THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

November 16, 2015

Walter G. Suarez
Chairperson
National Committee on Vital and Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road
Room 2402
Hyattsville, Maryland 20782

Dear Dr. Suarez,

In 2014, the National Committee on Vital and Health Statistics (NCVHS) considered the incorporation of unique device identifier (UDI) data into administrative transactions and issued several recommendations to advance the use, capture and exchange of this information.[1] Since then, many organizations—including hospitals, health plans and standards organizations—have expressed support for UDI in claims transactions, offering additional insights on the benefits of exchanging these data. This letter is intended to update you and the rest of the committee on progress and new developments since NCVHS last examined this issue, and to request additional support from the committee to advance UDI transmission in administrative transactions.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

As you know, in 2013 the Food and Drug Administration (FDA) finalized regulations establishing a UDI system—which ensures that each medical device has a code corresponding to its manufacturer and model—to improve patient safety and care quality by better tracking devices from manufacturer through their use in patient care. Achieving the benefits of UDI requires its incorporation into claims data. Currently, the claims transactions used by both private and public health plans only list the procedure—for example a hip replacement surgery—that a patient undergoes, but lack information on the specific manufacturer or model of implant used.

This letter will provide an overview of all the benefits articulated on UDI in claims; an examination of different technical solutions to exchange this information; an update on stakeholder support; an evaluation of potential objections; and an analysis of progress on NCVHS recommendations.

In addition, we request that you both clarify and expand your support for including UDI in claims based on new business cases, further encourage standards development organizations to support UDI incorporation into administrative transactions, and provide additional detailed recommendations for the development of pilot projects to refine best practices for the exchange of this information.

Benefits of UDI in claims

Since NCVHS last examined UDI capture in claims, health plans, providers, and other stakeholders have articulated several additional benefits associated with the exchange of this information. Specifically, adding UDI data to claims would yield the following benefits for quality improvement:

- *FDA evaluations of device safety:* FDA, as it does with drugs, could use claims data for analyses on the long-term effects of medical devices. For example, FDA's postmarket surveillance Sentinel system relies primarily on claims data to evaluate drug safety. FDA cannot efficiently expand this system to medical devices—as instructed by Congress in 2012—until claims contain UDI data.
- *Comparative effectiveness research by health plans:* Health plans often conduct research on their own data to better understand drug utilization, patient outcomes and cost. The lack of data on specific device types prevents health plans from comparing the safety and effectiveness of implants to other devices, surgery, drugs, lifestyle changes, and other interventions. Additionally, large databases that aggregate information from multiple health plans (including all-payer claims databases and private-sector collaborations that pool information) often lack information on the specific device model used. Should claims contain UDIs, researchers could then utilize these databases to evaluate product performance.
- *Enhancements to registries:* Registries often only collect information on patients for a set period—such as until hospital discharge—and link with other databases to conduct robust assessments of long-term patient outcomes. Including UDI in claims would support registries' ability to conduct longitudinal analyses of device performance.
- *Better care management and recall support by health plans:* Health plans can use their data to help patients manage their health. Since products may have different physical therapy or checkup requirements, knowing the device model can help health plans ensure that members receive coverage for appropriate care. In the event of a recall, the health plan could also notify members and ensure they obtain appropriate follow-up care.

Additionally, UDI in claims would also support efforts to address fraud, increase transparency and lower costs:

- *Fraud and abuse detection*: Health plans could utilize the UDI to detect fraud when providers bill for the use of products. For example, under existing federal policies, CMS requires hospitals to report to the agency any manufacturer credits they have received for certain costly medical implants that are recalled or fail prematurely. In turn, Medicare reduces the hospital's reimbursement for a set of specified procedures because the manufacturer already covered the cost of the device. The Inspector General for the Department of Health and Human Services has found that CMS often overpays because manufacturer credits were not received or reported to the agency. UDI information would equip CMS with data to help ensure that hospitals report applicable credits and proactively request credits for devices with known recalls.[2,3]
- *Transparency in Medicare spending*: The Centers for Medicare & Medicaid Services (CMS) and Congress have both recently supported policies to ensure public and researcher access to claims data, yet this information lacks a key component of care—the device implanted in patients. Incorporating the UDI in claims would infuse additional

transparency into the data and enhance the value of these transparency efforts for patients who rely on implanted medical devices.[4]

- *Support for alternative payment models:* As Congress and the administration continue to emphasize the use of new care delivery models based on quality and value, better understanding device use can help health systems demonstrate that they are providing more cost-effective care to patients without sacrificing patient care.[5]
- *Modeling, cost calculations, and payment:* By knowing which devices their members use, health plans can better understand all the factors that influence the cost of care. UDIs would help indicate if plan members are typically obtaining higher- or lower-cost products or better-quality devices. This information can improve modeling of expected expenditures and payment rates for procedures, including the development of policies to reflect the product type similar to how health plans treat drugs.

Alternatives to claims are insufficient

NCVHS urged stakeholders to consider options, including the claims form, for transmission of UDI. While UDI should be incorporated in various electronic health information sources, the claims transaction offers unique benefits when compared to alternatives:

- *Claims:* The claims transaction offers several benefits to UDI exchange unmatched by the other methods for transmission. First, claims are already used by providers and health plans to exchange structured, electronic data—including the prescription drugs that patients receive. Second, claims are standardized across all payers and providers, enabling claims to be aggregated and analyzed, which is why they are often used for research. Third, claims transactions are already supported by health information technology vendors and integrated into systems that evaluate patient outcomes, such as the Sentinel program and all-payer claims databases. As a result, claims are a standard transaction that is already utilized to exchange information similar to UDI (such as National Drug Codes) to achieve these benefits.
- *Claims attachments:* Unlike the claim itself, the claims attachment is currently not standardized. As a result, claims attachments cannot be aggregated, and some lack structured data, meaning that UDI could be documented in a manner that health plan personnel would need to manually extract the information. While the Affordable Care Act requires CMS to create a standard claims attachment, the agency has not indicated how or when it will implement this policy.[6] Additionally, given that the claims attachment may contain far more data than the claim itself, the information may not be retained and used electronically, requiring health plan personnel to manually review each attachment received.
- *New administrative transaction:* The creation of a new transaction to exchange UDI between the provider and health plan would not be a standard under Health Insurance Portability and Accountability Act (HIPAA) regulations. Therefore, each health plan and provider might exchange this information differently and health information technology may not support this transaction. To ensure that providers send UDI to the health plans in a standard format, the solution must be part of a HIPAA-adopted transaction.
- *Electronic health records:* As you know, many electronic health records are not interoperable, making it difficult to extract data into registries and other health information sources. In addition, there is no standard mechanism for hospitals to send

EHR data to health plans. Often, hospitals and health information technology vendors must develop custom interfaces to extract data from electronic health records. Sending UDI to health plans through EHRs is not feasible because it would require the costly and inefficient development of custom-built interfaces for each hospital and health plan to exchange this information.

- *Creation of a registry-based solution:* While registries are an important tool for postmarket surveillance, they are often expensive to establish and may not be appropriate for many products; as a result, the creation of a national registry or many product-specific registries is not feasible en lieu of transmitting UDI in claims data. Registries utilize data from many information sources over time; for this reason, many current registry administrators support including UDI in claims to enhance the information available to them on patient outcomes after the registry stops directly collecting data on a patient.
- *Adverse event reports:* Improvements to adverse event reporting could enhance postmarket surveillance, but are insufficient to replace UDI in claims Adverse events are underreported and often lack key data, particularly 'denominator' data on the size of the exposed population, hindering their utility for large-scale population health analysis. Finally, the exclusive use of adverse event reporting would not facilitate UDI exchange to health plans, which have several uses for these data.[7]

Given the deficiencies of the other approaches, the most efficient and robust method of exchanging UDI information between providers and health plans is on the HIPAA-adopted claims transactions.

Growing support across the health system for UDI in claims

Since the NCVHS hearing in 2014, many organizations have publicly expressed support for UDI in claims. The wide range of groups includes hospitals, accountable care organizations, health plans, clinical societies, public health groups, patient organizations, government agencies, and data exchange organizations. Please see the Appendix for a list of organizations that have expressed support for UDI in claims.

Addressing objections to UDI in claims

Notwithstanding some concerns, there are clear examples that show the utility and appropriateness of UDI capture in claims.

- *Value of claims for postmarket surveillance*: Despite concerns that claims data are not useful for postmarket surveillance, the FDA, health plans, researchers, manufacturers and other stakeholders regularly use these data to evaluate drugs, procedures, care quality and broad categories of devices.

  While claims-based surveillance has its limitations—including that patients can switch health plans, claims lack clinical data contained in other sources of health information and some individuals lack insurance—claims are nonetheless a proven tool for analyzing outcomes. For this reason, Congress, FDA and even CMS are exploring and

implementing new ways to leverage real-world evidence from claims to improve safety, quality and innovation.[8]

Researchers at Geisinger Health System recently used their claims data and patient records as a proof of concept to demonstrate how UDI capture in claims can enable analyses of device outcomes in a manner of hours—not days or weeks.[9] As the researchers state: "Health care data such as claims and electronic medical records can provide that capability in a fraction of the time required to conduct a traditional surveillance study, but only efficiently and robustly once UDI data are added."

While improved adverse event reporting and registries can be valuable tools, these data sources have deficiencies compared with the claims form. In addition, UDI capture in claims should be incorporated as part of a multi-layered approach that also includes adverse event reporting and registries. Through this multi-layered approach, each data source compensates for the deficiencies of the others.

- *Claims have multiple uses and UDI may be used in billing*: While hospitals and health plans use claims primarily for billing purposes, UDI exchange in these transactions is appropriate for several reasons.

  First, claims data—as mentioned—are already used for research and quality improvement purposes, not just billing.

  Second, some health plans and systems have suggested that they would utilize UDI for billing purposes.[10] For example, some health plans have indicated that they could monitor fraud through UDI capture or use this information as part of coverage determination for follow-up care based on the product labeling or in case of a recall.

  Third, claims data remain an important quality-monitoring tool as the entire health ecosystem shifts toward alternative delivery approaches, such as bundled and capitated payments. Under these systems, health plans will require additional data to ensure that care quality is not sacrificed for lower-cost care. Given that device selection can affect the quality of care, obtaining UDI could help monitor quality as part of these new payment approaches.[11]

- *Implementation costs are incremental and manageable*: Upgrades to health information technology systems—including those that process claims—requires investments from hospitals and health plans to support new capabilities. However, health plans and hospitals will upgrade their claims processing systems to accommodate upcoming updates to the claims form, prior authorization forms and several other administrative transactions adopted under HIPAA regulations. As a result, the cost to include UDI in just the claims form will be incremental to the investments that hospitals and health plans will already make while upgrading to the next versions of administrative transactions.

  Additionally, given that the claims form is only updated periodically, the inclusion of UDI outside of a scheduled revision would require additional costs.

Finally, some researchers have suggested that there may be direct, significant cost savings to health plans—including Medicare—by more quickly identifying product failures and stopping use of those products. For example, the failure of just one brand of implanted lead was estimated to have cost Medicare approximately $287 million, but may have reached as much as nearly $1.2 billion.[12]

Progress on NCVHS recommendations

While NCVHS recommended in 2015 that CMS and standards development organizations take several steps to advance UDI exchange, there has been limited progress to-date.

Recommendation 1: NCVHS recommended that the Department of Health and Human Services (HHS) work with the health care industry to understand and document the value, benefits, and cost of incorporating UDI in administrative transactions.

Progress-to-date: Since NCVHS' hearing, FDA has convened two groups of healthcare and device safety experts that have articulated the importance of claims data for postmarket surveillance.

First, the National Medical Device Postmarket Surveillance Planning Board—which convened many of the nation's thought leaders on device safety—issued a report in February 2015 and called for adoption of UDI in electronic health information sources, including claims. This group of device surveillance experts articulated several benefits to UDI in claims, including contacting patients affected by recalls, enhancing postmarket surveillance and generally strengthening quality improvement efforts.[13]

Second, the National Medical Device Registry Task Force issued recommendations in August 2015 stating that "ubiquitous" UDI capture throughout the supply chain, patient care and billing would help conduct better evaluation of device performance over time. The group of experts emphasized that different data sources—such as registries, electronic health records and claims data—provide complementary information that correct deficiencies, with claims providing long-term outcomes information.[14]

Aside from those expert groups that articulate the benefits of UDI in claims, CMS or other agencies have not released an analysis of the value, benefits or costs of UDI capture in administrative transactions.

Recommendation 2: NCVHS recommended that HHS and the health care industry should consider pilots to test and document the value, benefits, and cost of UDI transmission in administrative transactions, including claims.

Progress-to-date: There have been several pilots demonstrating the feasibility and benefits of UDI capture, including as part of administrative transactions. For example, by collecting UDI-like codes in administrative transactions, the California Department of Health Care Services was able to make more informed decisions, enhance quality controls, detect fraud and abuse, improve

patient safety, and generate cost-savings.[15] Additionally, Mercy, a multistate health system, launched a pilot project to integrate device identifiers used in cardiac catheterization labs into the supply chain and electronic health records systems.[16]

There are several other activities underway to demonstrate the utility of UDI for registries and to further demonstrate the value of hospital capture and exchange of UDI, including in claims processing systems. These pilots have been conceived by the Medical Device Epidemiology Network Initiative, which was developed by the FDA. Some have recently secured federal funding.

However, HHS and CMS have not announced any additional plans to study or demonstrate the benefits or costs of UDI exchange in claims or other administrative transactions. Given the timeline for the adoption of the next version of HIPAA standards, it is unlikely that HHS could conceive, develop, implement, and obtain the results of new pilot projects to inform the forthcoming revisions, which may be finalized within the next two years.

Therefore, in addition to recommending the inclusion of UDI in claims as part of the next update, we urge NCVHS to also articulate specific pilot projects that FDA, CMS, and the health industry can develop to identify best practices for the capture and exchange of this information. For example, NCVHS could recommend that CMS pilot the collection of UDI to evaluate its potential for addressing fraud and abuse as well as the enforcement of existing policies. Similarly, NCVHS could recommend that CMS or accountable care organizations examine the utility of UDI for monitoring quality of care when using bundled payments and other alternative payment models.

Recommendation 3: NCVHS recommended that standards development organizations develop guidance on UDI incorporation into existing versions of administrative transactions to support pilots and consider updates to future versions of these transactions.

Progress-to-date: In 2013, Pew submitted a change request to the Accredited Standards Committee (ASC) X12 to create a new field in claims transactions to document the UDI. Since that time, ASC X12 has been evaluating the Pew request, which is supported by many health plans, hospitals, public health organizations, patient groups, and other stakeholders. Given ASC X12 policies, that organization is best suited to give NCVHS an update on progress over the last two years in its evaluation of the change request.

Due to the timeline for adopting new claims transactions, UDI may not be incorporated into claims until approximately 2020 under the current schedule; missing this window could delay the exchange of this information until the subsequent update, which may not be finalized for another decade or more.

Additionally, there has been no public discussion of supporting UDI capture in existing administrative transactions, such as the claim, to enable pilot projects. Given the many potential benefits of UDI capture and because newly manufactured implants are already required to have UDIs, ASC X12 and other standards development organizations should promptly issue guidance

to enable the exchange of UDI as part of the existing claims form to demonstrate the value of this information.

Some standards development organizations are already supporting the transmission of this information. For example, Health Level 7 (HL7) is incorporating UDI into many of its standards, such as those that exchange data among EHR systems to meet new federal requirements from the Office of the National Coordinator for Health Information Technology for the transmission of UDI.[17] In a letter to HHS Secretary Burwell, HL7 also expressed support for a field for UDI in the next version of claims, stating that it would "facilitate a more efficient exchange of electronic health data to improve the delivery, management and evaluation of care for patients with cardiac stents, artificial joints and other implants."[18]

In addition, the National Council for Prescription Drug Programs has also begun evaluating the exchange of UDI in its standards and has urged other standards development organizations—particularly ASC X12—to support the transmission of this information for specific products.

Finally, leadership from the National Uniform Billing Committee and the National Uniform Claims Committee have participated in the ASC X12 process, but articulated their opposition to UDI incorporation into claims. Contrary to NCVHS recommendations, those organizations have not developed guidance on the exchange of UDI as part of existing versions of administrative transactions to support pilots, nor have these organizations invited Pew or other expert organizations that support UDI exchange to recent meetings to discuss this topic.

NCVHS should consider more explicit recommendations to standards development organizations to ensure that UDI can be incorporated into administrative transactions. Additionally, NCVHS should urge those standards development organizations that are not moving forward with any guidance to instead support UDI exchange to enable the transmission of this information for those trading partners seeking to transmit these data.

Recommendation 4: NCVHS recommended that FDA and other stakeholders should work together to improve postmarket surveillance of medical devices.

Progress-to-date: The two groups of experts mentioned earlier—the National Medical Device Postmarket Surveillance Planning Board and the National Medical Device Registry Task Force—have both articulated a comprehensive vision for improving the evaluation of devices throughout their entire life cycle.

Central to both groups' recommendations is ubiquitous UDI capture in health data sources—such as registries, electronic health records and claims. UDI can provide these data sources with specific, standard data on the devices used in care. Both groups also highlight, as mentioned, the specific utility of claims data—access to longitudinal data that is provider-agnostic and can be aggregated—to shore up deficiencies in other data sources. These recommendations also align with FDA's vision for improving postmarket surveillance, which includes UDI capture in claims data.[19]

These recommendations supporting UDI capture in claims are part of a larger strategy to improve the evaluation of device performance through better adverse event reports, registries, postmarket studies and active surveillance. Each part of this broader system includes deficiencies corrected by the other components. Through this multi-layered approach, which includes device incorporation into claims, FDA, patients, clinicians and other stakeholders can more quickly learn about device failures and monitor performance of these products.

Statement in Letter: Along with the recommendations, NCVHS stated in its letter that "[a]t the current time NCVHS does not recommend mandating the capture, reporting and use of UDI in administrative transactions."

Progress-to-date: Unfortunately, this statement from NCVHS has been misconstrued as an expression of opposition from NCVHS for UDI in claims.

It would be helpful for NCVHS to clarify that its position was that UDI should not be *mandated "at the current time,"* meaning until the above work had been done. This position—that the exchange of UDI should not be required to occur right now—is consistent with the views of other supporters of the exchange of this information.

Claims transactions should have capabilities to support the exchange of UDI, and the conversations held to-date have focused on future versions of the standard that hospitals and health plans would implement in approximately 2020. The creation of a field for the exchange of UDI would not mandate the exchange of this information; it would only afford the opportunity for those organizations—such as Aetna, Geisinger Health System, Mercy, Duke Medicine and others—that are interested in exchanging UDI.

We urge NCVHS to clarify that the committee does not oppose future incorporation of a field for UDI in claims. Additionally, given the demonstrated utility of device identification via claims and that many health plans and hospitals have sought the exchange of this information, we urge you to support the creation of new capabilities to enable these organizations to transmit and benefit from the new UDI system.

Conclusion

The new UDI system provides all stakeholders—including hospitals, clinicians, health plans and patients—with an opportunity to obtain better data on the medical devices used in care. The benefits of this UDI system, though, are only realized once it is used throughout health care, including claims as a data source already utilized by researchers, FDA, health plans, registries and others to track outcomes, improve quality and monitor costs. The inclusion of UDI in the next HIPAA update to claims will ensure that these stakeholders can use this data source for medical devices in much the same ways that they do for drugs and procedures.

In the interim, but not en lieu of, NCVHS should also encourage the development of specific pilot projects, clarify its position on a field for UDI, and oversee implementation of its recommendations so that organizations that seek to use UDI have a standard method for transmitting this information to improve patient care.

Should you have any questions or if we can be of assistance, please contact me at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

Josh Rising, MD
Director, Health Care Programs
The Pew Charitable Trusts

Appendix: Supporters of UDI in Claims

Providers/Payers

- Aetna
- Alliance of Community Health Plans
- America's Essential Hospitals
- Duke Medicine
- Geisinger Health System
- Intermountain Healthcare
- Mercy
- National Association of Accountable Care Organizations
- Nebraska Medicine
- Premier
- The American College of Cardiology
- The Society of Thoracic Surgeons

Government

- The Food and Drug Administration

Non-Profit Organizations

- American Joint Replacement Registry
- The Pew Charitable Trusts
- West Health Institute
- Altarum Institute
- Trust for America's Health
- The Brookings Institution
- Pacific Business Group on Health
- The Leapfrog Group
- The National Medical Device Postmarket Surveillance Planning Board

Data Exchange Organizations

- HL7 International
- First Databank
- WEDI Foundation

Patient/Consumer Groups

- National Health Council
- AARP
- Consumers Union
- Public Citizen
- The National Center for Health Research
- The National Women's Health Network
- The Center for Medical Consumers
- The National Physicians Alliance

- The Union of Concerned Scientists
- The American Medical Student Association
- WomenHeart: The National Coalition for Women with Heart Disease
- The Connecticut Center for Patient Safety
- The TMJ Association
- Woody Matters

---

[1] Larry A. Green, letter to Sylvia Mathews Burwell at Department of Health and Human Services, Sept. 23, 2014, http://www.ncvhs.hhs.gov/wp-content/uploads/2014/10/140923lt3.pdf.
[2] Department of Health and Human Services, Office of Inspector General, "Medicare Overpayments in Jurisdiction 15 for Unreported Cardiac Device Credits," Oct. 2014, http://oig.hhs.gov/oas/reports/region5/51300029.pdf.
[3] Josh Rising, comments to Docket ID: CMS-2015-0075, Aug. 31, 2015, http://www.pewtrusts.org/~/media/assets/2015/09/pew-comments-to-cms-on-hopps-final.pdf.
[4] Joseph M. Smith, letter to Sylvia Mathews Burwell at Department of Health and Human Services, Aug. 17, 2015.
[5] Lincoln T. Smith, letter to Sylvia Mathews Burwell at Department of Health and Human Services, Sept. 2, 2015.
[6] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).
[7] Department of Health and Human Services, Office of Inspector General, "Adverse Event Reporting for Medical Devices," Oct. 2009, http://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf.
[8] "CMS announces entrepreneurs and innovators to access Medicare data," June 2, 2015, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-06-02.html
[9] Jove Graham, Surya Cooper, A. Dhanya Mackeen, "How Safety Concerns About Essure Reveal A Path to Better Device Tracking," Health Affairs Blog, Oct. 15, 2015, http://healthaffairs.org/blog/2015/10/15/how-safety-concerns-about-essure-reveal-a-path-to-better-device-tracking/.
[10] Stuart Kilpinen, testimony to NCVHS Subcommittee on Standards Hearing on Administrative Simplification: Use of UDI in Administrative Transactions, June 10, 2014, http://www.ncvhs.hhs.gov/wp-content/uploads/2014/06/140610p26.pdf.
[11] Cybele Bjorklund, "Medicare is in the dark on device data," *The Hill*, Sept. 28, 2015, http://thehill.com/blogs/congress-blog/healthcare/254989-medicare-is-in-the-dark-on-device-data.
[12] Amit K. Mehrotra, et al., "Medtronic Sprint Fidelis lead recall: determining the initial 5-year management cost to Medicare," *Heart Rhythm* 8, no.8 (2011): 1192-1197, doi:10.1016/j.hrthm.2011.02.039.
[13] National Postmarket Surveillance Planning Board, "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.
[14] Medical Device Registry Task Force, "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research," (Aug. 2015), http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm459368.pdf.
[15] California Department of Health Care Services, "Universal Product Number (UPN) Pilot Project: Evaluation Outcome Report, Sept. 2011.
[16] James E. Tcheng et al., "Unique Device Identifiers for Coronary Stent Postmarket Surveillance and Research: A Report From the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration," American Heart Journal 168, no. 4 (2014): 405–413, e2, doi:10.1016/j.ahj.2014.07.001.
[17] 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).
[18] Stanley M. Huff and Charles Jaffe, letter to Sylvia Mathews Burwell at Department of Health and Human Services, June 24, 2015.
[19] 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, and Food and Drug Administration, "Strengthening Our National System for Medical Device

Postmarket Surveillance: Update and Next Steps," April 2013, http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf.