

*Aida Herenda (J.D. anticipated 2019) of Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Associate Director, supervised.*

### **Rethinking Perspective of HIV Exposure Lessons from California’s New Legislation**

California is departing from precedent with the enactment of SB 239, a statute reducing criminal charges for those living with HIV. The statute replaces felony charges with misdemeanor charges, while reserving penalties for the intentional transmission of HIV; repeals felony charges for solicitation by those with a positive HIV status; and decriminalizes the donation of blood or tissue by those living with HIV. California distinguishes itself from the rest of the country, where currently 34 states have HIV-specific criminal statutes and 23 have general statutes which criminalize HIV exposure. While retribution and deterrence are arguments for the criminalization of HIV exposure, evidence indicates that penalties are unevenly imposed on the basis of race and sex and that the presence of HIV-specific statutes does not make an impact on disclosures of HIV positive status. By treating transmission of HIV similarly to the transmission of other serious communicable diseases, California makes a positive impact on public health by reducing the stigma around HIV and encouraging people to get tested and learn their status. Y. Tony Yang and Kristen Underhill, *New England Journal of Medicine*, March 29, 2018 <http://www.nejm.org/doi/pdf/10.1056/NEJMp1716981>

### **Trump Administration Proposes Rule to Loosen Curbs On Short-Term Health Plans**

The Trump Administration has released a proposed rule that would allow insurers to once again sell short-term health insurance plans. Short-term health insurance plans are cheaper than ACA-compliant Marketplace plans, but most of these plans exclude coverage for maternity care, preventive care, mental health services, and substance abuse treatment. However, short-term plans could provide more choices to the market and broaden provider networks in rural areas. Anywhere from 100,000 to 200,000 “healthy people” are estimated to switch from ACA-compliant plans to a short-term plan. A shift of this size will cause premiums to increase, which in turn will cause federal subsidies for ACA Marketplace plans to rise, costing the government anywhere from \$96\$168 million. Julie Appleby, *Kaiser Health News*, Feb. 20, 2018 <https://khn.org/news/trump-administration-unveils-proposed-rule-to-loosen-restrictions-on-short-term-health-plans/>

### **CMS Cites University of Maryland Hospital for EMTALA Violations**

Following widespread outrage from a video showing the mishandling of a mentally ill patient, the University of Maryland Medical Center has been cited by the Centers for Medicare and Medicaid Services (CMS) for violating the Emergency Medical Treatment and Labor Act (EMTALA). EMTALA requires emergency departments to screen patients for emergency medical conditions and provide stabilizing treatment, regardless of a patient’s ability to pay. The video which prompted the investigation by CMS, featured

two security guards from the hospital abandoning a mentally ill patient, clad in nothing but socks and a gown, at a bus station in freezing temperatures. CMS' investigative report indicates that hospital security guards were responsible for deciding who could enter the hospital's locked ED waiting room, but the security guards involved with the incident were unaware of EMTALA requirements. CMS has accepted the hospital's corrective plan for addressing the deficiencies identified by an internal root cause analysis, an independent analysis by outside experts, and an audit by the Joint Commission. Harris Meyer, *Modern Healthcare*, March 20, 2018  
<http://www.modernhealthcare.com/article/20180320/NEWS/180329990/cms-cites-university-of-maryland-hospital-for-emtala-violations>

### **Trump Clears Path for States to Require Employment for Medicaid**

The Trump Administration has moved to allow states to impose work requirements to Medicaid programs for able-bodied and working-age Americans. Although the administration believes the requirements will strengthen the program and improve health outcomes by encouraging Americans to seek jobs, others fear that the number of uninsured Americans may increase. Medicaid is the largest provider of health insurance for Americans, with about 72 million covered by the program in 2017. New state systems will be necessary to determine who is subject to these work requirements and whether beneficiaries have fulfilled them, increasing the risk that those with the most barriers to work and individuals who fail to submit adequate documentation will lose their benefits. Roughly ten states have proposed adding work or community engagement requirements to their programs. Centers for

Medicare and Medicaid Services Administrator Seema Verma announced that the federal government will begin approving state plans for work requirements soon. Zachary Tracer, Justin Zink, John Tozzi, *BNA*, Jan. 11, 2018  
<https://www.bloomberg.com/news/articles/2018-01-11/trump-clears-path-for-states-to-require-employment-for-medicaid>

### **SCOTUS Nixes CareFirst Plea to Decide Data Breach Harm Standard**

The United States Supreme Court has decided not to respond to a request for review by CareFirst Inc., to answer how much harm a data breach victim must suffer to bring claims in federal court. Data breaches were at an all time high in 2017, and a split among federal appeals courts has left plaintiffs, attorneys, and companies awaiting an answer. Whereas, the Third and Fourth Circuits have ruled that mere fear of identity theft is too speculative of a harm to have standing in federal court, the Sixth, Seventh, Ninth, and DC Circuits have found that substantial fear of identify theft does constitute a sufficient harm to bring claims in federal court. The Supreme Court's refusal to review this question signals support for the Court's previous holding in *Spokeo, Inc. v. Robins*, noting plaintiffs must allege imminent or actual harm rather than speculative harm to have standing in federal court. Daniel R. Stoller, *BNA*, Feb. 20, 2018  
<https://www.bna.com/scotus-nixes-carefirst-n57982088996/>

### **CMS to Form Interagency Group to Review Stark Law**

The Centers for Medicare and Medicaid Services (CMS), the Department of Health and Human Services' Office of Inspector General, the Department of Health and Human Services' general counsel, and the Justice Department will convene in an effort

to deduce how to lessen the impact of the Stark Law on new value-based care models. The Stark Law prohibits physicians from referring patients to entities that provide designated health services with whom they have a financial relationship, unless a specific exception applies. One of the central tenets of value-based care is paying providers more when they meet certain quality metrics, but the Stark Law prohibits this as well, as such agreements are not susceptible to a fair-market value assessment. Although agencies are in favor of modernizing the application of the Stark Law, CMS Administrator Seema Verma has indicated that Congress will need to step in to truly effectuate a transformation of the Stark Law. Virgil Dickson, *Modern Healthcare*, Jan. 17, 2018  
<http://www.modernhealthcare.com/article/20180117/NEWS/180119915>

### **Cigna to Buy Express Scripts in \$52 Billion Health Care Deal**

As a wave of consolidations sweep through the health care industry, health insurance giant Cigna has announced its plan to purchase Express Scripts, the nation's largest pharmacy benefit manager. However, as the final major independent pharmacy benefit manager left for smaller insurers, the Federal Trade Commission and Department of Justice may not approve the acquisition. Vertical integration is happening across the health care industry, with just recently CVS Health and health insurer Aetna announcing a merger. This increase in vertical integration may be traced to rising health care costs for employers and consumers, unfavorable scrutiny of pharmacy benefit managers in recent years, and concerns about Amazon, JPMorgan Chase, and Berkshire Hathaway entering the health care industry. Antitrust experts are unsure how such mergers are going to impact the health care market, but

they predict the Justice Department will be on high alert for any anticompetitive effects.

Katie Thomas, Reed Abelson, and Chad Bray, *New York Times*, March 8, 2018  
<https://www.nytimes.com/2018/03/08/business/dealbook/cigna-express-scripts.html>

### **Can This Judge Solve the Opioid Crisis?**

Judge Dan Aaron Polster of the Northern District of Ohio is tasked with resolving more than 400 federal lawsuits surrounding the national opioid tragedy involving opioid manufacturers, distributors, and the pharmacy chains selling them. Judge Polster, who has experience mediating settlements in multidistrict litigation, ordered lawyers in the first hearing for the current case to prepare for settlement discussions immediately, indicating a refusal to spend years dragging out the case with traditional litigation. Touched by a personal experience related to the opioid crisis, Judge Polster has shown concern for the number of lives at stake each day that a resolution is delayed. Judge Polster's approach to handling the opioid lawsuits is already having an impact on the national crisis, with Purdue Pharma, the makers of OxyContin, announcing that they would no longer market OxyContin to prescribers. Jan Hoffman, *New York Times*, March 5, 2018  
<https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html>

### **Nakesha Williams Died Homeless on a Manhattan Street. Should She Have Been Forced Into Treatment?**

Nakesha Williams had a bright future ahead of her as a successful graduate of Williams College, but after developing serious mental issues and turning down aid from friends and outreach workers, she passed away at the age of 46, homeless on the streets of New York.

Sam Tsembris, founder of a nonprofit that helps homeless people secure housing, describes the ethical and legal issues associated with involuntary commitment programs for homeless people with mental illness. Ultimately, involuntary confinement requires someone to be an immediate danger to themselves or others, a factor Ms. Williams did not meet. Furthermore, although Ms. Williams was mentally ill, she was clear in her conversations with others about her preference to remain homeless instead of entering programs where she did not feel safe. In order for Ms. Williams to have been involuntarily committed, a petition would have been required in the mental health court of a hospital, stating that Ms. Williams was noncompliant with treatment and a danger to herself. However, the careful balance of , rights to make their own choices and keeping them healthy can be difficult and requires a “radical acceptance” of their point of view. Benedict Carey, *New York Times*, March 6, 2018  
<https://www.nytimes.com/2018/03/06/health/nakesha-williams-involuntary-commitment.html>

### What Happens When Amazon Takes on Health Care?

In head-turning news, Amazon, Berkshire Hathaway, and JPMorgan Chase, announced their plan to enter the health care sector as a new joint enterprise to exclusively serve the health care needs of the 1.2 million individuals employed by the three companies. The growing cost of health care seems to have been the key factor behind the unification of these three industry giants. If the enterprise is as effective as it is anticipated to be, reduced health care costs will not just benefit the three companies but also make a meaningful impact on the lives of their employees, with improved access to care and less of their paycheck spent on health care. Karl Vick, *Time Magazine*, Feb. 1, 2018

<http://time.com/5128377/amazon-and-friends-takes-on-a-new-industry-health-care/>

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### Blind Boy Might Be Able to See Again After New Breakthrough Gene Therapy Surgery

Nine-year-old Creed Pettit was the first person to receive Luxturna, possibly the first true gene therapy in existence. Creed has a rare genetic retinal disease called Leber congenital amaurosis, which causes blindness in adulthood. In December 2017, the FDA approved Luxturna.

This gene therapy utilizes a virus for delivering the corrected gene, which is injected under the retina of the patient. For Creed, the virus carried a corrected copy of RPE-65, which is responsible for making a protein essential to the health of the retina. Creed will receive gene therapy in his right eye first, then the left the following week. Dr. Bryon Lam, Creed’s physician, expects improved vision, but not perfect vision.

Luxturna is not a gene editing therapy, but rather injected corrected copies of the gene into the retina. However, Dr. Lam does not know what long-term effects of the therapy will be. For gene therapy in both eyes, Luxturna costs \$850,000, but Pettit’s insurance will cover the therapy. Now, we just have to wait and see what the future holds for Creed. Kate Sheridan, *Newsweek*, March 21, 2018  
<http://www.newsweek.com/9-year-old-gets-new-breakthrough-gene-therapy-blindness-853908>

## Opioid Epidemic So Dangerous, Says CDC, It's Finally Killing as Many Americans As Guns

According to the CDC, over 42,000 people died from opioid abuse in 2016. This figure is five times higher than in 1999. Because of this alarming increase in incidence, we have an opioid epidemic. While it is truly a tragedy and measures must be taken to fight opioid addiction, the number of fatalities from opioid abuse in 2016 highlights another problem: gun violence.

In 2016, over 38,000 people were killed in gun-related incidents. 2016 is the first year that deaths from opioid abuse surpassed those from gun violence—yet we don't speak about the epidemic of gun violence because the statistics have been stable over many years. However, the number of deaths from firearms has been increasing some the last several years.

Since the deaths associated with firearms are well-documented, the CDC ought to spend more on research related to firearms and public safety. But the 1996 Dickey Amendment prohibits the CDC from studying gun violence in its relation to public safety for the promotion of gun control. The statistics of the opioid epidemic should highlight the persistent epidemic of gun violence, causing us to examine our underlying ideological commitments. Ethan Siegel, *Forbes*, March 20, 2018

<https://www.forbes.com/sites/startswithabang/2018/03/20/opioid-epidemic-so-dangerous-says-cdc-its-finally-killing-as-many-americans-as-guns/#5f70cf306c21>

## Mississippi Imposes 15-Week Abortion Ban; Nation's Toughest

Mississippi now has the most restrictive abortion laws in the United States, banning most abortions after 15 weeks gestation. Republican Gov. Phil Bryant signed House Bill 1510 in a closed ceremony attended by supporters of the bill. This bill was immediately challenged by the Jackson Women's Health Organization, who argue that this bill is unconstitutional.

Under this new bill, abortion after 15 weeks gestation is only permitted if the fetus has health problems that are incompatible with life outside the womb or if the mother's health is in serious danger. Pregnancies resultant from rape and incest are not exempted.

In an email about the bill, Lt. Gov. Tate Reeves hoped to make Mississippi "the safest place in America for an unborn child." Jeff Amy and Sarah Mearhoff, *The Washington Post*, March 19, 2018

[https://www.washingtonpost.com/national/health-science/mississippi-imposing-nations-toughest-15-week-abortion-ban/2018/03/19/48eea592-2b5d-11e8-8dc9-3b51e028b845\\_story.html?utm\\_term=.67decf03fc62](https://www.washingtonpost.com/national/health-science/mississippi-imposing-nations-toughest-15-week-abortion-ban/2018/03/19/48eea592-2b5d-11e8-8dc9-3b51e028b845_story.html?utm_term=.67decf03fc62)

*Jacob Harrison, Ph.D. student, Albert Gnaegi Center for Health Care Ethics, Saint Louis University, contributed the following items to this Of Note column.*

## U.S. Immigration Policy Threatens Shake-Up in Home Health Business

Currently in the United States there are around three million people who provide homecare to the elderly and a quarter of these homecare providers are immigrants. The consideration by Congress and the White House to change the immigration policy has some within the homecare industry concerned that there will not be

enough people to care for the nation's growing elderly population.

Robyn Stone, senior vice president for research at Leading Age, which represents the nonprofit side of long-term care, argues, "If we shift in our policy [on] immigration, the pipeline for this workforce could be substantially affected." Furthermore, according to the article, the nation's rapidly aging population has made personal care assistants and home health aids the fastest growing low-skilled occupation in the United States.

Others, such as Steven Camerota, director of research at the Center for Immigration Studies, which advocates for restrictions on immigration, do not believe tighter immigration policies will hurt the home health business. He points to the many unemployed U.S. citizens that could fill these jobs.

The extent to which a change in immigration policy will impact the home health business remains to be seen but for those like Zoila Gutierrez, policy changes could have a personal impact. Gutierrez came to Albuquerque in 2004 without documentation, while her youngest is a citizen and her two older children are both registered under DACA. For her, being in a class to prepare her to be a state-certified home health aide is more than just an increase in her paycheck, it is a job where she finds meaning in caring for the elderly. Ina Jaffe, *National Public Radio*, March 5, 2018 <https://www.npr.org/sections/health-shots/2018/03/05/587691189/immigrants-who-staff-home-health-care-in-the-u-s-worry-about-deportation>

### **You've Detailed Your Last Wishes, but Doctors May Not See Them**

Dr. Daniela Lamas, through her work in the I.C.U., has felt firsthand the frustration of trying to search through electronic records for notes and scanned documents. Dr. Lamas has spent the last year researching advanced health care planning and electronic health records by interviewing clinicians who have first-hand experience of trying to retrieve these documents and talking with companies that are behind some of the most widely-used electronic records.

In the absence of nationwide standards, Dr. Lamas says, there is significant variability among hospitals as to the accessibility of end-of-life documentation. Even in hospitals such as her own where there is an "Advance Care Planning" tab, difficulties remain in accessing these documents. Dr. Lamas explains, "Habits are hard to break, and without a clear set of incentives, training and ongoing education, doctors (myself included) continue to record information about end-of-life conversations in progress notes, where they are not readily available, particularly when they are urgently needed." These difficulties become especially problematic when patients receive treatments that they have previously expressed they do not want, but the documentation of the advance wishes are lost or missed because of a difficulty locating the document.

Through her research, Dr. Lamas often heard that creating standards of sharing or "interoperability" across all electronic records would make a meaningful difference in ensuring that a patient's end-of-life wishes are not missed by the physicians. She says that maybe patients should be able to access their health records through a patient-facing interface that allows them to send in their own directives and possibly update related notes. But currently, health care is playing catch-up, which is putting patients at risk for receiving care that goes against their wishes.

Daniela Lamas, M.D., *The New York Times*, March 27, 2018,  
<https://www.nytimes.com/2018/03/27/well/live/advance-directive-end-of-life-wishes-electronic-health-record.html?rref=collection%2Fsectioncollection%2Fhealth&action=click&contentCollection=health&region=stream&module=streamunit&version=latest&contentPlacement=6&pgtype=sectionfront>

### **HHS Takes Major Actions to Protect Conscience Rights and Life**

On Jan. 19, 2018, the U.S. Department of Health and Human Services (HHS) announced two actions being taken to protect life and the conscience rights of Americans. The HHS' Centers for Medicare & Medicaid Services (CMS) issued new guidance to state Medicaid directors that rescinds a 2016 guidance that restricted states' ability to take certain actions against family-planning providers that offer abortion services.

Secondly, HHS' Office for Civil Rights (OCR) announced a "new proposed rule to enforce 25 existing statutory conscience protections for Americans involved in HHS-funded programs, which protect people from being coerced into participating in activities that violate their consciences, such as abortion, sterilization, or assisted suicide." OCR Director Roger Severino says that the new proposed rule will provide the new Conscience and Religious Freedom Division with enforcement tools for these conscience laws. HHS Press Office, January 19, 2018, *U.S. Department of Health & Human Services*,  
<https://www.hhs.gov/about/news/2018/01/19/hhs-takes-major-actions-protect-conscience-rights-and-life.html>