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Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
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Submitted electronically via regulations.gov

RE: (CMS-5517-P): Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Thank you for the opportunity to comment on the proposed regulations on the development of the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) for eligible clinicians by the Centers for Medicare & Medicaid Services (CMS).

The Pew Charitable Trusts is an independent, non-profit research and public policy organization with numerous initiatives focused on improving the health of Americans and the quality, safety and efficiency of health care. These comments will focus on provisions of the proposed regulations to:

- Promote the evolution of a person- and family-centered system that delivers quality palliative and end-of-life care (pp 2-10); and
- Encourage the capture and exchange of the unique device identifier (UDI) in order to enhance medical device safety and innovation (pp 11-14).

Should you have any questions, please contact me at jrising@pewtrusts.org or 202-540-6761.

Sincerely,

Josh Rising, MD
Director, Healthcare Programs
The Pew Charitable Trusts

Promoting the Evolution of a Person- and Family-Centered System that Delivers Quality Palliative and End-of-Life Care

The need for palliative care—the comprehensive care and management of the physical, psychological, emotional, and spiritual needs of patients with chronic, debilitating, or life-threatening illness and their families—is growing rapidly. One-quarter of adults in the U.S. have multiple chronic conditions and would benefit from palliative care to help manage their symptoms.¹ Research shows that access to palliative care can increase patient satisfaction, improve clinical outcomes, and reduce the cost of care.² Unfortunately, our health care system does not currently have an effective and consistent strategy to provide high-quality supportive care to this population.

The transformation of the physician payment system presents an opportunity to respond to these needs with policies that promote the evolution of a person- and family-centered system that delivers quality palliative and end-of-life care. Pew outlined three priorities in comments to the CMS November 2015 Request For Information on MIPS and APMs;³ our comments here suggest ways to advance these priorities in this proposed rule.

- 1) *More appropriate end-of-life and palliative care quality measures need to be developed and existing measures need to be better used to accurately assess the quality of this care.*

The lack of consistent, comparable, and appropriate performance indicators for palliative and end-of-life care across settings of care is particularly important for Medicare, which finances the care for 80 percent of U.S. decedents annually. Given the growing emphasis on integrated and value-based care, a core set of measures for end-of-life and palliative care that spans settings, clinicians, and populations is increasingly needed. At the same time, it is important to have measures that minimize the reporting burden on providers and ensure that quality care is provided to all patients, regardless of their diagnosis and setting of care.

To achieve more appropriate measures for palliative and end-of-life care, Pew’s comments are focused on the quality performance and clinical practice improvement categories of the MIPS. We recommend:

- Creating a specialty-specific measure set for palliative care;
- Increasing measurement of advance care planning;
- Capturing patient and family caregiver experience with regard to end-of-life care;
- Ensuring that advance care planning and the dissemination of palliative care are part of clinical practice improvement; and

¹ Brian Ward and Jeannine Schiller, “Prevalence of Multiple Chronic Conditions Among US Adults: Estimates From the National Health Interview Survey, 2010,” *Preventing Chronic Disease Public Health Research, Practice, and Policy* 10, Special Topic (April 25, 2013), http://www.cdc.gov/pcd/issues/2013/pdf/12_0203.pdf.

² Glenn Gade et al., “Impact of an inpatient palliative care team: a randomized control trial,” *Journal of Palliative Medicine* 11, 2 (March 2008):180-90, <http://www.ncbi.nlm.nih.gov/pubmed/18333732>.

³ Lee Goldberg, “Pew Comments: Proposed Changes to Physician Payment System,” November 17, 2015, <http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2015/11/pew-comments-proposed-changes-to-physician-payment-system>.

- Integrating facility-based measures into MIPS quality reporting to assess palliative and end-of-life care for MIPS clinicians where appropriate.
- 2) *CMS should incorporate the palliative and end-of-life care perspective into the new physician-focused payment models and other APMs.*

The health care system must incorporate models that address the increasing acuity of our population and the unevenness of access to services. One-third of U.S. hospitals do not have a palliative care program.⁴ Gaps are particularly significant among Southern states and in smaller hospitals.⁵ Additionally, Medicare payment rules make it difficult for people who are ineligible for hospice to access community-based palliative care.⁶ The development of criteria for physician-focused payment models and APMs provides a strategic opening to incorporate robust palliative care components in an evolving segment of the health care system.

To achieve these goals, Pew will comment on opportunities to prioritize APMs that include components of palliative and end-of-life care. We recommend:

- Streamlining quality reporting and evaluation of new models to facilitate their dissemination; and
- Working with stakeholders to ensure adequate measures to assess palliative and end-of-life care in APMs.

- 3) *Consumer goals, preferences, and values must be accurately and consistently documented in advance care plans and made available electronically across settings.*

In order to ensure the delivery of high-quality care, health care information must be securely exchanged between consumers, families, clinicians, and facilities.⁷ In particular, health information technology must accurately and consistently capture advance care planning conversations and documents that incorporate such person- and family-centered discussions, and ensure they can be accessed across care settings.

To achieve these goals, Pew will comment on opportunities within APMs to expand on current standards and certification requirements. Pew recommends health information technology standards for these critical documents that include:

- Alerts to the presence of advance care plans in EHRs;
- Standardized locations within EHR for advance care plans;
- A single definition and label to capture the multitude of advance care planning documents; and

⁴ Center to Advance Palliative Care, “America’s Care of Serious Illness: 2015 State-by-State Report Card on Access to Palliative Care in Our Nation’s Hospitals,” October 1, 2015, <https://reportcard.capc.org/>.

⁵ Ibid.

⁶ Tamara Dumanovsky et al., “The Growth of Palliative Care in U.S. Hospitals: A Status Report,” *Journal of Palliative Medicine* 19, 1 (September 29, 2015):8-15, doi:10.1089/jpm.2015.0351.

⁷ “Principles and Strategy for Accelerating Health Information Exchange (HIE)” (The Office of the National Coordinator for Health Information Technology, August 7, 2013).

- Incorporation of advance care plans as core clinical data that can be transferred between settings of care.

Developing More Appropriate End-of-Life and Palliative Care Quality Measures

The Physician Quality Reporting System (PQRS) is one of the main tools CMS uses to assess the quality of care provided by physicians and other clinicians and one of the three existing programs that will be combined to create the MIPS program. For clinicians who participate in PQRS reporting and care for people near or at the end of life, PQRS contains limited outcome measures to assess physical symptoms such as pain; PQRS also contains process measures that are primarily focused on documentation of care plans. There are, however, many other aspects of care that need increased quality reporting, both for physical symptoms such as pain and dyspnea, as well as for the holistic treatment of the individual. For example, biopsychosocial care, such as treatment for depression or the psychological effects of pain, has no quality indicators but is extremely important for those facing advanced and life-threatening illness.⁸

The *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) mandates that CMS improve the PQRS by developing metrics that more accurately assess care. MACRA mandated that CMS publish a Measure Development Plan (MDP) and Pew commends CMS for prioritizing palliative care in the MDP through measures that incorporate personal preferences and shared decision-making. The MDP also proposed to focus more on outcome measures that assess the results of a procedure or treatment, than on process measures that evaluate whether clinically appropriate steps were taken to reach the outcome. However, until more outcome measures are developed, quality reporting will be difficult for palliative care physicians as well as other physicians who care for individuals at the end of life. With only one outcome measure that captures the reduction of pain that is a common goal at end of life, the current suite of measures is inadequate to assess care quality.

In the proposed rule, CMS has made an effort to address this barrier to reporting by allowing eligible clinicians to report one of the designated outcome measures or one of the other prioritized metrics if none of the outcome measures are relevant. Prioritized measures include appropriate use, patient safety, efficiency, patient experience, and care coordination. Pew strongly supports CMS for its decision to provide flexibility to clinicians in specialties such as palliative care that lack adequate outcome measures, and to give equal weight to important measures like patient experience.

Creating a Specialty-Specific Measure Set for Palliative Care

In the proposed rule, CMS outlined several specialty-specific sets of measures for quality reporting to help clinicians easily find and report meaningful measures. As part of this effort, Pew encourages CMS to create a stand-alone specialty measure set that can be used by palliative care physicians and the many other doctors who provide palliative care. According to the

⁸ Jason A. Webb and Arif H. Kamal, "Integrating the Biopsychosocial Model Into Quality Measures in Palliative Care: A Case for Improving the Hospice Item Set," *Journal of Pain and Symptom Management* 48, 1 (July 2014):e1-e2, [http://www.jpmsjournal.com/article/S0885-3924\(14\)00259-0/pdf](http://www.jpmsjournal.com/article/S0885-3924(14)00259-0/pdf).

American Board of Medical Specialties, hospice and palliative care specialists can be certified under 10 separate general specialties.⁹ The variety of clinicians that may offer palliative care illustrates the importance of ensuring that they all have a core set of meaningful measures regardless of their specialty area.

Over the last decade, medical societies and academic experts have made significant progress in defining the core principles that are needed to assess the quality of palliative and end-of-life care, including the development of several measure sets. If CMS chooses to develop a specialty-specific set for palliative and end-of-life care, Pew strongly encourages CMS to consider PQRS and other relevant clinical measures that align with the *Measuring What Matters* initiative. This multidisciplinary effort reviewed published measures and selected the palliative and hospice performance improvement metrics that are thought to matter most to individuals with palliative care needs, regardless of setting.¹⁰

In addition to organizing specialty-specific measure sets, CMS proposed including additional measures to meet critical gaps in PQRS reporting for 2017. Five oncology measures focused on end-of-life care were included in this list and cover extremely important topics, including intensive care unit and emergency room admissions in the last month of life, that have yet to be assessed in any Medicare quality reporting program.¹¹ Pew supports the inclusion of these measures in PQRS but encourages CMS to also look beyond disease-specific measures to populations that are more likely to suffer avoidable and unwanted hospitalizations or procedures.

Pew notes that the MACRA legislation provides CMS with the discretion to add measures administratively to the MIPS quality reporting program. More specifically, MACRA allows CMS to forgo the MAP process and propose new measures to the current portfolio through the rulemaking process. This is critical for specialties that, like palliative care, have few measures and that have struggled to steward new measures through both the NQF and MAP approval process. Pew urges CMS to use this administrative flexibility to reduce measure stewardship burden on critical gap specialties.

Increasing Measurement of Advance Care Planning

In an effort to reduce the burden of measurement on clinicians, while also defining core metrics of health care, CMS has created a list of ten cross-cutting measures. Each eligible clinician will

⁹American Board of Medical Specialties, “Specialty and Subspecialty Certificates,” accessed May 30, 2016, <http://www.abms.org/member-boards/specialty-subspecialty-certificates/>.

¹⁰ Sydney Morss Dy et al., “Measuring What Matters: Top-Ranked Quality Indicators for Hospice and Palliative Care From the American Academy of Hospice and Palliative Medicine and Hospice and Palliative Nurses Association,” *Journal of Pain and Symptom Management* 49, 4 (April 2015): 773–81, doi:10.1016/j.jpainsymman.2015.01.012.

¹¹ Department of Health and Human Services, Centers for Medicare & Medicaid Services, Proposed Rule, “Medicare Programs; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models,” *Federal Register* 81, 89 (May 9, 2016): 28457-28460, <https://www.federalregister.gov/articles/2016/05/09/2016-10032/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm>.

choose one of the ten to report. Pew was pleased to see PQRS #047 Care Plan Measure¹² included in the list of cross-cutting measures that all eligible clinicians must choose from. Advance care planning can significantly improve outcomes of care, including increased compliance with patient preferences, fewer hospitalizations, and less intensive treatments.^{13, 14, 15} CMS' decision to include advance care planning is consistent with recommendations from both the Centers for Disease Control and Prevention (CDC)¹⁶ and the Institute of Medicine (IOM), both of which have advocated for increased use of advance care planning.¹⁷ This is also the only measure in the list of cross-cutting measures that is relevant to individuals facing the end of their lives. It ensures that eligible clinicians caring for these individuals can meaningfully participate in the MIPS program.

While the inclusion of PQRS #047 in the list of cross-cutting measures is a step forward, we encourage CMS to take the next step of funding the development of measures that assess the quality of these advance care planning conversations. Such new measures do not have to be cross-cutting, but are essential for providers of palliative care. Researchers identified core components of successful advance care planning programs, including a facilitated training process, a standardized documentation process for advance care planning, proactive but appropriate timing of conversations, and systems with processes to ensure that planning actually occurs.¹⁸ A recent survey of physicians by the John A. Hartford Foundation found that despite new codes that reimburse for these conversations, only three in 10 respondents say they have access to a formal system for assessing individuals' end-of-life wishes and goals of care.¹⁹ Evaluation of advance care planning is critical to person- and family-centered care and cannot stop at documentation of an advance directive.

¹² PQRS #047 Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.

¹³ Joan M. Teno, Andrea Gruneir, Zachary, Schwartz, Aman Nanda, Terrie Wetle. "Association between advance directives and quality of end-of-life care: a national study," *Journal of American Geriatrics Society* 55, 2 (Feb 2007):189-194, <http://www.ncbi.nlm.nih.gov/pubmed/17302654>.

¹⁴ Karen M Detering, Andrew D Hancock, Michael C Reade, and William Silvester, "The impact of advance care planning on end of life care in elderly patients: randomized controlled trial," *BMJ* 2010;340:c1345, <http://www.bmj.com/content/340/bmj.c1345>.

¹⁵ Bernard J. Hammes and Brenda L. Rooney, "Death and end-of-life planning in one Midwestern community," *Archives of Internal Medicine* 158, 4 (Feb 23, 1998):383-390, <http://www.ncbi.nlm.nih.gov/pubmed/9487236>.

¹⁶ Centers for Disease Control and Prevention's Healthy Aging Program, "Give Peace of Mind: Advance Care Planning," March 3, 2014, <http://www.cdc.gov/aging/advancecareplanning/>.

¹⁷ Institute of Medicine, *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*, (Washington, DC: National Academies Press, 2014), <http://www.nap.edu/download/18748>.

¹⁸ Susan E. Hickman et al., "Hope for the Future: Achieving the Original Intent of Advance Directives," *The Hastings Center Report*, 2005, S26-S30.

¹⁹ The John A. Hartford Foundation, "Physicians' Views Toward Advance Care Planning and End-of-Life Care Conversations," April 2016, http://www.jhartfound.org/images/uploads/resources/ConversationStopper_Poll_Memo.pdf.

Capturing Patient and Family Caregiver Experience

Ensuring person- and family-centered care means integrating an individual's preferences into his or her care. The most consistent method for documenting whether this has occurred is the MIPS Clinical/Group Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. This survey, like others that are administered across hospitals, nursing homes and other settings of care, is intended to reflect the quality of an individual's interaction with clinicians and other health care providers by asking questions such as whether he or she was treated with respect.

Pew encourages CMS to consider expanding the use of CAHPS for all clinicians as a tool in the quality measurement category of MIPS, with appropriate exclusions for rural and non-patient facing clinicians. Currently, federal rules currently require the survey to be administered to large group practices (100 or more individual clinicians). This has led to enhanced public reporting on clinicians involved in large practices. Pew recognizes that making CAHPS a requirement for smaller groups could entail significant investments for clinician groups that may not have the necessary financial resources; for that reason, we urge CMS to work with medical societies, practice management experts, and relevant parties in the Administration to evaluate the potential burden on small practices and examine policy options for reducing that burden since such an expansion could lead to a significant increase in quality of care.

Additionally, Pew encourages CMS to expand the target population for such surveys to include the families of patients who have died. Many individuals who die in the intensive care unit receive care they would not have wanted.²⁰ However, neither the experience of deceased patients nor that of their caregivers is captured in the current clinician and group experience of care CAHPS survey.²¹ Excluding these populations leaves systems without critical information about the population that has the most involvement in end-of-life care—limiting the ability of clinicians to improve care.²²

Finally, Pew strongly encourages CMS to adapt questions from the hospice instrument so they can be used in CAHPS surveys of other settings, particularly in-patient care, in order to assess palliative care eligible clinicians and eligible clinicians who treat the patients facing the end of life in other settings than hospice.

Ensuring that Advance Care Planning Is Part of Clinical Practice Improvement

The MACRA legislation established a new category—Clinical Performance Improvement—for assessment of clinicians that is intended to capture activities that lead to improved outcomes. It also establishes subcategories under this new assessment tool for care coordination and

²⁰ Joan Teno, Vicki Freedman, Judith Kasper, Pedro Gozalo and Vincent Mor, "Is Care for the Dying Improving in the United States?" *Journal of Palliative Medicine* 18, 8 (August 2015):662-6, doi: 10.1089/jpm.2015.0039.

²¹ "CAHPS Clinician & Group Surveys (CG-CAHPS)-Adult, Child," *NQF: Quality Positioning System*, accessed February 8, 2016,

<http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=902&print=0&entityTypeID=1>.

²² Teno, Joan M. and Pedro L. Gozalo, "Quality and Costs of End-of-Life Care," *JAMA: Journal of the American Medical Association* 312, 18 (November 12, 2014):1868-1869, <http://jama.jamanetwork.com/article.aspx?articleid=1930801>.

beneficiary engagement. Pew urges CMS to include conversations about advance care plans as part of those subcategories. Advance care plans are important for ensuring that the care provided to a person who can no longer speak for herself reflects that person's goals and preferences in terms of treatments and care settings. As the IOM noted, an estimated 70 percent of adults aged 60 and older in a hospital setting are unable to make their own treatment decisions due to illness or cognitive decline.²³ Advance care planning also reduces the emotional stress on the family members who struggle with the responsibility of making critical health care decisions unsure of what their loved one wants.

Including advance care planning conversations as an activity in the care coordination and beneficiary engagement subcategories would be consistent with recent CMS policy decisions to promote the use of advance care planning. First, the agency recently finalized a decision to reimburse eligible clinicians for holding advance care planning conversations.²⁴ Additionally, new federal rules for electronic health records ensure that patients' advance care plans can be captured electronically.²⁵ Finally, new quality measures for home health agencies require asking and documenting whether a beneficiary has an advance care plan.²⁶ The Clinical Practice Improvement Category provides another opportunity for CMS to ensure these critical conversations are taking place and being documented.

In addition, CMS seeks comments on proposed inventory and suggestions for future years. Pew supports proposed language from the National Partnership for Hospice Innovation, the Center for Advanced Palliative Care and other experts that would advance opportunities for physicians providing palliative care to meaningfully participate in this performance category. Pew suggests adding the following to the inventory of approved CPIA activities:

Coordinating or participating in interdisciplinary education efforts to disseminate basic advanced illness and palliative care skills, such as communication, symptom management and inter-professional collaboration.

We make this suggestion because of its potential to improve the functioning of provider teams and ultimately the care patients receive. By educating providers across disciplines on the capabilities of advanced illness and palliative care interdisciplinary teams, practices can leverage best practices to reach a broader set of patients. As MACRA seeks to encourage improvement and advancement of our health system, CMS should recognize activities that take advantage of peer-to-peer learning and best practices between disciplines and across the care continuum. Given the value of advanced illness and palliative care across a broad spectrum of Medicare beneficiaries, these skills should be incorporated into all aspects of a medical practice, rather than remain in a silo that could potentially limit patient access.

²³ Institute of Medicine, *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*, (Washington, DC: National Academies Press, 2014), <http://www.nap.edu/download/18748>.

²⁴ Beginning in January 2016, eligible providers will be able to bill under CPT codes 99497 and 99498 for advance care planning conversations.

²⁵ The Office of the National Coordinator of Health Information Technology mandated a "patient generated health field" as part of Meaningful Use Stage 3.

²⁶ Home health agencies are required to use NQF #0326 measure as part of the Home Health Value-Based Purchasing Model and ask beneficiaries 65 years and older if they have an advance care plan.

Integrating Facility-Based Measures into MIPS Quality Reporting

Pew commends CMS for considering the feasibility and appropriateness of incorporating measures from other Medicare quality reporting programs as part of MIPS for facility-based physicians. However, the progress made in developing and implementing palliative and end-of-life quality measures for hospice has not been replicated in other care settings. For example, almost 90 percent of large hospitals in the U.S. have palliative care programs,²⁷ but there are relatively few measures addressing the quality of palliative care delivered by those hospitals and their clinical staff. Moreover, current hospital quality programs, which include efforts to measure the mortality of vulnerable populations, may create disincentives for palliative care provision.²⁸

Pew believes that many measures from the hospice item set that assess individuals who die in a hospice setting could be incorporated into MIPS. While these measures are not currently as holistic as palliative and end-of-life care principles typically are, they would greatly expand the measures available to clinicians. These also closely align with the elements of the *Measuring What Matters* initiative. For these reasons, Pew recommends that as a first step CMS consider the feasibility of integrating measures from the current hospice item set into the MIPS program for eligible clinicians to assess care in hospice and palliative care programs. For instance, there are currently no PQRS measures that assess and treat dyspnea, a common symptom for individuals at the end of life. Allowing practitioners to utilize the hospice quality measures associated with dyspnea screening and treatment could greatly improve care for individuals both in hospice and other care settings.

Experts have long sought to harmonize measure sets among different clinicians and across care settings. The Institute of Medicine's report titled *Vital Signs: Core Metrics for Health and Health Care Progress* identified the need for such a core set of measures, specifically mentioning palliative and end-of-life care.²⁹ Pew strongly encourages CMS to continue to strive for consistent measures across settings that could one day assess the quality of both eligible clinicians and facility care.

Incorporating the Palliative and End-of-Life Care Perspective into the New Physician-Focused Payment Models and Other APMs

MACRA encourages the development of alternative payment models such as Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes (PCMH), both of which represent important opportunities to integrate access to palliative and end-of-life care services as part of the full continuum of care.

²⁷ Tamara Dumanovsky et al., "The Growth of Palliative Care in U.S. Hospitals: A Status Report," *Journal of Palliative Medicine* 19, 1 (September 29, 2015):8-15, doi:10.1089/jpm.2015.0351.

²⁸ National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Hospitals," February 15, 2016, https://www.qualityforum.org/Projects/i-m/MAP/Hospital_Workgroup/2016_Considerations_for_Implementing_Measures_Final_Report.aspx.

²⁹ Institute of Medicine, *Vital Signs: Core Metrics for Health and Health Care Progress*, (Washington, D.C.: National Academies Press, 2015), <http://www.nap.edu/catalog/19402>.

Streamlining Quality Reporting and Evaluation of New Models

The development of quality measures is essential to the success of integrated health. As the IOM noted, the dearth of quality metrics can result in a lack of transparency and accountability for palliative care programs.³⁰ The quality reporting requirements of APMs are similar to those of MIPS, but as with the PQRS measures, there are simply not enough NQF-endorsed process or outcome measures to assess the participation of palliative care eligible clinicians in APMs. The list of measures, for example, developed by the Core Measures Collaborative, a joint effort between CMS and America's Health Insurance Plans (AHIP), lacks quality indicators for ACOs or PCMHs that are specific to end-of-life care.

With the ambitious goal of having nearly 50 percent of all payments linked to alternative payment models by 2018, Pew is encouraged by the way in which CMS' Measure Development Plan has prioritized palliative and end-of-life care. But Pew believes that CMS must also be prepared to invest substantial resources into development of quality metrics designed to assess the palliative and end-of-life care provided by ACOs, PCMH, and other APMs. It will also take time to test, validate, and implement measures for both MIPS and APMs with funds from MACRA. In the meantime, it is critical that palliative care professionals not be left out of the development of new APMs simply because palliative care lacks adequate outcome measures. To that end, Pew supports CMS' proposal to not require an outcome measure if no applicable ones are available at the time an APM is established.

Working with Stakeholders to Ensure Adequate Measures to Assess Palliative and End-of-Life Care in APMs

Pew supports aligning quality measures across palliative and end-of-life care models. We request that CMS work with experts to identify metrics to consistently and effectively evaluate palliative and end-of-life care in APMs. Appropriate assessment of new models is critical to their success. There also needs to be greater alignment of measures among models to effectively gauge their comparative impact. This may help CMMI determine where to focus resources in the scaling of new models that are intended to improve quality of care and reduce costs.

Documenting Consumer Goals, Preferences, and Values in Advance Care Plans and Making Information Available across Settings

Pew strongly believes that the ability to consistently capture and transmit advance care plans across settings is a core health information technology function necessary for managing patient populations, coordinating care, and engaging patients. Care near the end-of-life is exceedingly complex and may require more coordination between settings and professionals than other types of care.³¹ While the final rules issued by CMS and the Office of the National Coordinator for Health Information Technology (ONC) in October 2015 were the first step to establishing standards in EHRs for providers to capture a patient's full advance care plan in patient-generated

³⁰ Ibid.

³¹ Institute of Medicine, *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*, (Washington, DC: National Academies Press, 2014), <http://www.nap.edu/download/18748>.

data, health information technology is still limited by setting and provider—making it difficult to coordinate care and leading to unwanted and unnecessary interventions at the end-of-life.

A study in the *Journal of the American Medical Association* found that people face an average of 3.1 transitions between different care sites in their final three months of life.³² These transitions are rife with opportunities for miscommunication and errors, many of which may be avoided when an advance care plan is available and the focus is on patient preferences for care. Another study found that a lack of standardization in where advance care plans were recorded made it difficult for providers to find plans in emergency situations.³³ The inability to quickly find these crucial documents puts the individual's values, preferences, and goals in jeopardy.

Creating an environment where patients and providers can easily store, share, and access advance care plans across settings and among providers and family members is essential for providing person-centered care that aligns with an individual's goals, values, and preferences. Pew encourages CMS as it develops APMs, to ensure that eligible clinicians who participate in such entities as well as their patients can easily and quickly access advance care plans and transfer them across settings. Specifically, Pew encourages CMS to adopt certification criteria for new health information technology standards that include:

- Requiring health IT standards that ensure clinicians are alerted to the presence of advance care plans in EHRs;
- Creating standardized locations within EHRs where advance care plans can be consistently stored and located;
- Implementing certification criteria that clearly defines a single label to capture the multitude of advance care planning documents such as advance directives, living wills, durable power of attorney, and Physician Orders for Life-Sustaining Treatment (POLST) forms; and
- Ensuring advance care planning documents are part of the core clinical data that can be transferred between settings of care.

Thank you for considering our comments regarding ways to improve palliative and end-of-life care in the proposed rule. If you have questions, please contact Lee Goldberg, Director, Improving End of Life Care Project, at lgoldberg@pewtrusts.org or (202) 552-2127.

³² Joan M. Teno et al., “Change in End-of-Life Care for Medicare Beneficiaries: Site of Death, Place of Care, and Health Care Transitions in 2000, 2005, and 2009,” *JAMA: Journal of the American Medical Association* 309, 5 (February 6, 2013):470-7, <http://jama.jamanetwork.com/article.aspx?articleid=1568250>.

³³ Caroline J. Wilson et al., “Multiple Locations of Advance Care Planning Documentation in an Electronic Health Record: Are They Easy to Find?” *Journal of Palliative Medicine* 16, 9 (September 2013):1089–94, doi:10.1089/jpm.2012.0472.

Encouraging the Capture and Exchange of the Unique Device Identifier (UDI)

Pew's medical device initiative seeks to enhance medical device safety and foster device innovation that benefits patients. An important step toward this objective is adoption of the new unique device identifier (UDI) system into electronic data sources, including patients' health records. Having this information in electronic health records (EHRs) will allow patients, clinicians, hospitals, and other healthcare facilities to locate individuals affected by recalled devices, support care coordination among physicians and provide people with accurate information on the implanted devices—such as artificial hips and pacemakers—in their bodies.³⁴

We support the advancing care information provisions in this proposed rule to foster the exchange of key clinical data to enhance care coordination and the data available to physicians and patients. However, we request that CMS clarify that the UDIs of implanted products are part of the information required for exchange—to both ensure that this key data is available and align the requirements with federal standards from the Office of the National Coordinator for Health Information Technology (ONC).

Exchanging UDI Will Improve Patient Care

The Food and Drug Administration (FDA) in September 2013 finalized regulations establishing the UDI system, which will provide each device with a code corresponding to its make, model and other clinically relevant information, such as the product's expiration date.³⁵ The highest risk devices were required to have UDIs in 2014, and all implantable devices must receive these identifiers starting last year.

Once incorporated into patients' health records, the UDI system will:

- *Facilitate recall resolution:* Putting UDIs for implanted devices into EHRs will help providers identify patients implanted with recalled products and deliver appropriate follow-up care, regardless of whether that physician inserted the product.
- *Improve adverse event reports:* As FDA has now required that providers submit UDIs in adverse event reports, inclusion of UDIs in EHRs will enable patients and providers to submit more precise adverse event reports that identify the make and model of a potentially malfunctioning device.
- *Enhance clinical decision support and care coordination:* Documenting UDIs in EHRs will allow providers to make more informed decisions on patient care, especially when patients switch providers or see multiple physicians.
- *Support patient engagement:* UDIs in EHRs will provide a clear, accessible source of data on the devices implanted in patients, enabling individuals to take more active roles in their care.

³⁴ The Pew Charitable Trusts, "Implementing Unique Device Identification: Recommendations for Integrating Medical Device Data Throughout the Health Care System," September 2015, <http://www.pewtrusts.org/~media/assets/2015/09/udiimplementation-report.pdf>.

³⁵ Food and Drug Administration, Final Rule, "Unique Device Identification System," *Federal Register* 78, 185 (September 24, 2013):58786-58828, <https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system>.

- *Enrich analyses on device performance:* Increased data on device utilization can support hospital analyses on product performance in their patients.

Advancing Care Information Should Explicitly Reference UDI

Under several regulations—such as Stage 3 of the Meaningful Use program for hospitals,³⁶ discharge planning policies³⁷ and conditions of participation in the Medicare and Medicaid programs for long-term care facilities³⁸—CMS requires the exchange of key clinical information.

As part of this proposed rule, CMS establishes two pathways to monitor quality and provide appropriate financial incentives to clinicians to improve care, including by exchanging clinical data. Under one pathway, the Merit-based Incentive Payment System (MIPS), CMS would evaluate quality measures for each physician. Under the second option, alternative payment models, CMS would use a different set of metrics to further evaluate—and reward—higher quality care. Both of these options include provisions to exchange of clinical data to foster care coordination among providers.

However, in previous regulations, CMS has required the exchange of key clinical data as defined by ONC. That information—called the common clinical data set (CCDS)—includes key information on patient care, such as the individual’s medication list, core problem list and the UDIs of products implanted in the patient.³⁹ As CMS mentions in the Meaningful Use Stage 3 final rule:

“[W]e believe the inclusion of the UDI in the CCDS reflects the understanding that UDIs are an important part of patient information that should be exchanged and available to providers who care for patients with implanted medical devices. The documentation of UDIs in a patient medical record and the inclusion of that data field within the CCDS requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety.”

CMS should similarly clarify that clinicians participating in both MIPS and alternative payment models exchange the CCDS, including the UDIs of implanted devices. While CMS explicitly

³⁶ Centers for Medicare and Medicaid Services, Final Rules with Comment Period, “Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 Through 2017,” *Federal Register* 80, 200 (October 16, 2015):62762-62955, <https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications>.

³⁷ Centers for Medicare and Medicaid Services, Proposed Rule, “Reform of Requirements for Long-Term Care Facilities,” *Federal Register* 80, 136 (July 16, 2015):42168-42269, <https://www.gpo.gov/fdsys/pkg/FR-2015-07-16/pdf/2015-17207.pdf>.

³⁸ Centers for Medicare and Medicaid Services, Proposed Rule, “Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies,” *Federal Register* 80, 212 (November 3, 2015):68126-68155, <https://www.gpo.gov/fdsys/pkg/FR-2015-11-03/pdf/2015-27840.pdf>.

³⁹ Department of Health and Human Services, Final Rule, “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modification,” *Federal Register* 80, 200 (October 16, 2015):62602-62759, <https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base>.

references the CCDS as the data that clinicians should exchange to meet the alternative payment model criteria, CMS is not as explicit for the MIPS pathway. As part of MIPS, CMS only states that clinicians should provide, receive and incorporate a “summary of care record” on the patient when transitioning care for an individual. Because CMS does not explicitly define the contents of the “summary of care record”, clinicians may not have certainty on the data that should be exchanged.

Therefore, we encourage CMS to clarify that physicians participating in MIPS should provide, receive and incorporate into their systems the CCDS as the information to be contained in summary of care records. This clarity would encourage the exchange of key information in patients’ health history, including on the devices implanted in their bodies.

Conclusion

CMS has previously recognized the patient care benefits of including device identifying information in electronic medical records. For example, hospitals—which, under current regulations, still must adhere to requirements under the Meaningful User program to encourage the use of EHRs—will begin receiving, sending and incorporating the UDIs of implanted devices when transitioning care.

Given the importance of medical device information as part of patients’ health histories, CMS should clarify that UDIs contained in patients’ EHRs should be exchanged in summaries of care to facilitate care coordination, enhance safety and improve quality.

Thank you for your consideration of our comments on the advancing care information provisions in this proposed rule. Should you have any questions, please contact Ben Moscovitch, Officer, Medical Devices, at bmoscovitch@pewtrusts.org or 202-540-6333.