2015 Retrospective on Meaningful Use, Healthcare Information Technology, and HIPAA

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In 2015, the U.S. Department of Health and Human Services (HHS) continued in its efforts to advance the implementation of Certified Electronic Health Record Technology (CEHRT) throughout the healthcare industry, primarily through the Centers for Medicare & Medicaid Services' (CMS') "Meaningful Use" program. Simultaneously, HHS's Office for Civil Rights (OCR) continued with its mission to enforce and ensure compliance with existing requirements for the use, disclosure, storage, and dissemination of protected health information (PHI). Mostly through these key programs, 2015 likely foreshadows major changes in 21st century health information technology in the United States.

Meaningful Use Stage 3 Final Rule and Beyond

Enacted in 2009 as part of the American Reinvestment and Recovery Act (ARRA), Meaningful Use, is the Medicare and Medicaid program which incentivizes providers to adopt CEHRT to improve patient care and outcomes.[1] Its implementation is designed in three stages: the promotion of basic EHR adoption and data gathering (Stage 1); coordination of care and limited exchange of patient data (Stage 2); and large-scale data sharing, interoperability, leading to improved healthcare outcomes (Stage 3).[2] Launched in 2011, Meaningful Use has become the flagship program for the Office for National Coordinator for Health Information Technology (ONC), which jointly oversees the program along with HHS.

In September 2014, providers struggling under the weight the Meaningful Use program received welcomed relief when the government extended the Stage 2 deadline for one year. It also required all eligible providers to use the 2014 Edition of CEHRT beginning in 2015 for year-long attestation reporting in 2015.[3] Beginning in 2015, providers who failed to demonstrate Meaningful Use faced penalties beginning at 1 percent of Medicare Part B reimbursements, which would increase in future years up to a maximum of 5 percent.[4]

Meaningful Use implementation in 2015 did not go as smoothly as hoped. In April of last year, CMS issued its notice of proposed rulemaking which, among other things, changed the incentive program reporting period from a full year to a 90-day interval aligned with the calendar year. It also reduced the number of core objectives that are required to be met for Stage 1 and Stage 2.[5] Between the NPRM in April and the Final Rule which was issued in October, a groundswell of opposition began to build from industry stakeholders who considered Meaningful Use unwieldy, overly burdensome, and inflexible. These efforts culminated with a September 28, 2015 letter signed by over one hundred members of Congress to HHS Secretary Burwell urging a delay in Stage 3 implementation and postponement of final Stage 3 rulemaking.[6] Among the reasons cited in this letter was the fact that the Meaningful Use program was developed prior to the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), commonly known as the "doc fix" legislation passed last year.[7]

Unfazed by industry and Congressional opposition, on October 6, 2015, CMS issued its Meaningful Use Stage 3 Final Rule (the "Stage 3 Final Rule") simultaneously with ONC's release of the 2015 Edition IT Certification Criteria (the "2015 CEHRT Final Rule"). Among the Stage 3 Final Rule's most salient features was a delay in mandatory Stage 3 compliance until January 1, 2018, which is a full year later than originally

indicated in the NPRM a few months prior.[8] Other changes to Stage 3 were designed to ease the transition between Stage 2 and Stage 3, including: refocusing the program on quality of care improvement through clinical decision support and information exchange rather than data entry, and aligning Stage 3 reporting requirements with other quality programs, so that providers may now report once and receive credit for multiple programs.[9] CMS and ONC appeared to end 2015 on a high note, triumphantly announcing the Stage 3 Final Rule, critics notwithstanding.

In early 2016, CMS abruptly changed course when acting CMS Administrator Andy Slavitt tweeted from the J.P. Morgan Healthcare Conference in San Francisco that that, "In 2016, MU as it has existed – with MACRA– will now be effectively over and replaced with something better #JPM16."[10] In his formal remarks at the conference, Slavitt reportedly said that CMS would be providing more details on future health IT incentive programs focusing on patient outcomes rather than technology issues by March 25, 2016.[11]

Healthcare Data (In)Security and OCR Enforcement Efforts

After 2015, it is undeniable that both large and small-scale targeting of healthcare data is taking place. Leading the pack, in February 2015, Anthem Blue Cross announced that approximately 78.8 million patient records had been breached, along with an additional 8.8 to 18.8 non-patient records.[12] Later in the year, Premera Blue Cross and Excellus Blue Cross Blue Shield would announce that they too suffered attacks which exposed 11 million and 10 million records, respectively.[13] Comparatively smaller breaches also occurred at UCLA Health Systems and CareFirst Blue Cross Blue Shield where 4.5 and 1.1 million individuals were affected.

Though large-scale breaches splashed across the headlines, and were ultimately eclipsed by the "advanced persistent threat" hack of the Office of Personnel Management which compromised the information of over 21 million individuals and included over 5 million fingerprint records, targeted attacks on healthcare data also came in smaller sizes.

In February 2015, a former hospital employee in Texas was sentenced to 18 months in federal prison after improperly obtaining PHI with the intent to use it for personal gain.[14] The following month, a Blue Cross Blue Shield of Michigan (BCBSM) employee (and ten others in multiple states) was indicted on multiple counts of identity theft related crimes based on her alleged theft of BCBSM subscriber information.[15] According to the indictment, the BCBSM employee shared subscribers' personal identifying information and distributed it to others who used it to apply for credit in subscribers' names and make purchases across the country. Co-conspirators were arrested in Texas, Ohio and Michigan in possession of BCBSM subscriber information, counterfeit identification cards, and credit cards that were fraudulently obtained in the names of BCBSM subscribers. At other suspects' homes, agents recovered BCBSM subscribers' names, dates of birth and Social Security numbers in addition to counterfeit and re-encoded credit cards and gift cards. The indictment alleges that three of the co-conspirators used counterfeit credit cards at different stores and fraudulently obtained more than $742,000 worth of merchandise from Sam's Club alone.[16]

OCR enforcement of HIPAA requirements resulted in six Resolution Agreements totaling over $6.1 million in penalties collected. Through these Resolution Agreements, OCR highlighted the importance of timely risk assessments and proper risk management, particularly regarding "cloud" services and applications.[17] In addition to the fines assessed, all Resolution Agreements in 2015 required that the allegedly non-compliant party adhere to a monitored "Corrective Action Plan" for between one and three years.[18]

OCR's enforcement of HIPAA was criticized by two reports from the Office of Inspector General issued in October 2015. The first of these reports examined OCR's oversight of covered entities' compliance with the Privacy Rule.[19] The second report looked at OCR's handling of covered entities' reported HIPAA breaches.[20] Both reports included recommendations to OCR for improvement in these areas. OCR agreed with all of OIG's recommendations in both reports, suggesting changes to OCR oversight and enforcement activities in the near future.[21]

The second half of 2015 also saw the implementation of the long-anticipated "Phase 2" HIPAA Audits of both covered entities and business associates. Although OCR remains unclear on the ultimate timeline for these audits, it is likely that these audits will spawn additional enforcement actions and influence OCR investigative and enforcement policy in the future.

OCR also signaled forthcoming rulemaking in the HIPAA arena. Specifically, it has said that covered entities and business associates may expect: (1) a proposed rule that would allow individuals adversely affected by breaches of their protected health information to share in a percentage of the fine assessed by OCR against the party or parties responsible for the breach; (2) additional guidance regarding the "minimum necessary" rule, which OCR views as intended to advance the policy goal that PHI only be used or disclosed when necessary for a particular purpose or to carry out a specific function; (3) further clarification and guidance concerning the use

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of cloud storage and cloud computing services that have proliferated since the last major regulatory pronouncements related to the Security Rule; and (4) rulemaking related to the provision of an accounting of PHI disclosures upon request to individuals.[22]

Maintaining the security and integrity of electronic medical records will continue to present challenges for the healthcare industry. Healthcare records and information will continue to be targeted by hackers and criminal elements. The increase in sharing of this information, whether under the flag of Meaningful Use or other similar programs, makes it more important than ever for data controllers and users to secure health information proactively rather than simply seeking to achieve "compliance" with regulatory models such as HIPAA.

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Footnotes

[1]Centers for Disease Control and Prevention, Meaningful Use. http://www.cdc.gov/ehrmeaningfuluse/introduction.html

[2]Ibid.

[3]*CMS Issues Final Rule To Extend Meaningful Use Requirements Tuesday,* September 2, 2014. http://www.ihealthbeat.org/articles/2014/9/2/cms-releases-final-rule-to-extend-meaningful-use-requirements

[4]An Introduction to the Medicare EHR Incentive Program for Eligible Professionals. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/beginners_guide.pdf

[5]*New CMS NPRM Offers Significant Meaningful Use Flexibility in 2015 through 2017 Program Years,* April 14, 2015. http://www.himss.org/News/NewsDetail.aspx?ItemNumber=41714

[6]Letter re: Medicare and Medicaid Electronic Health Record Incentive Program, September 28, 2015. https://ehrintelligence.com/images/site/attachments/Meaningful_Use_Letter.pdf

[7]Ibid.; http://www.medicareadvocacy.org/congress-passes-doc-fix-senate-unable-to-improve-the-bill-for-medicare-beneficiaries/

[8]*Congress Passes "Doc Fix" – Senate Unable to Improve the Bill for Medicare Beneficiaries,*

April, 2015. https://www.cms.gov/Newsroom/MediaRelease-Database/Fact-sheets/2015-Fact-sheets-items/2015-10-06.html

[9]*CMS Issues Stage 3 Meaningful Use Guidelines*, October 7, 2015. http://journal.ahima.org/2015/10/07/cms-issues-stage-3-meaningful-use-guidelines/

[10]*Slavitt: Meaningful Use is all but dead,* January 12, 2016. http://medcitynews.com/2016/01/slavitt-meaningful-use-all-but-dead/

[11]Id.

[12]*7 largest data breaches of 2015,* December 11, 2015. http://www.healthcareitnews.com/news/7-largest-data-breaches-2015

[13]*Cyberattack exposes data of 11 million Premera Blue Cross members,* March 17, 2015 .http://www.modernhealthcare.com/article/20150317/NEWS/150319904; *Excellus BlueCross BlueShield hacked; 10.5M patients affected,* September 10, 2015. http://www.washingtontimes.com/news/2015/sep/10/excellus-bluecross-blueshield-hacked-105m-patients/

[14]*Former Hospital Employee Sentenced for HIPAA Violations,* February 17, 2015. http://www.justice.gov/usao-edtx/pr/former-hospital-employee-sentenced-hipaa-violations

[15]*Eleven Individuals Charged With Stealing And Fraudulently Using Personal Information Of Blue Cross Blue Shield Subscribers,* March 11, 2015. http://www.justice.gov/usao-edmi/pr/eleven-individuals-charged-stealing-and-fraudulently-using-personal-information-blue

[16]Id.

[17]RESOLUTION AGREEMENT, St. Elizabeth's Medical Center and the United States Department of Health and Human Services, July 8, 2015. http://www.hhs.gov/sites/default/files/ra.pdf

[18]See e.g., RESOLUTION AGREEMENT, TRIPLE-S and the United States Department of Health and Human Services http://www.hhs.gov/sites/default/files/Triple-S%20-%20OCR%20Resolution%20Agreement%20and%20Corrective%20Action%20Plan%20in%20Final%20%28508%29.pdf (noting the effective date and term of the CAP).

[19]OCR Should Strengthen Its Oversight of Covered Entities' Compliance with the HIPAA Privacy Standards, September 2015. http://oig.hhs.gov/oei/reports/oei-09-10-00510.pdf

[20]OCR Should Strengthen its Follow up of Breaches of Patient Health Information Reported by Covered Entities, September 2015. http://oig.hhs.gov/oei/reports/oei-09-10-00511.pdf

[21]http://oig.hhs.gov/oei/reports/oei-09-10-00510.pdf at Page 11; Id. at 13.

[22]Jocelyn Samuels Gives Update on OCR Compliance Audits, September 4, 2015. http://www.hipaajournal.com/jocelyn-samuels-update-on-ocr-compliance-audits-8091/

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