.10(d). *See also* Chapter 2C: Consent to Healthcare-Decision Making for Incompetent Patients regarding surrogate decision-making for incompetent individuals.

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where the contemplated treatment involves significant risk. Implied consent may be relied upon, however, in the case of an emergency, or for alcohol tests under the Driver's Implied Consent Law, in some circumstances.

An emergency exists when immediate treatment is necessary to preserve life, or to prevent serious deterioration or aggravation of the patient's condition. When in an emergency, the patient's condition is such that the patient is unable to make an informed decision and the consent of another person qualified to represent the patient is not reasonably available, consent to treatment is implied by law and express consent is not required.²⁶

Every person who operates a motor vehicle in Washington State is deemed by statute to have given implied consent to testing of his or her breath to determine alcohol concentration in his/her breath.²⁷ Physicians, registered nurses, licensed practical nurses, advanced registered nurse practitioners, physicians assistants, advanced emergency medical technicians, paramedics, medical assistants, and hospitals or licensed clinical laboratories employing or utilizing the services of such persons are immune from civil and criminal liability as a result of withdrawing blood from any arrested person when directed to do so by a law enforcement officer for the purposes of a blood test pursuant to a search warrant, waiver of a search warrant, exigent circumstances, or as otherwise allowed by law.²⁸

2A.4.2 Express Consent

Express consent to medical treatment may be given by a competent patient, or the patient's authorized representative, in a variety of ways. Such consent may be given orally, in person or by telephone, or in writing, by facsimile, letter, electronic mail, or signed consent form. The more specific the express consent, the less the chance for misunderstanding. In effect, a written consent form serves as a memorandum of understanding between the patient and the health care provider.

2A.5 Elements of Informed Consent

Washington statute and case law defines the elements of disclosure required for informed consent. The statutory definition establishes an evidentiary basis on which health care providers may document the informed consent process, thus shifting the burden of proof to the patient to prove lack of informed consent. The case law puts flesh on the bones of these statutory elements, establishing general parameters of the information which must, and the information which need not, be disclosed.

2A.5.1 Statutory Requirements

Consent to medical care or treatment must be informed to be effective. RCW 7.70.060 establishes the necessary elements that must be included in a written consent which, when signed by the patient or the patient's legal representative if the patient is not competent, constitutes prima facie evidence that the patient gave informed consent. The written consent must set forth, in language which the patient can reasonably be expected to understand:

- The nature and character of the proposed treatment and procedures to be performed;
- The anticipated results of the proposed treatment and procedures;
- The recognized possible alternative forms of treatment; and

²⁶ RCW 18.71.220; RCW 7.70.050(4); *see also* discussion at Section 2.10.1 *infra*.

²⁷ RCW 46.20.308(1).

²⁸ RCW 46.61.508.

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- The recognized serious possible risks, complications, and anticipated benefits involved in the proposed treatment and in recognized possible alternative forms of treatment, including nontreatment.²⁹

The rationale for these elements has been well expressed by the Washington State Supreme Court, “The premise of the doctrine of informed consent is that every adult of sound mind has a right to decide what happens to his or her body. A necessary corollary is that the individual be given sufficient information to make an *intelligent* decision.”³⁰

If a patient has signed a form containing these elements, it is presumed, under the statute, that the consent was informed. If it should later be alleged that the consent was not informed, the burden of proof is on the patient, not the physician, health care provider, or hospital. It should be noted, however, that a written consent which includes the statutory elements is evidentiary only, and is not absolute proof of consent. Even if a signed consent appears to contain all of the elements required by statute, a patient may still claim that the consent was not informed. For example, the patient may claim that he or she did not understand the language used to describe the treatment, results, risks, and benefits, or that a material fact was omitted, which, if known, would have caused the patient to withhold consent.

Written consents for medical treatment generally should contain the following components:

- Identification of patient;
- Name of hospital in which treatment is to be performed;
- Name of attending physician;³¹
- Nature, anticipated results, alternatives to, and risks of proposed treatment;
- When the proposed treatment will be given;
- Date and time of signing the consent;
- Signatures of the patient or patient’s representative; and
- Signatures of witnesses.

For purposes other than medical treatment, the consent should contain such of the above components as are pertinent, and should be sufficiently specific to avoid misinterpretation of its scope.

RCW 7.70.060 also provides an alternative to the use of an informed consent form in obtaining and documenting informed consent called an acknowledgment of shared decision making. RCW 7.70.060(2). “Shared decision making” is a process whereby the physician discusses with the patient or his or her representative information regarding the services to be furnished, with the use of a patient decision aid, and the patient shares with the provider such relevant personal information as might make one treatment or side effect more or less tolerable than others. RCW 7.70.060(3). A “patient decision aid” is a written, audio-visual, or online tool that provides a balanced presentation of the condition and treatment, options, benefits, and harms,

²⁹ RCW 7.70.060(1).

³⁰ *Estate of Lapping v. Group Health*, 77 Wn. App. 612, 623, 892 P.2d 1116 (1995) (hereinafter cited as *Estate of Lapping*) (emphasis in original) (citing *Smith v. Shannon*, 100 Wn.2d 26, 29-30, 666 P.2d 351 (1983) (hereinafter cited as *Smith*)). See also *Brown v. Dahl*, 41 Wn. App. 565, 569-70, 705 P.2d 781 (1985) (hereinafter cited as *Brown*), quoting the same passage.

³¹ Note that the CMS Interpretive Guidelines regarding consents for surgical procedures require not only the name of the attending physician, but also the name of any other practitioner performing procedures. See footnote 22.

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including, if appropriate, a discussion of the limits of scientific knowledge about outcomes, and that is certified by one or more national certifying organizations. RCW 7.70.060(4).

Obtaining an acknowledgment of shared decision making from a legally competent patient, or the patient's representative if the patient is incompetent, constitutes prima facie evidence that the patient gave his or her informed consent to the treatment administered, provided that the acknowledgment of shared decision making includes the following elements:

- Statement shared decision making has been used as an alternative to other informed consent requirements;
- A brief description of the services that the patient and provider jointly have agreed will be furnished;
- A brief description of the patient decision aid or aids used to provide (i) high-quality, up-to-date information about the condition; (ii) values clarification for the patient; and (iii) guidance or coaching for the patient's deliberation;
- A statement that the patient or his or her representative understands: The risk or seriousness of the disease or condition to be prevented or treated; the available treatment alternatives, including nontreatment; and the risks, benefits, and uncertainties of the treatment alternatives, including nontreatment; and
- A statement certifying that the patient or his or her representative has had the opportunity to ask the provider questions, and to have any questions answered to the patient's satisfaction, and indicating the patient's intent to receive the identified services.³²

Although CMS has accepted shared decision making in a number of contexts,³³ it has not addressed the effectiveness of an acknowledgment of shared decision making in fulfilling the Conditions of Participation or meeting the requirements for informed consent described in the CMS Guidelines. An acknowledgment of shared decision making will be more likely to meet CMS requirements if, in addition to the statutory elements, it includes the following:

- Identification of patient
- Name of hospital in which treatment is to be performed
- Name of provider
- Date and time of signing of the acknowledgment
- When the proposed treatment or services will be given

³² RCW 7.70.060(2).

³³ See, e.g., "Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N)" at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274> and the shared decision-making milestone in "CPC Program Year 2015 Implementation and Milestone Reporting Summary Guide," December 2014 at <https://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf> (last visited April 30, 2016).

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- Signature of the patient or patient’s representative
- Signature of a witness

RCW 7.70.060(5) specifically provides that failure to use a written consent form or to engage in shared decision making, with or without the use of a patient decision aid, shall not be admissible as evidence of failure to obtain informed consent. Further, a health care provider will not be liable, in a civil action or otherwise, for choosing to use either the signed written consent form or the signed acknowledgment of shared decision making. RCW 7.70.060(5).

2A.5.2 Information Which Must Be Disclosed

The broad categories of information that must be disclosed to the patient include: (1) the nature, character and anticipated results of the treatment, (2) material risks inherent in the proposed treatment, (3) alternative courses of treatment, including no action, and their attendant risks, and (4) the existence of a potentially dangerous physical abnormality, if any, and the diagnostic steps, including tests, available to ascertain the significance of that abnormality. The scope of each of these categories of information has been developed under Washington case law.

All risks need not be disclosed, only those that are material.³⁴ Materiality in Washington was initially measured by a traditional malpractice standard—the plaintiff was required to establish by expert medical testimony a departure from medical custom in the information which was disclosed.³⁵ A physician’s duty to disclose information was governed by what a reasonable physician in the same or similar circumstances would have disclosed. This is no longer the law in Washington. Now, as a matter of law, there is a duty to disclose, and the measure of materiality is the patient’s need to know.³⁶ However, material risks are limited to those related to the proposed treatment and do not include facts relating to the physician’s competence or qualifications.³⁷ By both statute and case law, materiality of a risk is determined based upon whether a “reasonably prudent person in the position of the patient or his or her representative would attach significance to it in deciding whether or not to submit to the proposed treatment.”³⁸ Materiality is measured according to the reasonably prudent patient rather than a professional medical standard.³⁹ Additionally, materiality is determined by an objective standard as to a universal “reasonably prudent patient,” rather than a subjective standard under which materiality would be measured by whether a particular patient would have consented.

Courts also have used materiality to measure the type of information which must be disclosed about alternative forms of treatment. An alternative form of treatment must be discussed with a patient if a reasonably prudent patient would attach significance to the alternative.⁴⁰ If medical evidence establishes that there is an alternative course of treatment, including nontreatment, “the physician has a duty to inform the patient of that alternative

³⁴ *ZeBarth v. Swedish Hospital Medical Center*, 81 Wn.2d 12, 25, 499 P.2d 1 (1972), *overruled as stated in Young v. Group Health Cooperative*, 85 Wn.2d 332, 534 P.2d 1349 (1975) (hereinafter cited as *ZeBarth*).

³⁵ *ZeBarth*, 81 Wn.2d at 29.

³⁶ *Miller*, 11 Wn. App. at 282.

³⁷ *Whiteside v. Lukson*, 89 Wn. App. 109, 112, 947 P.2d 1263 (1997); *Housel v. James*, 141 Wn. App. 748, 756, 172 P.3d 712 (2007)

³⁸ RCW 7.70.050(2); *Adams v. Richland Clinic, Inc., P.S.*, 37 Wn. App. 650, 656-57, 681 P.2d 1305 (1984); *Miller*, 11 Wn. App. at 287; *Villanueva v. Harrington*, 80 Wn. App. 36, 38-39, 906 P.2d 374 (1995).

³⁹ *Estate of Lapping*, 77 Wn. App. at 623. *See also Christiansen v. Munsen*, 123 Wn.2d 234, 244-45, 867 P.2d 626 (1994).

⁴⁰ *Estate of Lapping*, 77 Wn. App. at 625.

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and of the material risks of pursuing that course of treatment, of each choice of treatment and of no treatment at all.”⁴¹ The ability to perform a procedure on an in-patient basis for example, rather than on an out-patient basis, may be a material alternative form of treatment, particularly where the patient has a history of seizures.⁴² Or where waiting and observing a tumor rather than performing surgery is an alternative, the patient is entitled to be told about that alternative.⁴³

The duty to disclose is not limited to treatment, but most include the full panoply of information necessary for the patient to make decisions about medical care. Therefore, the patient must also be advised of abnormalities in the patient’s body.⁴⁴ The existence of an abnormal condition is a fact “which a patient must know in order to make an informed decision on the course which future medical care will take.”⁴⁵ The duty to disclose an abnormality arises whenever a health care provider becomes aware of an abnormality which may indicate risk or danger.⁴⁶ The requirement to disclose is again based upon the patient’s need to know in order to make an informed decision.

2A.5.3 Information Which Need Not Be Disclosed

Courts in Washington have recognized that certain types of information need not be disclosed. The standard used by courts is that immaterial information need not be disclosed, such as risks to which a reasonably prudent patient would not attach significance, and risks so remote or minuscule as to be immaterial.⁴⁷ Risks that are probable for particular patients, however, should be disclosed.⁴⁸

Although caution is required when a physician decides not to disclose information to a patient, there are certain special circumstances in which a physician will not be required to disclose any or every potential risk. These include the following:⁴⁹

- A physician is not responsible for failing to disclose a risk which was not reasonably foreseeable and not inherent in the procedure;
- A physician may not be responsible for failing to disclose a risk to a patient where full disclosure would be detrimental to the patient’s best interests;
- A physician has no duty to disclose dangers which are commonly known and it can be assumed that the patient will know of them;
- A physician need not disclose to a patient risks of which he is already aware;

⁴¹ *Archer v. Galbraith*, 18 Wn. App. 369, 379, 567 P.2d 1155 (1977) (hereinafter cited as *Archer*).

⁴² *Estate of Lapping*, 77 Wn. App. at 625-26.

⁴³ *Archer*, 18 Wn. App. at 376.

⁴⁴ *Miller*, 11 Wn. App. at 282.

⁴⁵ *Gates, v. Jensen*, 92 Wn.2d 246, 251, 595 P.2d 919 (1979) (hereinafter cited as *Gates*).

⁴⁶ *Gates*, 92 Wn.2d at 251.

⁴⁷ For example, a risk of perforating the colon during surgery of the colon of 1 in 20,000 to 50,000 need not be disclosed. *Ruffer v. St. Francis Cabrini Hospital*, 56 Wn. App. 625, 628-29, 784 P.2d 1288, *rev. denied* 114 Wn.2d 1023(1990) (hereinafter cited as *Ruffer*). An imperceptible risk, such as a .75% risk of perforation during an esophascopy examination, is not reasonably foreseeable and therefore need not be disclosed. *Mason v. Ellsworth*, 3 Wn. App. 298, 313, 474 P.2d 909 (1970). The Washington Physicians Insurance Exchange recommends that physicians follow the 1 percent rule: If a complication has even a 1 percent chance of occurrence, it should be disclosed.

⁴⁸ Fay A. Rozovsky, *Consent to Treatment, A Practical Guide* § 1.02[A], 1-100 (4th ed. 2014); *see Estate of Lapping*, 77 Wn. App. at 625.

⁴⁹ These examples are set forth in *Holt v. Nelson*, 11 Wn. App. 230, 240-41, 523 P.2d 211 (1974), *rev. denied*, 84 Wn.2d 1008 (1974) (hereinafter cited as *Holt*); and cited in approval in a footnote in *Smith*, 100 Wn.2d at 30 n.1.

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- A physician need not disclose the hazards of treatment when the patient has requested not to be told about the dangers, has insisted on remaining ignorant of the perils involved and had the patient been told, the explanation might increase the risk of treatment because of the psychological results of apprehension that might be produced;
- A physician need not have informed the patient of the risk of procedure if the physician can establish the defense that the patient would have proceeded whether informed of the risks or not;
- A physician need not disclose risks which have no apparent materiality or relationship to the patient's decision;
- A physician need not disclose a risk of improper performance of an appropriate procedure; and
- A physician need not disclose the various alternatives and risks when an emergency situation exists, requiring prompt treatment in the face of the immediate possibility of permanent injury or death and the patient is in no condition to determine for himself.

2A.5.4 Scope of Consent

All medical care requires consent at some level. Implied consent will suffice for routine medical evaluations, consultations and emergencies. Express consent is required for medication, significantly invasive surgical, diagnostic, or therapeutic procedures, and medical treatment, involving significant possible risks, complications, or adverse outcomes. A patient's consent may be general or specific. A general consent usually will not satisfy the statutory elements of informed consent and has limited effectiveness. A specific consent from a patient, while potentially limiting the scope of consent, is necessary to satisfy both statutory and case law elements of informed consent.

2A.5.4.1 General Consents

A general consent form is useful in establishing consent to a minimal threshold of treatment. General consents are most often used by hospitals to establish a patient's consent to routine hospital services, routine diagnostic procedures, and routine nonsurgical medical treatment. These forms may be relied upon for such procedures as drawing blood and laboratory tests. They should not be relied upon for any treatment beyond routine hospital care. General consents to treatment should be used in conjunction with consents to specific procedures.

2A.5.4.2 Consent to Specific Procedures

Consent to specific procedures, documented by a written consent form signed by the patient, is the most effective way to assure that the patient has received the information necessary to make an intelligent decision about a medical treatment or procedure. The greater the extent to which the consent specifically describes the nature of the procedure, the alternatives available for treatment including nontreatment, and the anticipated benefits, risks, and complications, the less likely there will be a misunderstanding or an assertion that the patient was not informed. The more specific the discussion and the form documenting that discussion, however, the more difficult it will be for the provider to defend the omission of any information which is subsequently determined to be material.⁵⁰

⁵⁰ When in doubt, care providers should err on the side of documenting all specific information provided as well as more general "catch all" language if applicable because it may be awkward or even impossible to later rely on a care provider's personal recollection or general practices to rebut an allegation of lack of informed consent. *See Lasher v. University of Wash.*, 91 Wn. App. 165, 957 P.2d 229 (1998) (in an action for wrongful death, it was reversible error to allow a physician to testify regarding the habitual warnings he provided to his patients, because RCW 5.60.030, the "dead man's statute," precluded such evidence).

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If a written consent form is viewed as a written memorandum of understanding between the physician and the patient, it is by its terms limited to the understanding which has been memorialized. Therefore, a consent to medical or surgical treatment is limited to the procedure or treatment discussed with the patient. An additional or modified consent is required for additional procedures. Conducting a procedure different from that to which the patient consented may constitute a battery or may be actionable under the Consumer Protection Act for lack of informed consent.⁵¹

If a health care provider anticipates that it may be necessary to extend treatment beyond the specific procedure discussed and consented to, it is prudent for the provider to discuss that extension with the patient and document the patient's agreement to an extension in the consent form. In this process a balance must be struck between trying to spell out all possible necessary additional treatments or procedures and a blanket authorization extending to any procedure or treatment the physician deems necessary.

An ancillary issue is limitation of the consent to a specific provider. This issue has not been specifically addressed in Washington. The CMS Interpretive Guidelines regarding informed consent for surgical operations require identification of a specific provider.⁵² The fiduciary nature of the consent process may require that the knowledge of the health care provider's identity be considered an essential component of the consent. Thus, where a provider, different from the one anticipated by the patient, performs the procedure or provides the treatment, the substitution of the provider may negate the patient's informed consent. Although consent forms frequently include authorization of a specific physician "and/or his associates" to perform a procedure, reliance upon that authorization to substitute a physician's associate, absent an emergency, may pose a risk. After a discussion, the patient's agreement to a substitution should be documented.

2A.5.5 Length of Time Consent Is Valid

Ordinarily a consent is valid only for a reasonable time unless or until it is revoked. There is no specific number of days or hours after which a new consent must be obtained. The reasonableness of the period of time between the granting of the consent and the performance of the procedure or treatment will be determined by the facts and circumstances surrounding the particular situation. A good measure for the reasonable period of time that a consent form is valid may be 90 days. In general, a consent for treatment should not be considered valid after discharge from the hospitalization, unless it is clearly for continuing treatment. A patient can revoke consent at any time, orally or in writing.

2A.5.6 Use of Interpreters or Translators

Non-English speaking patients or patients with limited English proficiency are entitled to equal access to health care.⁵³ This means assuring that such patients provide informed consent. Patients with limited English proficiency must have information regarding all of the elements of informed consent, provided to them in a manner in which they can understand. One way to do this is through the use of an oral interpreter. Another

⁵¹ *Quimby v. Fine*, 45 Wn. App. 175, 724 P.2d 403 (1986), *rev. denied*, 107 Wn.2d 1032 (1987) (hereinafter cited as *Quimby*). But note that consumer protection claim based upon a lack of informed consent is limited to "dishonest and unfair practices used to promote the entrepreneurial aspects of a doctor's practice..." *Quimby*, 45 Wn. App. at 181. See also *Benoy v. Simons*, 66 Wn. App. 56, 65, 831 P.2d 167 (1992) ("To maintain a CPA claim there must be a showing of a lack of informed consent resulting from dishonest and unfair practices motivated by financial gain."); *Ambach v. French*, 167 Wn.2d 167, 178-79, 216 P.3d 405 (2009).

⁵² See discussion at Section 2.4.2(d) of Part A.

⁵³ See 45 C.F.R. § 80.3 (2004); *Lau v. Nichols*, 414 U.S. 563, 568, 94 S. Ct. 786, 39 L. Ed. 2d (1974).

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way is by written translation. Health care providers should consider four factors in determining the best approach to address obtaining informed consent from patients with limited English proficiency. The factors are: (1) the number or proportion of limited English proficient persons eligible to be served or likely to be encountered; (2) the frequency with which patients with limited English will come into contact with the health care provider; (3) the nature and importance of the treatment involved; and (4) the resources available and cost. Although obtaining informed consent is always important for invasive procedures, health care providers should consider the importance and urgency of the particular situation when determining the nature of language services to obtain and the immediacy with which they are required.⁵⁴ Providers also should consider whether translation or oral interpretation is more economical. Although use of family members or friends as interpreters may be seen as an economical approach to addressing patients with limited English proficiency, patients must be informed they have a legal right to an interpreter at no cost. Where it is necessary for a patient to provide written informed consent, the ideal approach is to have the consent form translated into the patient's primary language.

2A.6 Proof of Consent (Documentation)

A patient may provide consent to treatment orally or in writing. A written consent which contains all of the elements of an informed consent, that is, the nature and character of the proposed treatment, the anticipated results, the risks of the proposed treatment, including nontreatment, and the alternatives to the treatment, as set forth in RCW 7.70.060, constitutes prima facie evidence that the patient gave an informed consent. For this reason, many health care providers use a standardized consent form for various procedures that contains the prescribed information. This is not however, the only way in which consent may be documented.

2A.6.1 Written Consent

In addition to a written consent form, letters, facsimiles, and electronic mail may provide written evidence of an informed consent. Such evidence should be made a part of the patient's medical records. Be cautioned, however, that such written documentation is frequently defective, in that alone, it rarely covers in sufficient detail the risks and the specific treatment authorized. Letters, facsimiles, and electronic mail should be confirmed by having the patient subsequently sign the health care provider's appropriate special consent forms.

Whether the written consent is by a standard form or by letter, facsimiles, or electronic mail, it is useful for the writing to be signed by a witness as well as the patient. The purpose of the witness is to confirm both the patient's signing of the consent and the patient's competency to sign. In some cases, witnesses may also serve to confirm that the consent given was in fact "informed," that the form had been fully explained, that the patient had read it or had it read to him, and that he acknowledged he understood it. For example, once a physician informs the patient of the nature of the procedure, the alternatives available for treatment including nontreatment, and the anticipated benefits, risks, and complications, a nurse or other health care provider working with the physician may act as a witness to the patient's written consent.

The date and time should be included in any writing purporting to serve as written confirmation of an informed consent. Questions may later be raised whether the consent was given after the commencement of medical treatment, or at a time when the patient was under medication or sedated.⁵⁵ Situations should be avoided where

⁵⁴ See Agency for Healthcare Research and Quality, *Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals* (September, 2012); available at <http://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf>.

⁵⁵ See generally *Grannum v. Berard*, 70 Wn.2d 304, 422 P.2d 812(1967) (hereinafter cited as *Grannum*).

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the consent is obtained after the patient has no reasonable alternative but to consent; for example, when consent is obtained after the patient is on the gurney being wheeled to the operating room.

The signatures of the patient and the witness, and the date and time of the signing should be in ink. If a person is unable to sign, the patient's name should be written in by the person obtaining the consent and the patient should place the patient's "X" beneath it; and that signature should be confirmed by the signature of two witnesses.

2A.6.2 Oral Consent

In some cases, for example if a patient is illiterate or visually impaired or a written consent form is not available, oral consent may be the only type of consent which is obtainable. Where it is not possible to confirm an oral consent by a writing signed by the person giving consent, one or more witnesses to the oral consent should be obtained and each of those witnesses should substantiate the consent by his or her own written memorandum. This is particularly true where the medical treatment consented to is serious, and where the results of that treatment carry any risk of significant complications.

In the case of an oral consent by telephone, another person should listen in, as a witness, and a written record of the conversation should be maintained, identifying the parties, time and circumstances. Alternatively, the conversation should be recorded, in which case the consenting party must be notified that the conversation is being recorded and must agree to the recording. Both state and federal law make it unlawful to intercept or record any "private conversation" without a party's consent.⁵⁶ Consent to record will be considered obtained whenever one party has announced to the other parties engaged in the communication or conversation that it is about to be recorded, and there is no objection. If the conversation is to be recorded, the announcement that it is to be recorded must be recorded also.⁵⁷ Without these protective steps, proof identifying the voice is difficult, if the consent should later be denied.

In all cases of oral consent, written confirmation from the patient or an authorized representative of the patient should be obtained subsequently, if possible. This written confirmation could be obtained by having the patient or the authorized representative sign an appropriate special consent form. A less reliable alternative is to obtain a confirming letter, facsimiles, or electronic mail from the patient or authorized representative.

2A.7 Who May Give Consent

Ideally, the patient for whom the medical care is being provided will be the individual giving consent to the treatment or procedure. While the ideal is frequently achieved, certain circumstances may require that consent be obtained from someone other than the patient. Determining whether the patient may give consent requires assessment of the patient's legal and mental capacity.⁵⁸

⁵⁶ RCW 9.73.030; Federal Communications Act, 47 U.S.C. § 605; 18 U.S.C. § 2511.

⁵⁷ RCW 9.73.030(3).

⁵⁸ See Part B for a thorough discussion of special consent rules, and Part C for a thorough discussion of decision-making for incompetent patients.

2A.7.1 Legal Capacity

Legal capacity to give consent is determined by reference to relevant statutes and case law. The age and legal status of an individual will determine capacity to give consent. There is, however, a presumption in favor of the mental capacity of an individual to give informed consent to treatment.⁵⁹

2A.7.1.1 Adults

A person eighteen (18) years of age or older is an adult and is statutorily recognized as having the legal capacity to make decisions regarding his or her body, including, but not limited to, consenting to surgical operations.⁶⁰ Thus, a person 18 years of age or older may give consent to care, if otherwise competent. Such a person is presumed capable of giving informed consent, and must give his or her own consent to hospital, medical or surgical care.

For married persons, the consent of the patient's spouse is not required. Health care providers, however, frequently require an "informed consent" discussion with the spouse of a patient in matters involving danger to life or destroying or limiting sexual or reproductive function.⁶¹ Obtaining the spouse's consent in such circumstances may be prudent to avoid subsequent disputes. Health care providers may not require spousal consent, however, for federally funded sterilization or for termination of a pregnancy.⁶²

A person who has a court-appointed guardian of the person cannot give consent and consent must be obtained from that guardian.⁶³ If the guardian cannot be located within four hours after the need for such consent arises, a standby guardian appointed pursuant to RCW 11.88.125 may give consent for necessary medical procedures. A guardian, limited guardian or standby guardian may not consent to certain procedures. A court order must be obtained in order for a person under guardianship to undergo therapy or other procedure which induces convulsion, surgery solely for the purpose of psychosurgery, or other psychiatric or mental health procedures which are intrusive of the person's bodily integrity, or physical freedom of movement.⁶⁴

2A.7.1.2 Minors-Generally

In general, persons under the age of eighteen (18) are minors.⁶⁵ As such, they do not have the legal capacity to consent to medical care or treatment. The consent of a parent or a legal guardian is necessary, except in those situations defined by statute or case law in which certain minors may consent to certain types of treatment.⁶⁶ If the parents of a minor are married, or if the parents are divorced and have joint custody of the minor, either parent can validly consent to treatment.⁶⁷ Obtaining the consent of both

⁵⁹ *Grannum*, 70 Wn.2d at 307.

⁶⁰ RCW 26.28.010; RCW 26.28.015(5).

⁶¹ *But see Ponter v. Ponter*, 135 N.J. Super. 50, 342 A.2d 574 (Ch. Div. 1975).

⁶² 42 C.F.R. § 441.257(a)(6); *Planned Parenthood of Cent. Missouri v. Danforth*, 428 U.S. 52, 70, 96 S. Ct. 2831, 49 L. Ed. 2d 788 (1976).

⁶³ *See* Part C herein for a complete discussion of guardianship.

⁶⁴ RCW 11.92.043(5). Even for decisions that may be within the guardian's legal scope of authority, the guardian may seek specific court authorization before providing consent. For example, the guardian may request instruction from the court if end-of-life decision-making is contemplated in the context of family disagreement over the issue.

⁶⁵ RCW 26.28.010.

⁶⁶ *See* Part B, 2.12 *et seq.* for a complete discussion of the issues regarding consent by minors, and *see* Part B, 2.12.12 for a discussion of consent by mature minors.

⁶⁷ RCW 26.16.125.

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parents is preferable, if it can reasonably be obtained. For minors in other circumstances, the custody and status of a minor will determine who validly may give consent.

2A.7.1.3 Mental Capacity

The mental competency of a patient is essential for informed consent. For a consent to be effective, the patient must be of sound mind and must voluntarily grant the consent. The patient should have a basic understanding of the nature and the consequences of authorizing treatment. During the informed consent process, the patient should read the consent form, or the provider should read the form to the patient. Discussion with the patient about the procedure, its risks and alternatives should be documented in the chart. It is the goal of the informed consent process for the patient to know and understand the substance of what is being signed.

The presumption is that the patient has the mental capacity to consent to treatment.⁶⁸ A person who has not been declared legally incompetent may nevertheless lack capacity to make health care decisions.⁶⁹ Any challenge to mental capacity is determined by the facts and circumstances of each situation.⁷⁰ Mental capacity may be affected by a variety of factors. Any circumstances which preclude an individual from understanding the nature of the treatment to be provided, and the risks and alternatives presented, may call into question an individual's mental capacity. But these circumstances may be temporary or permanent. Some temporary circumstances which might impair mental capacity include head injury, being under the influence of drugs or alcohol, or being sedated. Permanent mental impairment might include mental illness, excessive use of drugs, or other mental incapacity to manage property or self. Under Washington law, these permanent mental impairments may result in a person being found to be "incompetent."⁷¹ For such a finding, there must be clear, cogent and convincing evidence that the patient could not comprehend the nature, terms, and effect of the consent given.⁷²

Mental illness, however, does not necessarily mean that a person is incapacitated for the purposes of granting consent in all cases. Again, a determination as to the mental capacity of a person must be made based upon all the facts and circumstances.

2A.7.1.4 Substituted Consent

When a patient is not mentally or legally competent to give an informed consent, substituted consent for medical treatment should be obtained. This means identifying another individual who is legally authorized to provide consent for the patient. Where medical treatment is required for an incompetent patient, who is not incompetent by reason of being a minor, persons authorized to give informed consent on behalf of the patient, in order of priority, are:

- The appointed guardian of the person;
- The individual to whom the patient has given a durable power of attorney encompassing the authority to make health care decisions;
- The patient's spouse or state registered domestic partner;
- The patient's children who are at least eighteen (18) years of age;

⁶⁸ *Grannum*, 70 Wn.2d at 307.

⁶⁹ *Morinaga v. Vue*, 85 Wn. App. 822, 830, 935 P.2d 637 (1997).

⁷⁰ *Grannum*, 70 Wn.2d at 307.

⁷¹ RCW 11.88.010; see Part C of this Chapter.

⁷² *Grannum*, 70 Wn.2d at 309.

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- The patient’s parents; and
- The patient’s adult brothers and sisters.⁷³

The rules for obtaining substituted consent, as provided in the statute, are:

- If the physician seeking the consent makes reasonable efforts to locate and secure authorization from a competent person in the first or succeeding class and finds no such person available, authorization may be given by any person in the next class, in the order of descending priority;
- No person may provide informed consent if a person of higher priority has refused to give such authorization, or if there are two or more individuals in the same class and the decision is not unanimous among all available members of that class; and
- The incompetent patient’s representative, before giving consent, must determine in good faith that the patient, if competent, would have consented to the proposed health care. If that determination cannot be made, the representatives then may consent only if the proposed health care is found to be in the patient’s best interest.

Where medical treatment is required by a minor, special rules of consent apply.⁷⁴ If a legally authorized person cannot be located and medical treatment is imperative, but an emergency does not exist, court authorization must be obtained. The reader is directed to Part B of this Chapter for further guidance as to dealing with substituted consent for minors.

2A.8 Refusal or Withdrawal of Notice

Consistent with a patient’s right to determine what will happen to his or her body, a patient not only has the right to consent to treatment, but also the right to refuse treatment and the right to withdraw consent to treatment. The same factors which are considered in determining the capacity to grant consent apply to the capacity to refuse or withdraw consent. A patient competent to grant consent to treatment, is competent to withdraw or refuse treatment.

The withdrawal of consent or refusal of treatment should be informed. The health care provider may have an obligation to advise the patient as to the consequences of refusing treatment or withdrawing consent.⁷⁵ Arguably, the requirement of informed refusal is consistent with the overall disclosure required as a part of the consent process.⁷⁶

2A.8.1 Adults

A competent adult may refuse treatment, for any reason, no matter how unreasonable this may appear to others. Health care providers have an obligation to respect the refusal of consent and/or the withdrawal of consent.⁷⁷ The refusal or withdrawal should be confirmed in writing by the patient, witnessed, and included in the medical record. If the patient will not sign written confirmation of the refusal of treatment or withdrawal of consent, the refusal or withdrawal should be witnessed and confirmed in writing in the medical record by the attending physician and at least one other person.

⁷³ RCW 7.70.065.

⁷⁴ See Part B of this Chapter.

⁷⁵ See *Truman v. Thomas*, 27 Cal. 3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980).

⁷⁶ Health care providers should always document a patient’s informed refusal of treatment.

⁷⁷ See 42 C.F.R. § 482.13(b)(2).

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2A.8.2 Minors

If medical treatment for a minor is refused by the parents or other legally-qualified person, except in those situations in which a minor is specifically authorized to give consent, and there is no emergency, the health care providers are faced with either: (1) doing nothing; or (2) seeking authorization of a court if treatment is considered necessary, or otherwise in the best interest of the minor.⁷⁸

2A.9 When Consent is Not Necessary

The courts and statutes recognize a variety of circumstances in which a health care provider may provide treatment without obtaining the patient's informed consent. The common basis for these exceptions to the general requirement for consent is a circumstance which makes it in the best interest of the patient to receive treatment without being informed. The recognized exceptions in Washington include medical emergencies, medical holds for minors, therapeutic privilege, and when a patient chooses not to be informed.

2A.9.1 Medical Emergencies

Medical treatment in an emergency does not require informed consent. Two statutes in Washington protect health care providers for claims based upon lack of informed consent in an emergency. One statute is specific and limited, the other is more general.

Under RCW 7.70.050(4), "If a recognized health care emergency exists and the patient is not legally competent to give informed consent and/or a person legally authorized to consent on behalf of the patient is not readily available, his or her consent to required treatment will be implied."⁷⁹

Hospitals and physicians are given general statutory immunity in rendering emergency care under RCW 18.71.220. This statute provides:

No physician or hospital licensed in this state shall be subject to civil liability, based solely upon failure to obtain consent in rendering emergency medical, surgical, hospital, or health services to any individual regardless of age where its patient is unable to give his or her consent for any reason and there is no other person reasonably available who is legally authorized to consent to the providing of such care: provided, that such physician or hospital has acted in good faith and without knowledge of facts negating consent.

On this basis, where there is an emergency and the patient's condition is such that the patient is unable to make an informed decision, and the consent of another person qualified to represent the patient is not reasonably available, consent to treatment is not required.

Emergency is not defined by the relevant statute; an emergency medical condition is defined elsewhere as a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in serious impairment to bodily functions or serious dysfunction of an organ or part of the body, or would place the person's health, or in the case of a

⁷⁸ See Part B herein.

⁷⁹ See *Orwick v. Fox*, 65 Wn. App. 71, 86, 828 P.2d 12, *rev. denied*, 120 Wn.2d 1014 (1992).

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pregnant woman, the health of the woman or unborn child, in serious jeopardy.⁸⁰ If delay would not so jeopardize the condition of the patient, consent must be obtained from the patient or a substitute.

The scope of treatment which may be provided in the absence of consent in an emergency is that which is reasonable under the circumstances. The theory supporting the implied consent rule is that the patient would have consented if able to do so in this emergency situation. Therefore, the treatment must be consistent with the treatment to which a patient would have given consent if able to do so. It normally should be limited to the immediate need for care.

2A.9.2 Medical Holds for Minors

Hospitals and physicians are specifically authorized by statute to detain a child without the consent of “a person legally responsible for the child,” if there is reasonable cause to believe “that permitting the child to continue in his or her place of residence or in the care and custody of the parent, guardian, custodian or other person legally responsible for the child’s care would present an imminent danger to that child’s safety...”⁸¹ The detention is authorized whether or not medical care is required. The hospital administrator or physician detaining a child without consent under these circumstances must notify the appropriate law enforcement agency or child protective service as soon as possible, but in no case longer than 72 hours after the detention. If a physician or hospital acts in good faith in accordance with this statute, there can be no civil liability for the lack of consent.⁸²

2A.9.3 Therapeutic Privilege

Informed consent is not required where the disclosure of the information necessary to make the consent informed would adversely affect the patient or the patient’s health. This “therapeutic privilege” to not disclose information to a patient has been recognized in Washington. It is clearly enunciated in a case relied upon by both the court of appeals and the Washington Supreme Court.⁸³ Information need not be disclosed “where full disclosure would be detrimental to the patient’s best interests.”⁸⁴ A physician has a privilege to keep information from the patient where the patient might become “so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage to the patient.”⁸⁵

The issue that the disclosure of information was not made because it would be harmful to the patient is a matter of defense for the physician.⁸⁶ The physician who withholds information must do so based upon a belief that full disclosure would have a significant adverse impact upon the patient. The amount and manner of the information disclosed must show an exercise of reasonable discretion as applied to that particular patient.

2A.9.4 Patient Request Not to Be Informed

A patient may choose not to be informed as to details about the medical procedures, including its risks and/or alternatives. In such circumstances, a physician will not be required to disclose all of the information necessary for an informed consent. Under RCW 7.70.060, prima facie evidence of informed consent may include a

⁸⁰ See, e.g., RCW 70.41.115(1)(a), RCW 48.43.005(13); C.F.R. § 489.24(b). See also *Stewart-Graves v. Vaughn*, 162 Wn.2d 115, 126-27, 170 P.3d 1151 (2007).

⁸¹ RCW 26.44.056(1).

⁸² RCW 26.44.056(3).

⁸³ See *Canterbury v. Spence*, 464 F.2d 772, 150 U.S. App. D.C. 263, cert. denied, 409 U.S. 1064 (1972) (hereinafter cited as *Canterbury*).

⁸⁴ *Holt*, 11 Wn. App. at 240.

⁸⁵ *Canterbury*, 464 F.2d at 789.

⁸⁶ See *Hunter v. Brown*, 4 Wn. App. 899, 906-07, 484 P.2d 1162 (1971) (hereinafter cited as *Hunter*).

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statement that the patient elects not to be informed of the nature and character of the proposed treatment, the anticipated results of the proposed treatment, the recognized possible alternative forms of treatment, and the recognized possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment.⁸⁷

2A.10 Consent Litigation

Lack of informed consent is an allegation in 30-35% of all malpractice claims nationwide.⁸⁸ The law of informed consent in Washington is shaped both by statute and by case law. Important components of such litigation include the elements of informed consent, the statute of limitations and other available defenses, the burden of proof, and the role of the expert.⁸⁹

2A.10.1 Elements

The elements required to hold a health care provider liable for failure to obtain informed consent are set forth in RCW 7.70.050(1)(a)-(d).⁹⁰ It provides:

The following shall be necessary elements of proof that injury resulted from health care in a civil negligence case or arbitration involving the issue of the alleged breach of duty to secure an informed consent by a patient or his or her representatives against a health care provider:

- That the health care provider failed to inform the patient of a material fact or facts relating to the treatment;
- That the patient consented to the treatment without being aware of or fully informed of such material fact or facts;
- That a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of such material fact or facts; and
- That the treatment in question proximately caused injury to the patient.

These elements may be more succinctly stated as: (1) the existence of a material risk unknown to the patient; (2) the failure to disclose the risk; (3) that had the risk been disclosed, the patient would have chosen a different course; and (4) resulting injury.⁹¹

Inherent in these elements is the existence of a patient-provider relationship. The informed consent obligation arises as a result of the fiduciary relationship between the physician and the patient. If the fiduciary (or treating) relationship does not exist, the threshold for establishing the elements of proof does not exist. A physician should not be liable for failure to disclose risks and alternatives to third parties.⁹² Because hospitals do not have

⁸⁷ If a patient elects not to be informed of the risks or alternatives to treatment, this should be documented in the patient's chart.

⁸⁸ Washington State Physicians Insurance Exchange, Physician Risk Management Update, May/June 1995.

⁸⁹ A claim for lack of informed consent is commonly pled in medical malpractice cases, but it is far less often the basis of a successful claim. Even when there is no claim for lack of informed consent, the signed consent form may potentially be used as evidence that the unwanted outcome was a known risk of the procedure.

⁹⁰ See *Bertsch v. Brewer*, 97 Wn.2d 83, 90, 640 P.2d 711 (1982); *Crawford v. Wojnas*, 51 Wn. App. 781, 783, 754 P.2d 1302, rev. denied, 111 Wn.2d 1027 (1988); *Coggle v. Snow*, 56 Wn. App. 499, 511-12, 784 P.2d 554 (1990).

⁹¹ *Harbeson v. Parke Davis, Inc.*, 746 F.2d 517, 522 (9th Cir. 1984).

⁹² *Crawford*, 51 Wn. App. at 783.

the same fiduciary relationship with the patient, hospitals are not held to have the same informed consent duties as physicians,⁹³ although they may be held liable for the consent obligations of their employed physicians.⁹⁴

2A.10.1.1 Material Fact

A critical element in a lawsuit alleging failure to obtain informed consent is the failure to inform the patient of a material fact or facts. RCW 7.70.050(2) defines a fact as material “if a reasonably prudent person in the position of the patient or his or her representative would attach significance to it in deciding whether or not to submit to the proposed treatment.” Case law in Washington has described this as the “reasonable patient” standard.⁹⁵ “The guide for disclosure of a possible risk is materiality.”⁹⁶

It is well accepted that:

[t]he determination of materiality is a 2-step process. Initially, the scientific nature of the risk must be ascertained, i.e., the nature of the harm which may result and the probability of its occurrence. The trier of fact must then decide whether that probability of that type of harm is a risk which a reasonable patient would consider in deciding on treatment.⁹⁷

The test is not whether the particular patient would have attached significance to the fact, but whether “a reasonable person in the patient’s position probably would attach significance to the specific risk in deciding on treatment...”⁹⁸

A risk must be serious in order to be material.⁹⁹ Whether or not a risk is foreseeable is a good measure as to whether the risk is serious and therefore material.¹⁰⁰ “If a risk is not foreseeable, it almost certainly is not serious and, therefore, not material.”¹⁰¹

2A.10.1.2 Causation

Causation involves the issue of whether, if the material fact had been disclosed, the patient would have refused the treatment. It is measured by a “reasonably prudent patient” standard.¹⁰² The test is whether a reasonably prudent person would have chosen a different course of treatment.¹⁰³ Causation is not measured by what the particular patient testifies he or she would or would not have done had the material fact been disclosed,¹⁰⁴ and such testimony, therefore, has limited value, and may not even be necessary.¹⁰⁵

⁹³ *Alexander*, 42 Wn. App. 234.

⁹⁴ *Keogan v. Holy Family Hospital*, 95 Wn.2d 306, 309 n.1, 622 P.2d 1246 (1980).

⁹⁵ *Smith*, 100 Wn.2d at 32.

⁹⁶ *Christiansen*, 123 Wn.2d at 245.

⁹⁷ *Smith*, 100 Wn.2d at 33 (internal citations omitted).

⁹⁸ *Miller*, 11 Wn. App. at 287. Washington uses the “reasonable patient” standard, while Oregon uses a subjective patient standard.

⁹⁹ *Ruffer*, 56 Wn. App. at 632.

¹⁰⁰ *Mason*, 3 Wn. App. 298.

¹⁰¹ *Ruffer*, 56 Wn. App. at 633.

¹⁰² RCW 7.70.050(1)(c).

¹⁰³ *Brown*, 41 Wn. App. at 574.

¹⁰⁴ *Keogan*, 95 Wn.2d at 323.

¹⁰⁵ *Holt*, 11 Wn. App. at 236; *Brown*, 41 Wn. App. at 574.

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2A.10.1.3 Proximate Cause

In addition to establishing the failure to disclose a material risk unknown to the patient that would have caused a reasonably prudent patient under similar circumstances to not have consented to treatment, the patient must establish that there is a causal connection between the failure to disclose the information and the injuries suffered.¹⁰⁶ “Altered conduct” has been described as the test for establishing proximate cause.¹⁰⁷ The patient must demonstrate that the injury suffered resulted from conduct that would not have occurred, but for the failure to disclose material risk. Again, however, the standard is objective rather than subjective. It is whether the conduct of a reasonably prudent patient would have been altered and the injury avoided. An important component in establishing proximate cause is the proof that the consented upon treatment caused the injury to the patient.¹⁰⁸

2A.10.2 Burden of Proof

The plaintiff in alleging failure to obtain informed consent has the burden of proving breach of the duty to obtain informed consent, and must make out a prima facie case of negligence. All of the elements of proof set forth in RCW 7.70.050(1) must be established: (1) that the duty on the part of the health care provider existed; (2) that the provider failed to disclose material facts; (3) that the patient consented to the treatment without being aware of the material facts; (4) that a reasonably prudent patient would not have consented to the treatment if informed of the material facts; and (5) that the treatment in question proximately caused the injury.¹⁰⁹

The plaintiff’s burden is to demonstrate these elements by a preponderance of the evidence. As to the issue of materiality, this burden has been described as follows:

Materiality presents a jury question if any rational trier of fact could find, based on a preponderance of evidence, that a reasonably prudent person in the position of the patient, when deciding whether to submit to the proposed treatment, would have attached significance to the fact in issue. Immateriality is shown as a matter of law if no rational trier could find, based on a preponderance of evidence, that a reasonably prudent person in the position of the patient, when deciding whether to submit to the proposed treatment, would have attached significance to the fact in issue.¹¹⁰

Once the failure to disclose a material fact has been established, along with proximate cause, the burden of proof shifts to the physician. The physician must provide a defense to the failure to disclose.¹¹¹

The existence of a patient’s written consent, or proof of oral consent, shifts the burden of proof back to the plaintiff. The consent form should include a description, in language the patient could reasonably be expected to understand, of:

- The nature and character of the proposed treatment;
- The anticipated results of the proposed treatment;

¹⁰⁶ *Gomez v. Sauerwein*, 180 Wn.2d 610, 331 P.3d 19 (2014).

¹⁰⁷ *Informed consent in Washington*, at 662.

¹⁰⁸ *Canterbury*, 464 F.2d at 790.

¹⁰⁹ *Miller*, 11 Wn. App. at 283.

¹¹⁰ *Estate of Lapping*, 77 Wn. App. at 624 (citations omitted).

¹¹¹ *Miller*, 11 Wn. App. at 284; *Canterbury*, 464 F.2d at 791.

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

A plaintiff's signed consent form, which sets forth the above information, constitutes prima facie evidence that the patient gave informed consent to the treatment administered, and the patient then has the burden of rebutting this by a preponderance of the evidence. As an alternative to a written consent, a statement that the patient elects not to be informed of the elements set forth above similarly shifts the burden.¹¹² The patient then has the burden of rebutting that the consent was valid by a preponderance of the evidence.

2A.10.3 Expert Testimony

Determination of materiality is a two step process as noted in Section 2.10.1.1¹¹³ First is a determination of the scientific nature of the risk and the probability of its occurrence. Second is a determination as to whether the probability of this type of harm is a risk which a reasonably prudent patient would consider in deciding on treatment. The first step requires an expert.¹¹⁴ "Expert testimony is necessary to prove the existence of the risk, its likelihood of occurrence, and the type of harm in question."¹¹⁵

RCW 7.70.050(3) sets out the facts which must be established by expert testimony in order for there to be a valid informed consent claim. The expert must testify regarding: (a) the nature and character of the treatment proposed and administered; (b) the anticipated results of the treatment proposed and administered; (c) the recognized possible alternative forms of treatment; or (d) the recognized serious possible risks, complications, and anticipated benefits involved in the treatment administered and in the recognized possible alternative forms of treatment, including nontreatment.

The use of expert testimony is critical in consent litigation to establish a genuine issue of material fact. The failure to provide expert testimony as to the "scientific nature of the risk" will usually result in dismissal of an informed consent claim on a summary judgment motion. Where there is ample expert testimony of the scientific nature of the risks, however, the claim most likely will not be dismissed.¹¹⁶

Once the nature of the risk and the likelihood of its occurrence is established, further expert testimony is not required. "[W]hether the probability of that type of harm is a risk which a reasonable patient would consider in deciding on treatment, is strictly an issue for the trier of fact."¹¹⁷

2A.10.4 Defenses

A number of defenses are available to a defendant in an action for negligence for failure to obtain informed consent.¹¹⁸ It may be established that consent was implied, that only limited disclosure was authorized, that the patient chose not to be informed, or that the patient did in fact give informed consent. The defense also might

¹¹² RCW 7.70.060.

¹¹³ *Smith*, 100 Wn.2d at 33.

¹¹⁴ *Id.*; *Brown*, 41 Wn. App. at 571.

¹¹⁵ *Smith*, 100 Wn.2d at 34.

¹¹⁶ *Villanueva*, 80 Wn. App. 36.

¹¹⁷ *Adams*, 37 Wn. App. at 658.

¹¹⁸ Some of these defenses pertain to issues discussed in detail in Sections 2.6.3 and 2.10.

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include “[e]vidence that the patient was not uninformed or that the facts undisclosed were immaterial or that disclosure might be harmful...”¹¹⁹

In the case of medical emergencies, consent is implied.¹²⁰ If there is a recognized health care emergency and the patient or the patient’s representative is unable to give consent, a physician has no obligation to obtain informed consent and will not be held liable for failure to do so.¹²¹

Evidence that the patient was in fact informed might include a signed consent form. RCW 7.70.060 makes a signed consent form which includes the pertinent information prima facie evidence of informed consent. That prima facie evidence is rebuttable, and deficiencies in the information contained in the consent form may be fatal.¹²²

Evidence that the patient was in fact informed might also include chart notes summarizing a conversation with the patient, or testimony from the physician regarding specific recall of the informed consent discussion or the physician’s standard format for such a discussion.¹²³ A defendant may assert therapeutic privilege—that the disclosure of the information would have been harmful to the patient—as a defense.¹²⁴ This privilege is an effective defense only if it can be shown that the disclosure would have had a substantial adverse impact upon the patient. This is an area in which a medical standard of disclosure may be used as a matter of defense.¹²⁵ It is not consistent with this privilege to assert it solely on the basis that had the provider disclosed the information, the patient would not have consented to the treatment.

Another defense is that the physician was not aware of the condition or ruled out a diagnosis which gave rise to the material facts.¹²⁶ “[A] health care provider who believes the patient does not have a particular disease cannot be expected to inform the patient about the unknown disease or possible treatments for it.¹²⁷ The problem with such a defense, of course, is that while it may be successful in defending an action on informed consent, it will likely form the basis for a medical negligence suit.¹²⁸

2A.10.5 Statute of Limitations

The breach of the duty to obtain informed consent is professional negligence. Therefore, the statute of limitations for suits alleging failure to obtain informed consent is the same as for other medical malpractice suits. The general rule is that the action must be commenced “within three years of the act or omission...or one

¹¹⁹ *Hunter*, 4 Wn. App. at 906.

¹²⁰ RCW 7.70.050(4); *see* Section 2.10.1.

¹²¹ *See Orwick*, 65 Wn. App. 71.

¹²² *Brown*, 41 Wn. App. at 572.

¹²³ *But see Lasher*, 91 Wn. App. 165 (deadman’s statute precluded testimony regarding discussion with deceased patient).

¹²⁴ *Hunter*, 4 Wn. App. at 906.

¹²⁵ *Klink v. G.D. Searle & Co.*, 26 Wn. App. 951, 957, 614 P.2d 701 (1980).

¹²⁶ *Burnet v. Spokane Ambulance*, 54 Wn. App. 162, 772 P.2d 1027 (1989); *Gomez v. Sauerwein*, 180 Wn.2d 610, 618, 331 P.3d 19 (2014).

¹²⁷ *Gomez v. Sauerwein*, 180 Wn.2d at 618. *But see Flyte v. Summit View Clinic*, 183 Wn. App. 559 (2014) (reversible error to submit an instruction stating “a physician has no duty to disclose treatments for a condition that may indicate a risk to the patient’s health until the physician diagnoses that condition,” where disclosure should be based on what a patient would want to know under the circumstance, and not triggered solely by those conditions that had been conclusively diagnosed.)

¹²⁸ *See Thomas v. Wilfac, Inc.*, 65 Wn. App. 255, 261, 828 P.2d 597, *rev. denied*, 119 Wn.2d 1020(1992); *Gomez*, 180 Wn.2d at 619.

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year of the time the patient or his representative discovered or reasonably should have discovered that the injury or condition was caused by said act or omission, whichever period expires later, except that in no event shall an action be commenced more than eight years after said act or omission...”¹²⁹ There are some exceptions for actions involving multiple defendants and minors.

¹²⁹ RCW 4.16.350.