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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

Submitted electronically via regulations.gov

RE: CMS-3317-P: Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies

Thank you for the opportunity to submit comments on the Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies issued by the Centers for Medicare & Medicaid Services.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization with a number of initiatives focused on improving the quality of care, as well as drug and medical device safety and innovation. These comments will focus on provisions of the proposed regulations that:

- Assist in making advance care plans more accessible across sites of care by including advance directives as a mandatory element of the discharge plan, and
- Support incorporation of unique device identifiers in discharge documentation to help clinicians access information on the products implanted in patients.

Thank you for considering our comments. Should you have any questions, please contact me at jrising@pewtrusts.org or (202) 540-6761.

Sincerely,

Josh Rising, MD
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The Pew Charitable Trusts

Improving Patient Care by Documenting Advance Care Plans

Thank you for the opportunity to comment on the revisions to the requirements for discharge planning for hospitals, critical access hospitals (CAHs) and home health agencies (HHAs). The Pew Charitable Trusts advances policies that help people receive high-quality health care as they near the end of their lives. Pew strongly supports the proposed change to the discharge planning requirements for post-acute care that would ensure that patients' advance care plans (ACP) are included as part of the discharge plan. We are also encouraged by the overall tenor of the proposed regulatory language that makes patient preferences a central part of the discharge planning process and post-discharge care.

Advance care planning involves the discussion and documentation of patients' care preferences, with the goal of ensuring that the care patients receive is aligned with their goals, values and preferences. Pew commends the Centers for Medicare & Medicaid Services (CMS) for taking a number of important steps last year to promote the use of advance care planning. The agency recently finalized a decision to reimburse eligible providers for holding advance care planning conversations.[1] Additionally, new federal rules for electronic health records ensure that patients' ACPs can now be captured electronically.[2] Finally, new quality measures for home health agencies require asking and documenting whether a beneficiary has an ACP.[3]

ACPs are vital for ensuring that the health care provided to a person who can no longer speak for him or herself reflects that person's goals and preferences in terms of type of treatments and care settings. As the Institute of Medicine noted in *Dying in America*, 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.[4] Research shows that advance care planning significantly improves outcomes of care, including fewer hospitalizations and increased patient satisfaction.[5,6] Advance care planning also reduces the emotional stress on the family members who struggle with the responsibility of making critical health care decisions.

Unfortunately, many people are not having these important conversations. Only an estimated 51 percent of individuals 65 years of age and older have an advance directive.[7] And the figure varies significantly across care settings: studies report that while 65 percent of nursing home patients had an advance directive, only 28 percent of home health patients did and hospital patients were least likely to have an advance directive.[8]

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

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

[3] 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.

[4] Institute of Medicine, "Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life," (Washington, DC: National Academies Press, 2014), 119.

[5] JM Teno, et al., "Association Between Advance Directives and Quality of End-of-Life Care: A National Study," *Journal of the American Geriatrics Society* 55 (2007):189-194.

[6] KM Detering, et al., "The Impact of Advance Care Planning on End of Life Care in Elderly Patients: Randomised Controlled Trial," *The British Medical Journal* 340 (2010):c1345; BJ Hammes and BL Rooney, "Death and End-of-Life Planning in One Midwestern Community," *Archives of Internal Medicine* 158 (1998):383-390.

[7] United States Government Accountability Office, "Advance Directives: Information on Federal Oversight, Provider Implementation, and Prevalence (Washington, D.C.: GAO, 2015), 23.

[8] Ibid, 21 (data derived from the 2004 National Nursing Home Survey and the 2007 National Home and Hospice Care Survey).

Pew supports the inclusion of patients' existing ACPs as a mandatory element in the "necessary medical information" that hospitals must send to a receiving facility as part the discharge process. In addition, Pew endorses language that requires hospitals and other providers to craft a discharge plan that "must address the patient's goals of care and treatment preferences." Care near the end-of-life is exceedingly complex and ACPs are essential for understanding patients' goals and treatment preferences.[9] 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.[10] These transitions are rife with opportunities for miscommunication and errors, many of which may be avoided when an ACP is available and the focus is on patient preferences for care. Including the ACP and patient preferences in discharge planning will help to ensure that patients' goals for care are met during post-discharge care.

Pew however, recommends that the final rule also require that hospitals, CAHs and HHAs offer patients who are being discharged an opportunity to participate in advance care planning as part of the discharge planning process.[11] Given that many patients do not have advance care plans, such an addition is critically important to help facilities and providers understand and meet patient goals of care and preferences. This would also help providers transfer patients to their preferred site of care and deliver post-discharge care that is concordant with patients' values.

A requirement for hospitals, CAHs and HHAs to offer advance care planning as part of the discharge plan would also establish a uniform discharge planning process across post-acute sites of care since nursing homes and skilled nursing facilities are already required to offer advance care planning as part of their Conditions of Participation (CoPs). Advance care planning would of course remain voluntary and patient-centered; a patient's chart could indicate if the patient declined to have an advance care planning discussion or if the offer led to discussion without the patient documenting his or her preferences.

Finally, in order to ensure that all types of advance care planning documents are part of patients' records, Pew advises that CMS change the term "advance directive" to "advance care plan" under the required elements of a discharge plan. ACP documents may include an advance directive such as a living will or a durable power of attorney for health care, but there are many other types of ACP documents, such as a Physician Orders for Life-Sustaining Treatment form signed by a health professional or do-not-resuscitate orders. All types of ACPs should be included in the discharge plan, not just advance directives.

Conclusion

Pew applauds CMS's continued support for increasing the use of advance care planning and facilitating ACPs traveling with patients across sites of care. Pew supports the inclusion of ACPs as an element of the discharge plan for hospitals, CAHs, and HHAs as required by the proposed rule. Moreover, we urge CMS to take an additional step to increase the use of ACPs by requiring that hospitals, CAHs, and HHAs offer advance care planning as part of the discharge planning

[9] Committee on Approaching Death, "Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life" (Washington, D.C.: Institute of Medicine, 2014).
[10] JM 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.* 309 (2013):470-477.
[11] An advance care planning requirement could be added under subsections 482.43(c), 484.58(a), and 485.642(c).

process. We further recommend that CMS change the language in the final rule from "advance directive," to "advance care plan" under required elements of a discharge plan so that all types of ACPS, not just advance directives, are covered under the revised discharge planning requirements.

Improving Patient Care by Documenting Implanted Devices

Pew's medical device initiative seeks to enhance medical device safety and foster device innovation that benefits patients. Through this initiative, Pew conducts research and advocacy to promote adoption of the new unique device identifier (UDI) system into electronic data sources, including patients' health records. Having this information in patients' medical records will allow hospitals to locate individuals affected by recalled devices, support care coordination among physicians and provide patients with accurate information on the products implanted in their bodies, such as artificial hips and cardiac stents.

We support the proposed requirements for hospitals, critical access hospitals and home health agencies to incorporate the UDIs of patients' implanted medical devices in documents sent to other health care providers when transitioning care for the individual.

In 2013 the Food and Drug Administration (FDA) finalized regulations establishing the UDI system, which provides each device with a code corresponding to its make, model and other clinically relevant information, such as the product's expiration date. The highest risk devices were required to have UDIs last fall, and this year all implantable devices—regardless of risk class—must now have these identifiers.

Recent final regulations from the Office of the National Coordinator for Health Information Technology (ONC) also facilitate the inclusion of UDIs in patients' electronic health records (EHRs).[12] In those regulations, ONC requires that medical records used by providers as part of the Meaningful Use program—designed to encourage adoption of EHRs—contain fields for the UDIs of implanted devices and support exchange of this information as part of summary of care information, known as the Common Clinical Data Set (CCDS).

The UDI system, once incorporated into transfer of care documentation, will:

- *Enhance clinical decision support and care coordination*: Documenting UDI in patients' health records will allow providers to make more informed care decisions, especially when individuals transition to another providers.
- *Facilitate recall resolution*: Putting UDIs into patients' health records will help providers identify individuals 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 this information in patients' health records will enable

[12] 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications, 80 Fed. Reg. 62601 (Oct. 16, 2015).

more precise reporting that identifies the make and model of a potentially malfunctioning device.

Establishing procedures for exchanging UDI

The UDI of implanted devices will help reap the benefits outlined above if this information is incorporated into patients' medical records, including via transfer of care documentation when individuals move between hospitals and other facilities.

Under the proposed discharge planning requirements for participation in the Medicare and Medicaid programs, hospitals, critical access hospitals and home health agencies must send the UDI and other key clinical information—such as diagnoses, laboratory test results and medications—to other medical facilities when transferring care for an individual. In addition, these facilities must have a written plan in place outlining how they will ensure the exchange of this key clinical information when transferring care to another medical facility. These proposed regulations will spur adoption and exchange of device-specific information and enable the Centers for Medicare & Medicaid Services (CMS)—should audits reveal that these policies are not followed—to hold hospitals, critical access hospitals and home health agencies accountable.

Alignment of policies with Meaningful Use will encourage and expand UDI adoption

In this proposed rule, CMS stated that it is aligning the data elements—including UDI—required when transferring care with the CCDS as defined in ONC's EHR regulations. Synchronizing the data elements will allow hospitals to meet both the Meaningful Use and discharge planning requirements with a single set of information and will further UDI integration into patients' medical records.[13]

In addition, this proposed rule would encourage UDI adoption by and exchange among facilities that do not or cannot participate in the Meaningful Use program, which does not apply—for example—to home health agencies. While these proposed regulations do not require the transmission of transfer of care documentation electronically, many electronic health record systems will be able to store and transmit UDI due to its inclusion in the EHR certification final rule released by ONC.

Conclusion

The UDI system has the potential to improve care coordination and safety, but only once it is transmitted among providers caring for a patient. The incorporation of UDI in the discharge planning proposed regulations would help advance clinicians' access to this key information by requiring hospitals to transmit the identifiers of implanted devices and develop written plans for meeting that requirement.

[13] Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62761 (Oct. 16, 2015).