Policy Brief

January 17, 2020

Medicare Tool May Have Exposed Thousands of Patients' Data

The Centers for Medicare and Medicaid Services (CMS) discovered a bug in their Blue Button 2.0, prompting them to temporarily shut down the data-sharing tool. Blue Button 2.0 is designed to allow Medicare beneficiaries to share their claims data with third-party software applications (apps), services and research programs. The bug caused more than 200 beneficiaries' claims data to be shared with the wrong app; thousands more had their data assigned to the wrong person. CMS has stressed that the security issue only impacts Blue Button 2.0, not Plan Finder or Medicare.gov. Below is more on the bug, which apps were impacted and what CMS is doing to remedy the issue.

What happened?

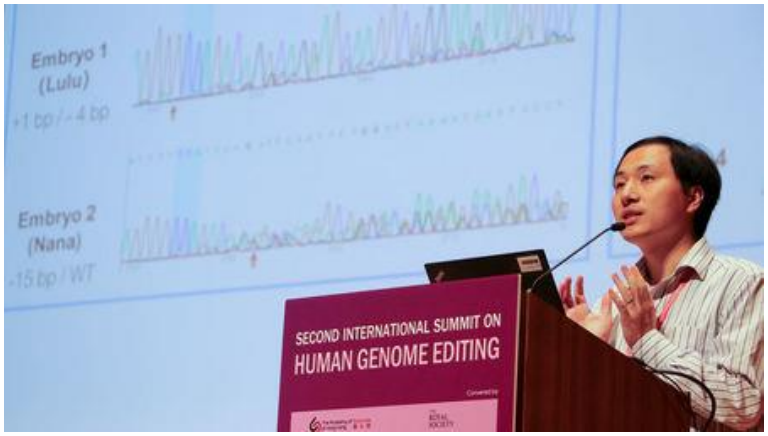
The Blue Button 2.0 system links claims data to a specific beneficiary using a randomly generated, unique user ID. These user IDs were then shortened and not sufficiently randomized, which caused some beneficiaries to end up with the same ID. No social security numbers or banking information appears to have been compromised. In the future, CMS is committed to more robust testing, code review and cross-team collaboration to prevent such errors.

Who was impacted?

Nearly 30 apps that use the Application Programming Interface (API) were impacted by the coding bug. Roughly 10,000 beneficiaries potentially had their protected health information inadvertently shared. CMS is in ongoing communication with these patients and is considering offering credit monitoring or extended enrollment periods as needed. Some of the affected apps include Humana, Rush University and Ascension Complete.

When can patients use Blue Button 2.0 apps again?

CMS is now allowing impacted third-party app developers to resume using the API. App developers must provide CMS with the details of their updated implementation plans; these must include steps to correct incorrect beneficiary data. As services are restored, all users will need to re-authenticate and will be given a new user ID.



Editing the Human Genome: How Far Should Science Go?

CRISPR stole the biopharmaceutical spotlight in 2019 with gene-based therapies that shattered cost records. However, when Dr. He Jiankui announced to the world that he had used this technology to alter twin embryos—a process known as "germline editing"—researchers recoiled. In the wake of Dr. He's recent sentence to three years in prison in China (for illegal practice of medicine), legislators and regulators in the U.S. must now contend with the reality of genetically modified humans. READ MORE about the germline editing controversy, the U.S. status quo and the critical role of the science community.

Why is germline editing controversial?

New gene therapies generally fix broken DNA in somatic cells (i.e., cells not involved in reproduction). Germline editing, however, modifies egg or sperm cells to correct mutations that result in often devasting inherited genetic diseases, like Huntington's Disease. This correction is then passed down through every successive generation. However, the same technology can be used to edit the human genome for virtually any trait, artificially—and permanently—altering the human species.

What is the U.S. doing about germline editing?

Germline editing is functionally illegal in the United States—but not in any federal criminal statute. Instead, an appropriations rider bans the Food and Drug Administration (FDA) from considering Investigational New Drug (IND) applications that involve genetically modifying an embryo for gestation.

While a Senate committee briefly took up the issue for consideration in 2017, the U.S. has been conspicuously quiet despite countries like the U.K. and Canada staking out clear positions. In 2019, some lobbied for a mitochondrial disorder exception to this policy, but it was not adopted.

Where can health system stakeholders weigh in?

Responsible use of germline editing could spell the end of dreaded diseases like muscular dystrophy and heritable cancers, but fears of widespread abuse of this science raise genuine concerns about increasing social divisions and health disparities. Accordingly, medical, bioethical and institutional researchers will be essential to educating state and federal legislators on appropriate safeguards as CRISPR continues to dominate the biotech frontier.

Will the New Director Reinvigorate CMMI?

Brad Smith, co-founder of the palliative care provider Aspire Health, was recently named as the new director for the Center for Medicare and Medicaid Innovation (CMMI). CMMI has faced brain drain as many of the top officials have left the agency. There has also been a delay in the release of expected models. Senator Lamar Alexander (R-TN) has said, "Brad has exactly the right experience to lead a center charged with coming up with innovative ways to lower health care costs and improve quality. He has founded a successful health care company and knows how state and federal governments work." Below is more about Brad Smith and what his experience may mean for CMMI and upcoming models.

Following in the footsteps of the previous CMMI director, Adam Boehler, Smith is another health care entrepreneur. He co-founded Aspire Health, a recognized health disrupter known for its innovative solutions for patients, such as developing workflows that better create specific interventions based on each individual. He also has an impressive educational background, graduating summa cum laude from Harvard University and being a Rhodes Scholar. In addition to co-founding Aspire, Smith spent time working at McKinsey consulting and was the former Chief Operating Officer of Anthem's Diversified Business Group where he led an array of emerging health businesses. Smith has also worked closely with several politicians, including Tennessee Republican Governor Bill Haslam and Senator Bob Corker (R-TN).

Smith's experience with innovating in health care and working with government officials may help increase CMMI's ability to launch models. CMMI has had many of their top experienced officials leave in the past few years, which may have played a role in the center's ability to launch models. CMMI also struggles with finding success in its models, as only two out of 37 models in 2018 were recommended for

expansion by the Government Accountability Office. Given Brad Smith's educational and professional background and disruptor mindset, could his leadership be enough to reinvigorate the Agency?

Federal Health Information Tech Agency Adds SDOH to 2020 Recommendations

In its annual update to the Interoperability Standards Advisory (ISA), the Office of the National Coordinator (ONC) for Health Information Technology (HIT) now encourages health systems to capture patient data on social determinants of health, specifically access to food, transportation and housing, as well as drug use. As a priority of post-Affordable Care Act (ACA) health transformation, interoperability involves ensuring electronic medical and health records systems work together seamlessly to improve quality of care and patient experience. The ONC serves as the federal lead on promoting interoperable health systems, and its guidance serves as an aspirational standard for the industry.

Part I Advanced Notice on Changes to the Medicare Advantage Risk Adjustment Model

On December 20, 2019, CMS released an advanced notice of the Risk Adjustment Model Part I changes for Medicare Advantage. This advanced notice includes the continued transition of the new risk adjustment model that meets the requirements of the 21st Century Cures Act. These requirements include adding chronic kidney disease and behavioral health as payment conditions and adjusting for a beneficiary's total number of medical conditions in the risk score. Additionally, CMS proposes to further shift from using diagnosis data to determine a beneficiary's risk score to using encounter data that includes records of providers' products and services. Part II of the advanced notice will be released next month. Comments on Part I are due March 6, 2020.

A Look at the Federal Register

Annual Update of the Health and Human Services Poverty Guidelines

The Department of Health and Human Services (HHS) released a notice of its updated poverty guidelines to account for last calendar year's increase in prices as measured by the Consumer Price Index. The poverty threshold for a household of four is now $26,200.

Annual Civil Monetary Penalties Inflation Adjustment

HHS also issued a proposed rule updating civil monetary penalties for violation of its regulations. These updates are inflation-related increases.

Ensuring Equal Treatment of Faith-Based Organizations

HHS released a proposed rule that seeks to provide regulatory clarification and bring current regulations into conformity with Trump administration policy, legal decisions and the Religious Freedom and Restoration Act, which have relaxed non-discrimination requirements applicable to faith-based health care providers.

Coordinating Care from Out-of-State Providers for Medicaid-eligible Children with Medically Complex Conditions

CMS issued a request for information seeking input on how to best work across state lines to reduce barriers to care for medically complex kids, including ways to improve timeliness, screening and enrollment for benefits and ease of administration.

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