October 14, 2015

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

Submitted electronically via regulations.gov

Re: CMS-3260-P: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

Thank you for the opportunity to submit comments on the conditions of participation for long-term care facilities by the Centers for Medicare & Medicaid Services (CMS).

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 to:

- Encourage the capture and exchange of the unique device identifier (UDI); and
- Implement antibiotic use protocols and a system to monitor antibiotic use.

Thank you for considering our comments. Should you have any questions, please contact Sarah Despres at sdespres@pewtrusts.org or (202) 540-6601.

Sincerely,

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The Pew Charitable Trusts

Improving Patient Care by Documenting Implanted Devices in EHRs

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 electronic health records will allow hospitals, nursing homes, hospices and other long-term care facilities 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 implantable cardiac defibrillators.

We support the proposed requirements for long-term care facilities to transmit the UDIs of devices implanted in patients to other health care providers when transitioning the individual to an acute care hospital, hospice or other settings.

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. The highest risk devices were required to have UDIs last fall, and all implantable devices must receive these identifiers starting last month.

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

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

UDI exchange from long-term care facilities is critical to coordinate care

Under the proposed conditions of participation in the Medicare and Medicaid programs for long-term care facilities, CMS intends to support the exchange of key clinical information on patients from nursing facilities as part of transitions of care.

CMS proposes that long-term care facilities exchange key clinical information on patients—based on the common clinical data set (CCDS) as defined in recent final regulations from the

Office of the National Coordinator for Health Information Technology (ONC)—from nursing homes to acute care hospitals, hospice and other care providers.[1] Under this proposal, long-term care facilities would transmit the patient's medication list, drug allergies, advance directive information, surgical history and other key clinical data, including a list of the UDIs of devices implanted in the individual.

Ensuring the exchange of the UDIs of implants among providers is essential for patients treated at long-term facilities. For example, patients transferred from long-term care facilities to emergency departments or acute care hospitals may be suffering complications from their implanted devices. These individuals may experience pain from a faulty joint replacement or cardiac distress as a result of a failed pacemaker. The attending physician caring for that patient should know the specific brand or model of device in case it was recalled or has higher rates of certain adverse events to inform care decisions.

Similarly, hospice facilities receiving patients from nursing homes should also obtain the UDIs of devices implanted in those individuals, particularly for products—like cardiac defibrillators—intended to prolong life. Deactivation procedures may vary depending on the model of the implanted device and the way to know which model a patient has is through the UDI. A 2013 study indicated implantable cardioverter defibrillators remained active in approximately half of patients with do-not-resuscitate orders, and a quarter of those individuals received at least a single shock within the last day of life.[2,3] Additionally, a survey published in 2010 revealed that less than half of patients admitted to hospice had their implanted defibrillators deactivated. By transmitting the UDI of cardiac defibrillators or other devices, hospices can be more aware that patients have these implants to inform care decisions, including deactivation.[4]

While the incorporation of implanted device UDIs in patients' health records can benefit all providers, these examples specific to long-term care facilities underscore the importance of the exchange of this information from nursing homes when transferring care for their patients.

Conclusion

The proposed conditions of participation for long-term care facilities harmonize with requirements in the final Meaningful Use Stage 3 requirements also recently issued by CMS.[5]

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[1] 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications, scheduled to be published in the *Federal Register* on October 16, 2015 (October 6, 2015).

[2] Annika Kinch Westerdahl et al., "Implantable Cardioverter-Defibrillator Therapy Before Death, High Risk for Painful Shocks at End of Life," *Circulation* 129 (2014): 422-429, doi: 10.1161/CIRCULATIONAHA.113.002648.

[3] Daniela J. Lamas, "Lifesaving implants complicate end-of-life care," *Boston Globe*, March 3, 2014, https://www.bostonglobe.com/lifestyle/health-wellness/2014/03/03/lifesaving-implants-can-complicate-end-life-care/T6nNPacKniAk01ON1FkcRM/story.html.

[4] Nathan Goldstein et al., "Brief Communication: Management of Implantable Cardioverter-Defibrillators in Hospice: A Nationwide Survey," *Annals of Internal Medicine* 152 no. 5 (2010): 296-299, doi:10.7326/0003-4819-152-5-201003020-00007.

[5] Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017, scheduled to be published in the *Federal Register* on October 16, 2015 (October 6, 2015).

Under those policies, hospitals and providers would be encouraged to exchange the UDIs of implanted devices along with other key information from the patient's health history. As CMS mentions in the Meaningful Use Stage 3 final rule:

> *"As we noted in the Stage 3 proposed rule…, we 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."*

We agree with CMS on the importance of exchanging the UDI of implanted devices among all providers caring for a patient. As long-term care facilities do not participate in the Meaningful Use program, these proposed conditions of participation are needed to help ensure that the list of patients' implanted devices will be exchanged among providers treating an individual transferred from a nursing home.

Many organizations representing providers, public health groups, patients and large businesses all support efforts to incorporate UDI information into EHRs to provide clear information to patients and their doctors. Those organizations include: FDA, the Brookings Institution, the National Medical Device Postmarket Surveillance Planning Board, the American Association of Orthopaedic Surgeons, the American Joint Replacement Registry, Geisinger Health System, Intermountain Healthcare, Mercy, the Pacific Business Group on Health, The Leapfrog Group, The Society of Thoracic Surgeons, and Trust for America's Health.[6-9]

Including UDIs in patients' medical records and transmitting that information from nursing homes to acute care hospitals, hospice and other facilities will improve care coordination and ensure that clinicians have the data they need to inform decisions—including at the end of life.

Thank you for your consideration of our comments on the UDI provision in this proposed rule.

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[6] Food and Drug Administration, "Strengthening Our National System for Medical Device Postmarket Surveillance," (Sept. 2012), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf.

[7] The Pew Charitable Trusts."Pew Submits Letter to Health and Human Services Regarding Electronic Health Records." (Jan. 20, 2015), http://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2015/01/pew-submits-letter-to-health-and-human-services-regarding-electronic-health-record-certification

[8] The Brookings Institution, "Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation," (Dec. 2014), http://www.brookings.edu/~/media/research/files/papers/2014/12/05 medical device tracking system/udi final 12052014.pdf.

[9] The Brookings Institution, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," (Feb. 2015), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM435112.pdf.

Improving Public Health by Strengthening Stewardship in Long-term Care Facilities

Antibiotic overuse is a major public health threat, and a significant proportion of antibiotic use in long-term care facilities is considered inappropriate.[10] Antimicrobial resistance frequently results from inappropriate or unnecessary use of antibiotics. We strongly support the provisions in the proposed rule that would reform the infection control and antibiotic stewardship requirements that long-term care facilities must meet to participate in Medicare and Medicaid programs, as well as those that integrate infection control into a facility's quality improvement program and pharmacy services. While we support these proposals, we also have several recommendations to strengthen these efforts to ensure appropriate prevention of antibiotic-resistant infections and control of antibiotic use.

The Pew Charitable Trusts' antibiotic resistance project seeks to address the growing issue of antibiotic resistance in the United States, and is actively engaged in three key areas: (1) encouraging the appropriate stewardship of antibiotics in health care settings; (2) eliminating the overuse of antibiotics in animal agriculture; and (3) spurring innovation of new antibiotics to treat the growing number of infections resistant to currently available therapies. As part of our work on antibiotic stewardship, Pew supports enhanced surveillance of antibiotic use and resistance patterns to enable public health authorities to track trends and progress over time.

Though CMS implemented its original rule, which included infection control requirements, for nursing facilities in 1989, the entire rule has not been revised since 1991. Since the current rule was established, antibiotic-resistant organisms have significantly increased. This, coupled with a reduction in the development of new antibiotics, contributes to growing public health concern.[11-12]

There is wide consensus that infection prevention programs in long-term care facilities should include an antibiotic stewardship component,[13,14] and, while we support the inclusion of such a recommendation in the proposed rule, we urge CMS to offer guidelines that are more consistent with the Centers for Disease Control and Prevention's Core Elements of Antibiotic Stewardship for Nursing Homes, to fully ensure judicious use of antibiotics in these settings.[15] For example,

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[10] Lindsay E. Nicolle et al., "Antimicrobial Use in Long-term Care Facilities," *Infection Control and Hospital Epidemiology* 21, no. 8 (2000): 537-545, doi: http://dx.doi.org/10.1086/501798.

[11] Centers for Disease Control and Prevention. "Antibiotic Resistance Threats in the United States, 2013," (July 21, 2015), http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

[12] Brad Spellberg et al., "The Epidemic of Antibiotic-resistant Infections: a Call to Action for the Medical Community from the Infectious Diseases Society of America," *Clinical Infectious Diseases* 46, no. 2 (2008):155-164, doi: 10.1086/524891.

[13] Phillip W. Smith et al., "SHEA/APIC Guideline: Infection Prevention and Control in the Long-term Care Facility," *American Journal of Infection Control* 36, no. 7 (2008):504-535, doi: 10.1016/j.ajic.2008.06.001.

[14] Infection Control Today. "IDSA Supports Proposed Stewardship Requirement for Long-term Care, Touts ID Physician Leadership," (July 16, 2015), http://www.infectioncontroltoday.com/news/2015/07/idsa-supports-proposed-stewardship-requirement-for-long-term-care-touts-id-physician-leadership.aspx.

[15] Centers for Disease Control and Prevention, "The Core Elements of Antibiotic Stewardship for Nursing Homes," (September 15, 2015), http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html.

CMS should require that antibiotic stewardship programs monitor antibiotic use and, at a minimum, apply that information to guide clinical decision-making, design targeted interventions, and develop antibiotic use protocols as recommended by professional guidelines for long-term care facilities using antibiotic stewardship programs.[16] Robust antibiotic surveillance is a critical part of stewardship that allows facilities to develop antibiotic use protocols tailored to their resident population, as outlined in the condition of participation.

Broadening requirements of long-term care facilities' Infection Prevention and Control Programs to incorporate antibiotic stewardship programs that include both antibiotic use protocols and a system to monitor antibiotic use would allow facilities to:

- *Optimize antibiotic use:* studies suggest that antimicrobials are prescribed excessively in long-term care facilities.[17-20] Implementation of an antibiotic stewardship program would allow long-term care facilities to improve antibiotic prescribing and healthcare quality by ensuring that antibiotics are used appropriately, and only when necessary.
- *Combat the rise of resistant infections:* the incidence of antibiotic-resistant bacterial infections in long-term care settings has significantly increased over the years,[21] and such infections are associated with higher morbidity and mortality, which can lead to increased healthcare costs.
- *Facilitate benchmarking and monitor progress*: documentation of antibiotic use and resistant infections data will enable facilities to conduct a baseline evaluation of antibiotic use, track changes in drug use over time, and allow for inter-facility comparison.[22]
- *Avoid antibiotic-related adverse outcomes for all residents*: over-prescribing of antibiotics not only directly exposes individuals to antibiotic-related adverse outcomes (such as *Clostridium difficile*, or *C. diff.*, infection), but also increases potential for cross-transmission of such infections among residents. Excessive antibiotic use destroys protective gut bacteria, which can lead to infection with *C. diff* through increased selective pressure for this and other antibiotic-resistant organisms.[23]

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[16] Phillip W. Smith et al., "Antibiotic Stewardship Programs in Long-term Care Facilities," *Annals of Long-term Care* 19, no. 4 (2011), http://www.annalsoflongtermcare.com/article/antibiotic-stewardship-programs-long-term-care-facilities.

[17] Paschalis Vergidis et al., "Patterns of Antimicrobial Use for Respiratory Tract Infections among Older Residents of Long-Term Care Facilities," *Journal of the American Geriatrics Society* 59, no. 6 (2011):1093-1098, doi:10.1111/j.1532-5415.2011.03406.x.

[18] Terri-Diann Pickering et al, "The Appropriateness of Oral Fluoroquinolone-Prescribing in the Long-Term Care Setting," *Journal of the American Geriatrics Society* 42, no.1 (1994): 28-32, doi:.1111/j.1532-5415.1994.tb06069.x

[19] James G. Zimmer et al., "Systemic Antibiotic Use in Nursing Homes: a Quality Assessment," *Journal of the American Geriatrics Society* 34, no. 10 (1986):703-710, doi: 10.1111/j.1532-5415.1986.tb04301.x.

[20] Robert A Bonomo. "Multiple Antibiotic-Resistant Bacteria in Long-Term-Care Facilities: An Emerging Problem in the Practice of Infectious Diseases," *Clinical Infectious Diseases* 31, no. 6 (2000): 1414-1422, doi: 10.1086/317489.

[21] Christopher J. Crnich et al., "Longitudinal Trends in Antibiotic Resistance in U.S. Nursing Homes, 2000-2004," *Infection Control and Hospital Epidemiology* 28, no. 8 (2007):1006-1008, doi: 10.1086/518750.

[22] Susan M. Rhee and Nimalie D. Stone, "Antimicrobial Stewardship in Long-term Care Facilities," *Infectious Disease Clinics of North America* 28, no.2 (2014): 237-246, doi: 10.1016/j.idc.2014.01.001.

[23] Nick Daneman et al., "Variability in Antibiotic Use Across Nursing Homes and the Risk of Antibiotic-related Adverse Outcomes for Individual Residents," *The Journal of the American Medical Association Internal Medicine* 175, no. 8 (2015): 1331-1339, doi:10.1001/jamainternmed.2015.2770.

In Section M, under the Pharmacy Services portion of the updated rule, CMS also proposes that a pharmacist be required to review a resident's medical record monthly when that resident has been prescribed or is taking an antibiotic. We support regular pharmacy review of antibiotic prescribing, and recommend that monthly evaluation be the minimum standard. Evidence shows that antibiotics are frequently given for extended periods of time in long-term care facilities and thereby directly expose residents to harmful risks such as antibiotic allergies and *C. diff* infections.[24] Vigilant monitoring of medical records is essential to optimize patient care, as well as to change or stop antibiotics when duration of therapy is prolonged without clinical justification.[25]

The proposed revisions to infection prevention and control programs in this rule would encourage long-term care facilities to participate in antibiotic surveillance, improve antibiotic prescribing, and enhance patient care. The development of these requirements enables facilities with even minimal resources to become good stewards of antibiotics, and to preserve effectiveness of these life-saving agents. With these rules, CMS addresses the growing challenge of antibiotic resistance, but offers flexibility by allowing more prescriptive guidelines to be developed as research continues.

Thank you for your consideration of our comments on the inclusion of antibiotic stewardship provisions in this rule.

[24] Daneman et al., "Variability in Antibiotic Use Across Nursing Homes and the Risk of Antibiotic-related Adverse Outcomes for Individual Residents," 1331-1339.
[25] Oliver J. Dyar et al., "Strategies and Challenges of Antimicrobial Stewardship in Long-term Care Facilities," *Clinical Microbiology and Infection* 21 no. 1(2015): 10-19, doi:10.1016/j.cmi.2014.09.005.