



Office of the General Counsel

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Attn: CMS-1625-P

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (“USCCB”), we respectfully submit the following comments on the Proposed Rule to amend various aspects of the Medicare program. 80 Fed. Reg. 39840 (July 10, 2015). Our comments relate specifically to the proposal to reimburse Medicare providers for Advance Care Planning counseling sessions. *See id.* at 39882-83.

Background

The Catholic Church has no objection to encouraging patients to consider treatment decisions that may have to be made in the future, in light of their personal values and medical condition, in case they become unable to communicate their wishes. On the contrary, the Church has a long and rich tradition on the parameters for such decision making, providing concepts and distinctions that have long played an important role in secular medical ethics as well. We hold that each human life, at every stage and in every condition, has innate dignity, and that acts or omissions directly intended to take an innocent life are never justified. We also recognize that the moral obligation to preserve one’s life has limits, particularly when the means offered for supporting life may be useless or impose burdens that are disproportionate to their benefits.¹

Accordingly, Catholic dioceses and other organizations have actively participated in the nationwide debate on end-of-life decision making and on the pros and cons of various “advance directives.” Many state Catholic conferences have even provided their own advance directives

¹ See the texts listed under “Church Documents and Teachings” at <http://usccb.org/issues-and-action/human-life-and-dignity/end-of-life/euthanasia/index.cfm#church>.

that conform to the requirements of state law while providing essential moral guidance.² Therefore we are interested in any action proposed by the Federal government to promote what the government calls advance care planning.

Outline of Concerns

While we do not object in principle to the government's proposal to reimburse health care providers for advance care planning, the current open-ended proposal has several deficiencies that merit attention before a final rule is considered. We will outline these briefly and then comment on each.

1. The preamble to the proposed rule, which offers the only explanation of what the government means by advance care planning, reflects a confusing and inconsistent definition of what constitutes an "advance care plan," apparently showing a bias toward the kinds of advance directive that has drawn the most extensive and justified criticism in recent years.

2. Similarly unclear is whether the government's primary goal in promoting such planning is to enhance patient autonomy or to save health care costs. Those goals are not always compatible with each other.

3. In neither the preamble nor the proposed rule does the government acknowledge or reflect important statutory guidance on this issue found in the Patient Self-Determination Act, the Assisted Suicide Funding Restriction Act, or the Affordable Care Act.

Specific Concerns

I. The Meaning of Advance Care Planning

A patient might make advance plans for future medical situations, in which he or she may no longer be able to communicate, in a number of ways. First, the patient may arrange to discuss his or her values and priorities with loved ones such as spouse and adult children, so they will be ready to discuss the best course of action in light of up-to-date medical information at the time a decision is needed. Second, the patient may formally designate one of these trusted associates to serve as a surrogate decision maker. Third, the patient may sign an advance directive such as a "living will," attempting to make choices in advance regarding particular treatments in particular future scenarios despite the current unavailability of detailed information.

The preamble to the proposed rule is not entirely clear but seems to favor only the second and third of these options, and to call only the third one an "advance care plan." The preamble calls for measuring the percentage of patients "that have an advance care plan *or* surrogate decision maker documented in the clinical record," or with whom "an *advance care plan* was discussed" but "the patient did not wish or was not able to name a surrogate decision maker *or*

² See the resources listed at *Now and at the Hour of Our Death: Catholic Guidance for End-of-Life Decision Making*, <http://www.catholicendoflife.org/resources/>.

provide an advance care plan.” 80 Fed. Reg. at 39882-83 (emphasis added). Then the goal of this program is described as furthering “an increase in the number of patients with *advance care plans*.” *Id.* at 39883 (emphasis added). No explanation is provided as to why the first and second of the approaches described above should not qualify as “advance care plans.”

This is especially unfortunate because the third approach, the advance directive known broadly as the “living will,” has come under increased criticism in recent years for being, at best, a blunt instrument for making medical decisions. Such a document cannot take into account the myriad details of a patient’s future condition, and the probable risks and benefits of various treatments considered alone or in combination with each other. It can only err in one direction or another: Stating broad parameters that medical personnel must still wonder how to apply to the situation that actually occurs, or describing scenarios in such detail that the situation that actually occurs is likely to be missed.

These documents also carry an inevitable bias, as they must somehow predict in advance how a patient would assess life in a future condition without having the opportunity to experience it. Life with a permanent disability, for example, appears very different to an outside observer and to someone who has adjusted to this life – prompting the President’s Council for Bioethics to ask whether such documents encourage us as able-bodied people to discriminate against the persons with disabilities we may become.³

Most states have authorized specific texts for such advance directives, and some of these documents are more biased toward certain outcomes than others. Drafters of the documents inevitably make decisions that are morally significant, reflected in the way the text describes the patient’s alternatives and even makes certain “default” decisions in the absence of specific guidance from the patient. For example, in many of these documents: (1) withdrawal of treatment is offered as a response not only to a terminal illness but also to an irreversible disabling condition, with the implication that life with a disability is tantamount to no life at all; (2) assisted feeding and fluids are assumed to be optional medical “treatments” on the same plane as aggressive medical or surgical procedures, despite considerable moral and medical objections that such means are best seen as forms of normal “care” generally owed to all patients; (3) advance refusals of life-sustaining treatment by a woman who later becomes pregnant are assumed to authorize an early death for her unborn child as well, unless the patient takes the initiative of insisting otherwise.⁴

³ See The President’s Council on Bioethics, *Taking Care: Ethical Caregiving in Our Aging Society* (Washington D.C. 2005) at 53-93 (Chapter 2: The Limited Wisdom of Advance Directives), especially 83-4.

⁴ These are three deficiencies that the National Conference of Catholic Bishops (now USCCB) criticized in the Uniform Rights of the Terminally Ill Act when it was issued by the National Conference of Commissioners on Uniform State Laws. See NCCB Committee for Pro-Life Activities, *Statement on Uniform Rights of the Terminally Ill Act* (1986), at note 1 *supra*. When this uniform act was superseded by a new Uniform Health Care Decisions Act several years later, these failures to make ethically important distinctions were hailed by supporters as key advantages of the new legislation. See C. Sabatino, “The New Uniform Health Care Decisions Act: Paving a Health Care Decisions Superhighway?”, 53.4 *Maryland Law Review* 1238-54 (1994) at 1239: “Execution requirements such as witnessing are absent. Also absent are preconditions such as certification of diagnosis of a terminal condition or permanent unconsciousness, the need for life-sustaining procedures, and special rules for nutrition and

A variation of the living will known as the Physician Order for Life-Sustaining Treatment (“POLST”) or Medical Order for Life-Sustaining Treatment (“MOST”) has been criticized for being subject to these problems and additional ones. It is generally completed by medical staff, presumably after consultation with the patient, but in some states need not even be signed by the patient, yet has all the force of a physician’s orders to nurses and other medical personnel. In some forms it may contain the most problematic features of the living will while also marking a further remove from the patient’s own wishes.⁵

For these reasons, in its regulations and policy guidance, the government should not show a preference for documents such as the living will, POLST, or MOST regardless of their contents. Counseling on advance care planning should present all the approaches to making an advance care plan, provide information on the risks as well as benefits of advance directives, and invite patients to explore whatever resources on the issue may be provided by their own religious denomination or other sources of moral guidance.

II. The Goal of Advance Care Planning: Autonomy or Cost Control?

The preamble to the proposed rule says the purpose of advance care planning is “to ensure that the wishes of the patient regarding their [sic] medical, emotional, or social needs are met across care settings... Advance care planning ensures that the health care plan is consistent with the patient’s wishes and preferences.” 80 Fed. Reg. at 39882-83. It proceeds to say that “[i]ncreased advance care planning among the elderly is expected to result in enhanced patient autonomy *and* reduced hospitalizations and in-hospital deaths,” *id.* at 39883 (emphasis added) -- yet the only documentation cited for this claim is a study showing a correlation between advance directives and reduced “end-of-life Medicare expenditures,” not enhanced patient autonomy.

When the living will was first developed in the 1970s there was reason to believe that these two goals would largely be compatible. Health care reimbursement policies tended to pay providers for each particular treatment, potentially rewarding overuse of high-technology treatments when they were of waning effectiveness. Patients were seen as needing to assert their right to refuse such overtreatment. But in an age of HMOs, capitated fees and reimbursement caps, an equally vital concern is that patients will be able to receive affordable care when they want it. Yet many advance directives have not caught up with this change in the situation.

As noted above, some kinds of advance directives have been criticized for imposing their own bias on patient decision making or even taking a significant part of the decision making away from the patient. More pointedly, many of these documents have been charged with tilting

hydration or pregnancy. This unencumbered approach keeps the focus of decision making where it should be--on discerning what the patient meant by his or her words and instructions, *even if they are less than clear*, rather than on what the legislature meant by its terms and instructions” (emphasis added, citations deleted).

⁵ See C. Brugger *et al.*, “The POLST paradigm and form: Facts and analysis,” 80.2 *The Linacre Quarterly* 103–138 (2013). This is a White Paper presenting the conclusions of the Catholic Medical Association. The Catholic bishops of Wisconsin and Minnesota have also cautioned Catholics against agreeing to POLST documents. See the resources listed for these states at note 2 *supra*.

decisions heavily toward refusal of life-sustaining treatment in an effort to cut health costs for health care providers, insurers, and government.⁶ Any implication that this is the basis for the government's decision to reimburse for advance care planning would undermine public acceptance of this decision, as was apparent during the public debate on the Affordable Care Act and "death panels."

Any regulations or policy guidance issued on this subject should be clear that the well-being and autonomy of the individual patient, not cost savings for the government, are paramount. Physicians counseling patients in this area should encourage them to read any document carefully to ensure that it will protect their right to receive life-supporting treatment as well as to refuse it.

III. Statutory Guidance for the Final Rule

At least three federal statutes provide precedent and guidance for the rule on advance care planning. Unfortunately none of the three is reflected or acknowledged in the preamble to, or text of, the proposed rule. Because federal rulemaking should first of all reflect pertinent policy guidance enacted by Congress, and incorporation of such guidance in this case would address some of the concerns expressed above, we proceed to these statutes.

1. The Patient Self-Determination Act

The Patient Self-Determination Act ("PSDA") was enacted into law as Sec. 4206 of the Omnibus Budget Reconciliation Act of 1990. The PSDA requires health facilities receiving Medicare reimbursement to make information available to each individual in their care regarding "an individual's rights under State law ... to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives." 42 U.S.C. § 1395cc(f)(1)(A)(i). It also requires these facilities "not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive." 42 U.S.C. § 1395cc(f)(1)(C). The PSDA defines the term "advance directive" as "a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State) and relating to the provision of such care when the individual is incapacitated." 42 U.S.C. § 1395cc(f)(3).

In several respects this statute provides more balance on the issue of advance care planning than the statements in the preamble to the proposed rule. The information about a patient's rights is to include a right to complete an advance directive but is not focused solely in this direction; a surrogate decision making document such as a durable power of attorney has the same status as a living will; and the statute forbids discriminating in any way against a patient who chooses to plan future treatment without such a written document.

⁶ See Robert Powell Center for Medical Ethics at the National Right to Life Committee, *The Bias Against Life-Preserving Treatment in Advance Care Planning* (Washington, DC 2015), at <http://www.nrlc.org/uploads/communications/advanceplanningbias2015.pdf>.

One study of the impact of the PSDA found that after its enactment, patients were better informed about the availability of advance directives, but there had been no significant increase in the number of patients completing these forms. The authors concluded from this finding that “simply informing patients about their right of self-determination is insufficient to meet the intended goals of the legislation.”⁷ We respectfully disagree. Simply getting more patients to sign certain kinds of documents, regardless of those documents’ text or bias, was not the stated goal of the PSDA. Once one is informed, a decision to plan for the future in ways other than through these documents is also an act of self-determination, and it may be the best choice for some patients.

2. Assisted Suicide Funding Restriction Act

In 1997, Congress enacted the Assisted Suicide Funding Restriction Act, Pub. L. No. 105-12 (“ASFRA” or “Act”). The Act states that its “principal purpose” is “to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual.” ASFRA, § 2, codified at 42 U.S.C. § 14401. This principle was implemented throughout a wide range of Federal programs serving people with illnesses and disabilities, including Medicare. For example, the Act states that “no funds appropriated by Congress for the purpose of paying (directly or indirectly) for the provision of health care services may be used ... to provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.”⁸ ASFRA, § 3, codified at 42 U.S.C. § 14402.

It seems clear that the kind of physician counseling session contemplated here constitutes a “health care item or service” under Medicare, and therefore any final rule or other guidance with respect to reimbursement for advance care planning should clearly reference this statutory requirement.

Section 7 of the Act (42 U.S.C. § 14406) specifically applies this anti-assisted-suicide policy to advance directives, and to the information on advance directives to be provided to Medicare beneficiaries under the PSDA. Congress directed that the required information provided to patients under the PSDA is *not* to include information or counseling regarding any “right” to obtain lethal items or services such as assisted suicide. 42 U.S.C. § 14406. And the PSDA’s requirements do not “apply to ... any requirement with respect to a portion of an

⁷ M.K. Robinson et al., “Effects of the Patient Self-Determination Act on patient knowledge and behavior,” 37.4 *Journal of Family Practice* 363-8 (1993).

⁸ The Act’s rule of construction (Sec. 3, codified at 42 U.S.C. § 14402) makes it clear that this policy does not apply to abortion, the withholding or withdrawing of medical treatment, or the use of drugs with the intention of controlling pain rather than causing death. This rule of construction provides its own objective statement against items and services “furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual,” instead of simply opposing “assisted suicide,” thereby ensuring that the federal government’s policy applies even in jurisdictions that refuse to recognize the deliberate prescribing and providing of lethal drugs to terminally ill patients as “assisted suicide” under state law.

advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual” such as by assisted suicide or euthanasia. *Id.*

Finally, Section 12 of the Act authorized a grant program under the Public Health Service Act “to reduce the rate of suicide (including assisted suicide) among persons with disabilities or terminal or chronic illness by furthering knowledge and practice of pain management, depression identification and treatment, and issues related to palliative care and suicide prevention.” Clearly this population would overlap considerably with the population being offered advance care planning counseling under the proposed rule.

To reflect the policy guidance of this Federal law, therefore, the final rule and any other guidance concerning reimbursement for advance care planning should include clear statements that:

- (1) Counseling that treats assisted suicide or euthanasia as any part of legitimate medical treatment options is excluded from these counseling sessions;
- (2) Any advance directive that includes or furthers the option of choosing these procedures is not to be considered as an “advance care plan” under the rule;
- (3) Physicians conducting the counseling should be attentive to signs that a patient’s treatment decision making may be affected by depression, including any suicidal feelings, so that the patient can be referred for suicide prevention care before being advised to complete an advance care plan.

3. Section 1302 of the Affordable Care Act

In establishing standards for the “essential health benefits” to be required in all qualified health plans in the United States, the Affordable Care Act requires that the Secretary “not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.” ACA, § 1302(b)(4)(B), codified at 42 U.S.C. § 18022(b)(4)(B).

This principle of nondiscrimination or “equality of life” should also be incorporated into any final rule or other guidance to health care professionals on advance care planning. Counseling on such planning should not present a life involving old age or disability as having little value, or as a “burdensome” life to be avoided through refusal of all life-sustaining measures.

Conclusion

Concern for the well-being and freedom of patients, as well as for consistency with existing statutory precedent, should lead the government to incorporate the following elements into any final rule and any other published guidance on this subject as well as other efforts to encourage “advance care planning”:

- Acknowledge the full range of advance care planning options, including those which rely on discussion and collaboration among family members instead of on pre-packaged documents that may be biased toward withdrawal of treatment;

- Caution patients about the need to read any document carefully before signing it, to ensure that it fully protects the individual patient's well-being and values, and inform them that additional resources may be available from their religious denomination or other sources of moral guidance;

- Completely exclude counseling and documents that present lethal actions such as assisted suicide or euthanasia as treatment options;

- Treat the counseling session as an opportunity for suicide prevention;

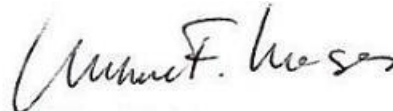
- Reflect current law's commitment to an "equality of life" standard that upholds life with a disability or permanent impairment as having inherent worth.

We believe changes in this direction will enhance the usefulness of advance care planning for patients as well as its acceptability to the general public.

Respectfully submitted,



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