

April 25, 2000

Ms. Jean Seifarth
Coordinator
Education and Project Management Department

I am writing in response to your request for advice about the distinction between a patient's exercise of informed consent, on the one hand, and the creation of an oral advance directive, on the other. Relying primarily on an important recent case, *Wright v. Johns Hopkins Health Systems Corp*, 353 Md. 568 (1999), this letter will first discuss the legal basis for the distinction between these two different methods of decision making. Then the letter presents a few examples to illustrate the distinction.

I

Legal Background

Since a landmark decision of the Maryland Court of Appeals in 1977,¹ Maryland law has recognized that a physician is negligent if he or she performs a medical procedure without the informed consent of the patient. Of course, this legal requirement presupposes that the patient has the capacity to make an informed decision, which encompasses the ability to understand the nature, extent, or probable consequence of the proposed treatment or course of treatment, ... to make a rationale evaluation of the burdens, risks, and benefits of the treatment or course of treatment, ... [and] to communicate a decision.² The Court of Appeals has explained succinctly the basis for the informed consent doctrine:

(1) the decision to undergo an elective medical procedure rests with the patient, who, if competent, retains the right to exercise control over his or her body, (2) a physician

¹ *Sard v. Hardy*, 281 Md. 432 (1977).

² § 5-601(l) of the Health-General Article (defining "incapable of making an informed decision").

therefore has no right to subject a competent patient to a medical procedure without the patient's consent, (3) the patient will ordinarily be unable to make an intelligent decision whether to proceed without a clear and adequate explanation by the physician of the nature, benefits, and risks of, and alternatives to, the contemplated procedure, and (4) the physician therefore has a duty, before proceeding, to provide that explanation and obtain the patient's *informed consent*.³

The Court's language) Athe nature, benefits, and risks of, and alternatives to, the contemplated procedure@) makes clear that informed consent is decision making about a specific diagnostic or treatment procedure. Ordinarily, the procedure is one that is proposed to be done in the very near future by the patient's current attending physician. Sometimes, the procedure might be one that, although not an immediate issue, can be discussed while formulating a care plan linked to the well-known future course of a disease. Whatever the exact time in which the clinical decision would be implemented, the informed consent doctrine applies when the physician and patient together can explore, in meaningful detail, the risks and benefits of, and alternatives to, the proposed treatment, given the patient's diagnosis and prognosis. If the diagnosis or prognosis were to change markedly, the informed consent doctrine contemplates that a new decision making process would precede treatment.

If a health care decision has sufficient concreteness to be encompassed by the informed consent doctrine, the procedures for documenting the decision are simply those of ordinary medical practice. For surgery and certain other procedures, the patient's consent is reflected in a signed document; for other clinical procedures, the patient's consent may be noted in the chart or simply inferred from the patient's participation in the procedure.

By contrast, some health care decisions are so Ageneralized and open-ended@ that they cannot fairly be called the product of informed consent.⁴ Decisions about future life-sustaining treatment are often anticipatory and contingent; for example, classic A living will@ language might refer to an individual's desire not to receive

³ *Dingle v. Belin*, No. 98 Sept. Term 1999 (April 11, 2000), slip op. at 16.

⁴ The quoted phrase is from 79 *Opinions of the Attorney General* ____ (1994) [Opinion No. 94-023, at 20 (May 3, 1994)], as approved by the Court of Appeals in *Wright*.

life-sustaining procedures that would only prolong an inevitable dying process. This kind of decision, while it certainly reflects the individual's values in a medical context, is typically made by someone who is not already in the condition described and who seeks to control the basic direction of future care when, although the exact circumstances cannot be known, a specified contingency has occurred. A decision to decline (or request) life-sustaining procedures when this future, hypothetical situation occurs surely requires the individual to reckon with an assumed set of benefits, risks, and alternatives, but clinical immediacy is lacking. Moreover, the decision is intended to guide the actions of an unknown set of future health care providers.

For this kind of open-ended decision, the Health Care Decisions Act provides a mechanism: written or oral advance directives. These advance directives, however, gain their intended effect only if the Act's procedural requirements are satisfied. In the case of an oral advance directive, the Act specifies that it ~~be~~ made in the presence of the attending physician and one witness and documented as part of the individual's medical record. The documentation shall be dated and signed by the attending physician and the witness.⁵ In addition, an advance directive that states a decision to forgo life-sustaining treatment, as distinct from an advance directive that names a health care agent, may be implemented only if, at that time, the patient is certified to be within one of three conditions defined in the Act: terminal condition, end-stage condition, or persistent vegetative state.⁶

II

Illustrative Cases

The following examples, will, I hope, illustrate the distinction between the exercise of informed consent and the making of an oral advance directive. All of these examples assume that the patient has sufficient decision making capacity at the time that he or she makes the statement.

1. A patient with severe renal disease is considering whether to decline further kidney dialysis. The patient is told by the attending physician that a

⁵ ' 5-602(d). Under recently enacted legislation, Senate Bill 684 (effective October 1, 2000), the substance of an oral advance directive, not merely the fact of it, is to be documented in the medical record.

⁶ ' 5-606(b). The three conditions are defined in ' 5-601(i), (o), and (q).

discontinuation of dialysis would quickly result in death and that no alternative to dialysis is available. The patient decides to decline further dialysis. This decision is an exercise of informed consent; it is not an oral advance directive and therefore need not meet the special procedural requirements of the Health Care Decisions Act to be legally effective. The decision remains valid, without certification of condition or surrogate approval, even if the patient loses capacity.

2. A renal disease patient who is continuing on dialysis has decided that, in the event of a future cardiac arrest, CPR should not be attempted. The patient's preference about CPR, which is intended to affect an open-ended period of time and is not dependent on the context of a particular clinical encounter, is not an informed consent decision. Rather, it is an exercise of patient self-determination that can be reflected in an advance directive, following the procedures in the Health Care Decisions Act. The decision could be captured in an oral advance directive if the statement were made to the attending physician with a witness and properly documented. If the documentation in the patient's record were copied and made available to the patient, what was originally an oral advance directive in effect would become a written one and could be given later to other health care providers. As a practical matter, however, if a patient will be discharged from a facility, decisions in an oral advance directive should be embodied in a more conventional written advance directive, which in other settings is more likely to be recognized for what it is than a copied page from a chart. Implementation of this kind of decisional advance directive would be predicated on certification of one of the three qualifying conditions.

3. A patient with severe cardiovascular disease enters the hospital for treatment. The attending physician discusses with the patient what the patient's code status should be, in the event of a cardiac arrest during this hospital stay. After a discussion of the benefits and risks of attempted CPR, given the patient's condition, the patient requests palliative care measures, rather than attempted CPR, in the event of an arrest. This is an exercise of informed consent, not an oral advance directive.

4. The facts are the same as in the preceding example, but in addition to declining attempted CPR during this hospital stay, the patient also says, "Even after I get out of here, I don't ever want people pounding on my chest. I just want to go in peace when the time comes." The patient's preference that CPR not be attempted in the future, even under potentially changed clinical circumstances, is not an informed consent decision. To be given legal effect, it should be reflected in a properly executed written or oral advance directive. As in Case 2, assuming that the advance directive simply states this decision, rather than empowering a health care agent to decide, it could be implemented only upon certification of a qualifying condition.

III

Conclusion

Imagine an informed consent/advance directive scale, in which 1 = archetypal informed consent (Case 1 above, a renal disease patient who declines dialysis scheduled this week) and 10 = an archetypal advance directive (for example, a healthy 40 year old who wants to decline life-sustaining treatment whenever he or she happens to become terminally ill, which actuarially would not be for decades). A "1" has all of the following characteristics: a highly detailed clinical context, a patient already experiencing the disease, the treatment issue immediately at hand, and a patient decision that addresses the current health care team only. A "10" has all of the following characteristics: a completely abstract or hypothetical clinical context, the individual not even close to experiencing the disease, the treatment issue remote and speculative, and a decision that addresses a universe of future, unknown health care providers. The legal rule of thumb, based on the *Wright* case, is that oral statements must be down around a 2 or a 3 to count as an effective informed consent. The more that an oral statement tends toward the "10" end of the scale, the more important it is to follow the Health Care Decision Act's requirements for an oral advance directive

I don't mean, by these numbers, to lend a bogus air of precision to what will often and inevitably be a judgment call; by their nature, legal categories are always a good deal neater than clinical reality. Nevertheless, I hope that this letter of advice has been helpful in clarifying the distinction. Please let me know if I may be of further assistance.

Jack Schwartz
Assistant Attorney General
Director, Health Policy Development