



NORTH AMERICAN HEADQUARTERS:
800 E. Campbell Road, Suite 320
Richardson, Texas 75081
United States of America
(469) ADVAULT -- (469) 238-2858

INTERNATIONAL HEADQUARTERS:
Portland House
69-71 Wembley Hill Road
Wembley Middlesex HA9 8BU
England

www.MyDirectives.com

March 5, 2018

The Honorable Seema Verma, Administrator
Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director, Center for
Medicare
Centers for Medicare and Medicaid Services

Submitted Via Email: <https://www.regulations.gov>, Docket Number CMS-2017-0163

Dear Administrator Verma and Mr. Kouzoukas,

Thank you for the opportunity to comment on the 2019 Advance Notice Call Letter. As you know, the Calendar Year 2017 Final Call Letter confirmed that advance care planning is a Medicare covered benefit, and as such, is required to be covered by Medicare Advantage (MA) plans. Based on our experience in the advance directives and advance care planning field over the past 10 years and for the reasons discussed in detail below that are supported by more than 40 years of documented, published evidence and research, we believe CMS should create a new requirement for MA plans to go further and offer an unbiased, confidential and digital advance care plan (ACP) to all beneficiaries in the 2019 plan year. Now is time for CMS to move on this issue. Various market forces in the private sector are beginning to look at and understand the value of an advance care plan; allowing consumers to ensure their healthcare choices are readily available when they are not able to speak for themselves; however, the private sector continues to look to the Medicare program before moving toward widespread adoption. We are pleased to have worked with members of the House and Senate to introduce bipartisan legislation in the U.S. House of Representatives (H.R. 3181) and the U.S. Senate (S. 1530) that has been endorsed by the National Right to Life, the American College of Emergency Physicians as well as a variety of other organizations.

ADV Vault, Inc. and MyDirectives®

ADV Vault, Inc. is the creator and operator of MyDirectives® and MyDirectives MOBILE™, a leading digital emergency, critical and advance care planning platform. ADV Vault was one of the first small businesses to reach full Blue Button® compatibility, and MyDirectives was a certified EHR module for advance care planning under the 2011 CERHT criteria.

Since 2007, ADV Vault has focused solely on empowering consumers by giving them a voice in their healthcare, even when they suffer a medical emergency and cannot communicate. MyDirectives is the result of several years of in-depth research and discussions with hundreds of doctors, nurses, healthcare administrators, lawyers, ethicists, healthcare informaticists, healthcare

IT developers and vendors, policymakers, regulators and consumers. Representatives and supporters of ADVault and MyDirectives have testified before Congress and actively participated in many meetings of the HIT Policy Committee, the HIT Standards Committee, their respective Work Groups and Task Forces, and other initiatives of the Office of the National Coordinator for Health Information Technology (ONC) like the S&I Framework; they have submitted statements, testimony and comment letters to HHS and ONC regarding various aspects of the Medicare and Medicaid EHR incentive programs; and they have demonstrated how consumer-generated information can be safely, securely, easily and reliably incorporated into EHRs.

ADVault representatives have worked with policymakers, regulators, industry thought leaders and international standards organizations like The Regenstrief Institute, National Library of Medicine, and Health Level 7 International for over nine years. Together, these groups have built a substantial body of knowledge around the safe, secure, reliable and interoperable creation, storage, sharing, transmission and retrieval of consumer-generated information such as the data stored in advance directives (ADs) and advance care plans (ACPs). We believe the focus of our work for the past decade makes us distinctly qualified to comment on matters relating to the use of technology to improve advance care planning processes for Medicare beneficiaries and the providers who serve them.

A Consensus

As noted in our introduction; the private sector is already starting to explore the value of advance care plans. Some health plans are offering their members the opportunity to create advance care plans, some electronic health record vendors have worked tirelessly to ensure those records can be readily available among various providers and settings to ensure a patients' voice and health choices can be known when they are not able to speak for themselves. The Medicare Choices Empowerment and Protection Act (H.R. 3181/S. 1530) has been introduced by Representatives Diane Black (R-TN), Mike Thompson (D-CA), Chris Collins (R-NY) and Peter Welch (D-VT). It has also been introduced by Senators Chris Coons (D-DE), Bill Cassidy (R-LA), Michael Bennet (D-CO) and John Barrasso (R-WY). The legislation has been endorsed by: the National Right to Life, the Coalition to Transform Advanced Care, National Partnership for Hospice Innovation, American Nurses Association, Third Way, Healthwise, Center for Practical Bioethics, Get Real Health, Coordinated Care Health Network, Cerner, Altarum, American College of Emergency Physicians, Zen Hospice and the Bipartisan Policy Center. A broad political and social consensus supports electronic advance care plans.

Advance Directives, Advance Care Planning and Quality of Care at the End of Life

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. For example, CMS already requires MA plans to provide information on advance directives to beneficiaries, and it requires other MA organizations to document in a prominent part of the individual's medical record whether the individual has executed an advance directive.¹ Similarly, many states have adopted laws designed to enforce advance

¹ 42 CFR 422.128(b) and, more specifically, 42 CFR 422.128(b)(1)(ii)(E).

directives and educate their citizens about their rights to direct their medical treatment even if they are experiencing a healthcare emergency and cannot effectively communicate with medical personnel or their caregivers.² Unfortunately, by 2008 only 18-36% of Americans had completed any form of advance directive.³ A 2013 poll conducted by the National Council on Aging, UnitedHealthcare and *USA Today* indicates that the percentage of adults over the age of 60 who have an advance directive is only slightly higher at 54%.⁴ Moreover, two-thirds of physicians whose patients have advance directives are unaware of the existence of those documents.⁵

In the absence of high-quality advance care planning, people are much more likely to receive unwanted, non-beneficial, high-suffering, and high-cost medical interventions if and when they become patients:

- Cancer patients who do not engage in advance care planning are seven times more likely to be placed on mechanical ventilation and eight times more likely to undergo attempts at resuscitation prior to death;⁶
- Nursing home patients that *do engage* in advance care planning have less frequent hospitalization, improved patient and family satisfaction, and 33% lower costs of care;⁷ and
- Patients in general who engage in advance care planning are more likely to receive treatment compatible with their personal values.⁸

According to the 2008 Report to Congress on advance directives and advance care planning and the September 2014 report issued by the Institute of Medicine of the National Academies (IOM) entitled, “*Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*,” one of the primary reasons for the failure of advance directives and ACPs over the course of the last 40 years has been the lack of structural and financial incentives for having advance care planning discussions.⁹

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 IOM (Institute of Medicine). *Dying in America: Improving quality and honoring individual preferences near the end of life*. Washington, DC: The National Academies Press. 2014:127.

⁵ 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.

⁶ B Zhang, AA Wright, ME Nilsson, HA Huskamp, et al. *Associations between advanced cancer patients' end-of-life conversations and cost experiences in the final week of life*. J Clin Oncol. (Meeting Abstracts) May 2008; 26(15), suppl 9530.

⁷ DW Molloy, et al. *Systematic Implementation of an Advance Directive Program in Nursing Homes: A Randomized Trial*. JAMA. March 15, 2000; 283(11):1437-1444.

⁸ KM Detering, AD Hancock et al. *The Impact of Advance Care Planning on End of Life Care in Elderly Patients: Randomized Controlled Trial*. BMJ 2010;340:c1345.

⁹ IOM (Institute of Medicine). *Dying in America: Improving quality and honoring individual preferences near the end of life*. Washington, DC: The National Academies Press. 2014.

By incorporating a requirement into the CMS 2019 Call Letter that all Medicare Advantage plans offer their beneficiaries an opportunity to complete a digital emergency, critical and advance care plan (ECACP), we believe CMS will significantly improve the advance care planning process for Medicare beneficiaries, greatly improve the quality of care and potentially save healthcare costs associated with unnecessary and unwanted interventions. This is not unlike the requirement for hospitals, long-term assisted living facilities and skilled nursing facilities to inform patients of their right to create an AD – something that federal law and regulations already require – but it is more progressive in that beneficiaries will be offered a vehicle to do so, and more timely in that beneficiaries will have the opportunity to engage their families and providers in important conversations *before* the health crisis/point of care.

Paper ADs provide limited functionality. At best, they are scanned into a single provider's EHR, but more typically they are stored at home, in a safe, or in an attorney's office. Consistent with the government's encouragement to use technology solutions to meaningfully assist in the delivery of care, improvement of outcomes and reduction in costs, today's technology now supports a completely digital ECACPs, accessible 24/7 anywhere in the world. We respectfully request that the 2019 Call Letter be consistent with encouraging such digital best practices.

We believe that there is a great deal of momentum across our country regarding the importance of emergency, critical and advance care planning, and that the time is right to create a formal requirement for MA plans. For example, there has been bipartisan support, under the leadership of Senators Coons (D-DE) and Cassidy (R-LA) for recent legislation that would offer a \$75 incentive for individuals who create and digitally store an advance directive. Organizations across the political spectrum have pledged their support for the legislation, provided the AD is digital. As mentioned above, hospitals are already required to let patients know of their right to create an AD and, at a cost to them, frequently sponsor engagement events and seminars that do not reach all MA plan enrollees. The Aspen Health Strategy Group chose end-of-life (EOL) care as its charter topic.¹⁰ CMS has been encouraging physicians to have EOL conversations with their patients and added two CPT codes for reimbursement, although CMS does not currently require documentation of these conversations.

Payers support the digital ECACP concept because it has the potential to improve the patient experience, ensure care delivered is reasonable, necessary and consistent with the wishes of the patient as well as engage their members and provider networks. While payers understand the value from an enrollee, family, network provider and cost standpoint, they are frequently concerned about being the initial voice in this conversation, risking the label of “death panel” or otherwise being perceived as trying to limit care. A requirement by CMS to offer a digital ECACP to all MA beneficiaries would set a precedent and help eliminate this stigma.

MA plans are in an ideal position to reach their beneficiaries prior to them becoming patients or requiring urgent, immediate medical care, thus allowing the beneficiaries time to consider their personal wishes, have conversations with their family and physicians, and prepare a digital ECACP that can be accessed 24/7 from anywhere in the world.

¹⁰ The Aspen Institute. *Improving Care at the End of Life: A Report of the Aspen Institute Health Strategy Group*. Washington, DC. 2016. See pp. 12-13.

While ADVault has the most advanced digital platform, we believe a requirement that MA plans offer a digital ECACP will result in increased market response with competitive offerings. Further, CMS might offset any concerns over this requirement by allowing the cost of the digital ECACP to be incorporated into the medical loss ratio as a direct benefit to the Medicare beneficiary.

If, for any reason, CMS does not feel it can *require* the offering of a digital ECACP, it can be strongly encouraged through the Call Letter language or further incentivized by incorporating the offering of a digital ECACP into the Star Ratings.

Our commentary on the CMS CY 2019 DRAFT Call Letter specifically references the following sections of the Call Letter:

- **Page 99: How to Use this Call Letter.**
 - The required offering of a digital ECACP to all MA plan enrollees supports Outcome #1 by improving quality of care through attending to the individual's specific desires;
 - The required offering of a digital ECACP to all MA plan enrollees supports Outcome #3 by improving program integrity and beneficiary/taxpayer value, again by attending to the individual's desires and avoiding unnecessary and unwanted services; and
 - The required outcome of making a digital ECACP available to all MA plan enrollees supports Outcome #4 by improving the beneficiary experience, giving them a voice in their care that can be accessed at critical times.
- **Page 106: Enhancements to the 2019 Star Ratings and Future Measurement Concepts.** In this section, CMS states that the Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by physicians, hospitals, and other providers. **The required/encouraged offering of a digital ECACP to all MA plan beneficiaries clearly supports this stated goal of CMS by incorporating the voice of the individual into the care provided by the physicians, hospitals and other providers.**
- **Page 107: New Measures for 2019.** This section references a number of changes to the Star Ratings. We recommend adding a Star Rating component for those MA plans that offer a digital ECACP to all beneficiaries and further support the mapping of the ECACP to their provider network EHRs (in addition to being available via the Internet).

Finally, to ensure that Medicare Advantage plan beneficiaries, their families, caregivers, and healthcare providers will fully benefit from improved emergency, critical, advanced illness and EOL planning, we strongly recommend that CMS include the following language in the 2019 Call Letter:

Emergency Care — CMS encourages carriers to recognize their role in helping their beneficiaries live with confidence they can get their wishes known and voices heard in the event of a health crisis if they cannot communicate, by (a) providing workflows to create, update and share their emergency, critical and advance care plans (ECACPs) during the normal enrollment period; (b) ensuring such ECACPs are connected to public and private registries so they can be found anytime, anywhere; and (c) ensuring those registries provide secure event notifications so carriers can assist by alerting providers of the ECACP's existence and location. While we note that Medicare now reimburses providers for advance care planning services rendered in person or using telemedicine, CMS believes these benefits should be offered to all beneficiaries over the age of 18 in order that there be no misperception that certain people are being singled out for more or less attention and care. Your proposals for 2019 should describe relevant services you cover, public or private ECACP registries to which you are connected using standards-based healthcare information technology, the associated costs to beneficiaries, if any, and related payment arrangements.

EOL Care — CMS recognizes that while an ECACP can give important meaningful guidance to providers (and confidence to individuals) during any health emergency, ECACPs can be extremely timely and helpful in the gravest of health situations in which death is imminent. Therefore, CMS encourages carriers to support their beneficiaries by not only alerting providers of the ECACP's existence and location, but also expanding access for those who want hospice at the end of life.

Thank you in advance for your consideration of our recommendations. Please do not hesitate to contact us with any questions or concerns you may have on this matter.

Respectfully submitted,



Jeff Zucker
Chief Executive Officer



L. Scott Brown
President