May 4, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0044-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: File Code CMS-0044-P

Dear Ms. Tavenner:

We are pleased to submit comments on Section II.A.3.d(6)(e) of CMS's proposed rule entitled, "*CMS-0044-P – Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2*."

Executive Summary

Real-time access to a database of quality advance medical directives is one of the most powerful tools the government can help establish to empower consumers and embody the "patient-centered healthcare" goal. In February 2012, the HIT Policy Committee recommended moving advance medical directives from a "menu" to a "core" requirement in Meaningful Use Stage 2. The American Medical Association (AMA), the Joint Commission, and the National Quality Forum have all clearly stated their support for advance directives. However, CMS's proposed rule rejects these calls for reasons such as jurisdictional issues, technical concerns regarding interoperability, and actionable access via EHRs. We explain below why each of these concerns is unfounded. In addition, however, we believe CMS's fundamental reason for not moving advance directives to a core requirement is an aversion to what has become a politically sensitive issue: the "Death Panel." We also discuss how the marketplace has solved the death panel issue by empowering consumers to record their wishes without needing to consult and compensate doctors to facilitate the discussion. CMS now has a powerful opportunity to use its meaningful use leverage to (a) encourage a dramatic improvement in the quality and cost of healthcare in the United States, and (b) honor the public policy goal that began in 1969 with the first "living will" to encourage the widespread creation and use of quality advance medical directives. The 21st century marketplace has offered CMS many user-friendly, consumer empowering, cost effective (some even free) ways of accomplishing this noble goal.

We respectfully request that CMS follow the strong recommendation of the HIT Policy Committee and make advance directives a core requirement of Meaningful Use Stage 2, with the requirement being that certified EHRs document in a prominent part of the individual's current medical record

17304 Preston Road - Suite 800
Dallas, Texas 75252
P: (972) 733-6814 F: (972) 733-6809
www.mydirectives.com

whether the individual has executed an advance directive[1] and include a copy of the directive when available. With respect to eligible professionals (EPs) only, the objective should be that 50% of (i) patients 55 years old or older, and (ii) patients with terminal illnesses, who have the EP documented as the primary care physician (PCP) have the existence of an advance directive documented, with the directive accessible via the EHR. If the EP is not documented as the PCP for any patients in this age range or any terminally ill patients, the EP should be excluded from the measure. All eligible hospitals (EPs) and critical access hospitals (CAHs) should be required to comply with the 50% threshold set forth above for all patients who are 55 years old or older, as well as all terminally ill patients. As discussed in depth below, these objectives are achievable today without unduly burdening EPs, EHs or CAHs.

Background

Since the adoption of the Patient Self-Determination Act in 1990, Congress and various federal agencies have tried to raise public awareness about advance directives and encourage their adoption and use. Similarly, many states have adopted laws designed to enforce advance directives and educate their citizens about their rights to direct their medical treatment at the end of their lives.[2] Unfortunately, by 2008 only 18-36% of Americans had completed any form of advance directive.[3] Moreover, two-thirds of physicians whose patients have advance directives are unaware of the existence of those documents.[4]

The barriers to the effective use of advance directives to improve quality of medical care and decrease medical care costs can be overcome using a three-pronged approach:

1. Patients must be encouraged to create advance directives. Private enterprises like ADVault and Aging with Dignity are already making this happen.

2. Patients, their families, and their medical care providers must understand that, more than a signature on a legal form, in order for their advance directives to have meaningful value within the healthcare system, they must be thorough, updated and relevant.

3. Perhaps most critically, if medical care is ever to be truly patient centered, physicians *must* have access to patients' high-quality advance directives 24 hours a day, 7 days a week, anywhere, and they *must* be required – or at least incentivized – to record the existence of an advance medical directive and include a copy of the directive when available.

---

[1] For reasons discussed further below, we do not believe that the requirement should be the actual recordation in the EHR of patient wishes on end-of-life medical treatment. Doctors to not want to have this discussion with patients, the government does not want to reimburse doctors for having that discussion, and frankly, in most cases, technology has already empowered patients to make these decisions without the requirement of a prolonged discussion with doctors. The requirement to document the existence of an advance directive already applies to Medicare Advantage plans, so requiring the same thing of EPs, EHs and CAHs should not be difficult or even controversial. See 42 CFR 422.128(b)(1)(ii)(E).

[2] *Advance Directives and Advance Care Planning: Report to Congress*, prepared under contract #HHS-100-03-0023 between the U.S. Department of Health and the RAND Corporation (August 2008). See http://aspe.hhs.gov/_/office/specific/daltcp.cfm.

[3] *Idem* at page 13.

[4] Kass-Bartlemes BL, Hughes R, Rutherford MK, Boches J. *Research in Action Issue #12. Advance Care Planning: Preferences for Care at the End of Life*. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). Mar 2003; AHRQ Pub No. 03-0018.

If CMS and HHS leadership are honestly seeking ways to leverage the efficiencies offered by modern technological platforms to deliver better care and control costs, then there is no easier, quicker or more cost-effective way to do so than to follow the HIT Policy Committee's recommendation to require advance directives as a core requirement of Meaningful Use Stage 2.

Analysis

In Section II.A.3.d(6)(e) of the proposed rule, entitled "*Objective and Measure Carried Over Unmodified From Stage 1 Menu Set to Stage 2 Menu Set*," CMS justifies its intention to keep the objective "record advance directives" in the menu set for EHs and CAHs as part of Meaningful Use Stage 2 by stating, ". . . we have continuing concerns that there are potential conflicts between storing advance directives and existing State laws. Also, we believe that because of State law restrictions, an advance directive stored in an EHR may not be actionable. Finally, we believe that eligible hospitals and CAHs may have other methods of satisfying the intent of this objective at this time . . ." (77 FR 13731). With all due respect to CMS and the drafters of the proposed rule, we believe that the expressed concerns are erroneous and unfounded.

State Law Conflicts on Advance Directives

Despite support for the effective use of advance directives expressed by your own HIT Policy Committee, the AMA, the Joint Commission, the National Quality Forum, and many others, CMS claims to have "continuing concerns that there are potential conflicts between storing advance directives and existing State laws." *This concern simply has no credible basis or foundation in law.* Attached to this comment letter as Appendix A is a table entitled, "*Health Care Power of Attorney and Combined Advance Directive Legislation: Selected Features Compared – December 2009*." This table, issued by the American Bar Association's Commission on Law and Aging, includes a column entitled, "*Out-of-State Directives Recognized*." A quick review confirms that almost every state has adopted legislation recognizing the validity of advance directives from other jurisdictions. Those states that have not adopted such legislation have remained silent on the subject, acquiescing to the Supreme Court decisions establishing the principle that patients have a right to express their wishes with respect to end-of-life medical treatments and to have those wishes respected by healthcare providers. Most importantly, as a practical matter, almost any doctor will tell you he/she will respect the end-of-life medical treatment wishes (to the extent possible) even if they are written on a napkin. The substance is infinitely more important than the form.

Inactionability of Directives Stored in EHRs

CMS's statement that, "because of State law restrictions, an advance directive stored in an EHR may not be actionable," is also unsupported by facts. In every state, non-profit and for-profit enterprises are already demonstrating that access to advance directives on a massive scale across state lines is possible. The U.S. Living Will Registry, in existence since 1996, has worked with several states to develop and launch state advance directive registries. The non-profit organization Aging With Dignity, also around since 1996, sells its *Five Wishes* document and introduced a fee-based online storage option in April 2011. Since January 2012, MyDirectives® has been offering the first worldwide, free-to-consumers, HIPAA-compliant, web-based system for creating, storing and retrieving a universal advance directive that combines all of the elements of a living will, a medical power of attorney, patient preferences regarding attempts at resuscitation, and organ donation information. MyDirectives operates both as a stand-alone system and as a module within almost any EHR, EMR or patient portal platform. *MyDirectives was certified as a 2012 compliant EHR*

Module by an ONC-ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services on May 3, 2012. (This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.) As of the writing of this letter, people in over 35 states, Canada, most of Western Europe, select Eastern European countries, Russia, Israel, Japan, Singapore and Australia are using MyDirectives. Thus, contrary to CMS's claim, state law restrictions have not made advance directives created or stored using any of these solutions inactionable.

Alternative Methods of Satisfying the Advance Directives Objective

CMS believes that EHs and CAHs have other methods of satisfying the objective of recording advance directives in EHRs. While the success of private-sector solutions – some of which are outlined above – has shown the marketplaces' ability to innovate without the government's encouragement, it is only one half of the solution. Making advance directive access and retrieval a core requirement of Meaningful Use Stage 2 is the other half. In other words, if success is defined as widespread use of advance directives by the healthcare system, then while the marketplace can help create the directives, CMS has the opportunity through Meaningful Use incentives to create the "pull" of healthcare professionals to look for them and use them. Without CMS requiring the "pull," the marketplace solutions will not work.

Remember, the status quo is that less than 25% of Americans have directives, 98% of them don't have them when they need them and only 33% of doctors even know their patients have directives in the first place. Obviously, something is not working and needs to be changed if CMS really wants to make healthcare patient centered for all citizens, especially those most vulnerable – aging and chronically ill Americans.

The Real Concern: "Death Panels"

We believe the real, fundamental reason that CMS has chosen not to move advance directives to a core requirement of Meaningful Use Stage 2 is to avoid a discussion of what has become a politically "toxic" subject – "death panels." The provision authorizing Medicare to reimburse physicians for the time they spend discussing patients' goals and preferences surrounding end-of-life care had widespread bi-partisan support until the summer of 2009, when health reform critics began attacking the provision with misleading references to "death panels." Although the provision was removed from the pending legislation, CMS included similar provisions in regulations proposed in the fall of 2010. Again, public and industry support for the provisions was strong, but the death panel controversy was rekindled, and CMS backed down. Over the past year, CMS has published several additional rules and regulations, but it has failed to mention advance care planning even once. As one commentator has stated, "Given the support of CMS for patient-centered care and value-based purchasing, it [is] reasonable to expect that advanced care planning-related measures would be included in at least some of the new CMS rules, regulations, and programs. Their absence is notable."[5]

It seems as if CMS felt the only way to get more people to create advance directives was to pay doctors to help their patients do so. The facts are doctors don't want to have these conversations

[5] Tinetti ME. *The Retreat From Advanced Care Planning*. JAMA, 307:9, p. 915 (March 7, 2012).

with their patients[6] and, frankly, 21st century consumers are capable of addressing this issue themselves. Thus good news: CMS *does not have to* reimburse doctors for those talks. Several private solutions now exist that empower consumers to record their wishes without needing to consult and compensate doctors to facilitate the discussion. MyDirectives® is only one example. *The market has effectively solved the death panel controversy, but if EPs, EHs and CAHs are not required to go search for the directives that individuals create using those solutions, then the healthcare system will continue to be wasteful and ineffective*.

Conclusion

Almost 25 years after the adoption of the Patient Self-Determination Act, the adoption rate for advance medical directives is still too low. To put it simply, too many people are suffering. CMS has the power to make a real difference in the lives of many citizens. Public and private institutions are taking measures to dramatically improve both the quantity and quality of advance directives, but if EPs, EHs and CAHs aren't required to look for those directives when they're needed most, what good do they do? CMS is concerned about potential conflicts between storing advance directives and existing state laws – yet almost every state has adopted legislation addressing that very issue. CMS also believes that because of state law restrictions, an advance directive stored in an EHR may not be actionable – yet the ABA, the AMA, the Joint Commission, the National Quality Form, and many other organizations across the United States have expressly argued the contrary. CMS claims that EHs and CAHs already have other methods of satisfying the advance directives objective. That may true, but those methods cannot successfully lead to more patient-centered healthcare without CMS's help. Besides, close to 100% of medical care providers already had other methods of recording demographics such as preferred language, gender, race, ethnicity, and date of birth in July 2010. That didn't stop CMS from making the recording of such demographics the very first requirement on the list of core objectives for Meaningful Use Stage 1 certification. Most importantly, CMS's refusal to move advance directives to the core requirements of Meaningful Use Stage 2 may be an attempt to avoid the politically toxic death panel discussion. Private market solutions such as MyDirectives® and others are the solution to the death panel, but even the very best advance directives are only useful if EPs, EHs and CAHs are actually required to locate and retrieve them and link them to EHRs and EMRs.

The President of the United States and members of Congress from both the Democratic and Republican parties have repeatedly called upon HHS and the CMS to adopt rules and regulations ensuring that medical care providers respect advance directives. HHS and CMS have also preached "patient-centered care" to all of the stakeholders in the healthcare system. *There is nothing more patient-centered than a patient's advance medical directive. That directive needs to be of good quality and it needs to be accessible, then the government needs to take every measure necessary to ensure that doctors and hospitals actually have access to patients' directives when they are needed.*

We have no doubt that CMS is committed to achieving better care for patients, better health for populations, and reduced expenditure growth. Multiple reputable studies and peer-reviewed journals over the course of many years have shown that the effective use of advance directives can improve the quality of patient care while simultaneously decreasing the costs associated with medical care at the end of life, whether that be at the age of 18 or 118. High quality, comprehensive,

[6] Murray K. *How Doctors Die: It's Not Like the Rest of Us, But It Should Be*. See http://zocalopublicsquare.org/thepublicsquare/2011/11/30/how-doctors-die/read/nexus/ (accessed on April 24, 2012).

universal advance directives that medical care providers are required to locate and access in a time of need are absolutely crucial to the success of these objectives. Accordingly, we respectfully request that CMS follow the recommendation of the HIT Policy Committee and make advance directives a core objective of Meaningful Use Stage 2, with the requirement being that certified EHRs state the existence of a digital advance medical directive and have a real-time link to that directive: a true 21st century innovation.

If you have any questions, or require clarification of our comments, please feel to contact Scott Brown by telephone at (972) 733-6814, or by electronic mail at sbrown@advaultinc.com.

Respectfully submitted,

L. Scott Brown