

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, associate director, supervised the contributions of Michelle Meloche (J.D. anticipated 2019) and Nicole Strombom (J.D./M.H.A. anticipated 2020).

Costs of Zika Among the Many Unknowns of the Virus

The Zika virus, which has been linked to microcephaly in infants, poses a potential threat to the United States, but the federal government has not yet addressed funding to address the Zika epidemic. Children born with microcephaly will need increased medical attention and likely several million dollars worth of medical care into adulthood. The scientific work surrounding Zika faces strict regulatory hurdles that will need to be overcome to effectively fight Zika. The Zika outbreak is being equated to the rubella outbreak in the 1960s, which was the last time the United States faced the scare of potentially widespread disease with long-term health and financial impacts. The World Bank has estimated that Zika will cost the world \$3.5 billion in 2016. The process for vaccine development and testing can take more than ten years. If a Zika vaccine is not created, federal and local public health officials will need to spend their own funds to educate individuals about the risk of Zika, without truly knowing how the disease spreads. The

spread of Zika may not be limited to the vector of mosquitos. Shannon Muchmore, *Modern Healthcare*, July 20, 2016
<http://www.modernhealthcare.com/article/20160720/NEWS/160719976>

Big Driver of Medicare Spending: Doctors Doing More Tests in Their Offices

In recent years, several medical tests and procedures have become more readily available due to new products that allow doctors to perform the tests in their office. Doctors can perform the test or procedure immediately instead of having to provide a patient a referral. Examples include testing sweat response to low-voltage currents to determine nerve damage, testing tear saltiness for dry eyes, and electro brachytherapy that can be used for either breast cancer or skin cancer treatment. The increased frequency of these tests and procedures has increased costs to the Medicare system. Any unexpected spike in the Medicare system, though small in comparison to the whole Medicare budget, plays a role in increased health care costs. New tests can be lucrative for doctors because Medicare sets prices based on assumptions of time and costs of procedures so new tests often require guess work to establish the original price. Therefore, a test that is actually simple and cost efficient may have a high reimbursement rate in the Medicare system at the outset. New tests or products can also be used in a

way the Medicare system did not predict. The utility rate of the test is observed alongside an increased payout from the Medicare system, which takes time. Billing codes are eventually reassessed and reflect the new technology's actual implementation, time for the procedure, and cost. Implementing new technologies can be lifesaving and Medicare approval of these tests and procedures is a balancing act. Christopher Weaver and Coulter Jones, *The Wall Street Journal*, August 9, 2016 <http://www.wsj.com/articles/big-driver-of-medicare-spending-doctors-doing-more-tests-in-their-offices-1470762389>

Scores of Students Without Vaccine Proof Sent Home on First Day of School

A new statewide law took effect on July 1, 2016 that eliminates personal belief exemptions and religious-belief exemptions for children. Governor Jerry Brown signed legislation into law last year that makes California the third state to eliminate religious and personal belief exemptions for vaccinations. The law was sparked by a measles outbreak, which steamed from exposure at Disneyland. Throughout California, immunization records are checked at kindergarten, seventh grade, and when a child transfers schools. At the start of this school year several hundred students were sent home around the Sacramento area for lacking proof of vaccination. Within the first week of school,

many children who were turned away on the first day were able to obtain the needed vaccinations and begin attending classes. Immunizations have been required in California since 1962 when the polio vaccination became required. School districts first tracked immunization records, in California, during the 1978 school year. Loretta Kalb, *The Sacramento Bee*, August 12, 2016

http://www.sacbee.com/news/local/education/article_e95393367.html

Medical Devices Are Finally Marked With Unique IDs. Only A Few Hospitals Can Use Them.

The Food and Drug Administration has rolled out a new policy for unique medical device identifier system to help track down medical devices if something goes wrong or if a recall needs to be issued. The software-based system will help ensure a better standard of care for patients in a medical market that constantly sees new products and advancements. By 2020, the unique device identifier system will be routine for all classes of medical devices both on the production and use side. The unique device identifiers have been shown to prevent procedure delays, lower costs, and increase revenues through more efficient management of medical device inventories. Manufacturers and distributors have embraced the new system, but hospitals are scrambling to catch up. Many hospitals lack the software necessary to implement the new

protocol causing slow adoption of the use of unique device identifiers. The CMS has begun incorporating unique device identifiers into regulations for electronic health record products. Customer demand for unique device identifiers will likely drive the market to become adopted quickly as the system offers improved patient safety. Adam Rubenfire and Joseph Conn, *Modern Healthcare*, September 17, 2016
<http://www.modernhealthcare.com/article/20160917/MAGAZINE/309179999>

When Should Children Take Part in Medical Decisions?

A new policy statement addressing the issue of informed consent by pediatric patients, with a companion technical report, was released this August by the American Academy of Pediatrics. The policy discusses how children as young as seven may be capable of expressing informed agreement, which leads to the issue of their ability to give informed consent, and assent. Moving toward a pediatric practice with children being properly informed and involved in the medical discussion is hoped to “foster the moral growth and development of autonomy in young patients.” Dr. Aviva Katz, pediatric surgeon and director of the Ethics Consultation Service at the Children’s Hospital of Pittsburgh, explains that integrating children into their own medical decisions and treatments when

they are young will better prepare them to make knowledgeable and informed decisions when they are of legal age. The policy does not, however, expect children to be the sole decision maker in their health care; parents and physicians will still give the final say in important decisions, such as life-sustaining treatments and surgeries. The goal of the policy is to include children in as much of the medical process as possible, so they feel comfortable making their own decisions in the future. Perri Klass, *New York Times*, September 20, 2016
<http://www.nytimes.com/2016/09/19/well/family/when-should-children-take-part-in-medical-decisions.html>

The Pill Mill Doctor Who Prescribed Thousands of Opioids and Billed Dead Patients

Hussein Awada, convicted of unlawful distribution of a controlled substance and conspiring to commit health care fraud in December 2012 and sentenced to seven years in federal prison last November, has agreed to pay \$200,000 in settlement for the lawsuit accusing him of falsifying records to charge dead patients, subjecting patients to unnecessary tests, billing for office visits that never happened, and other such offenses. Awada wrote prescriptions for 80,000 doses of Oxycodone, Roxicodone and other painkillers to groups of patients recruited by James Lyons, a marketer who then bought the pills from said patients he recruited, reselling the pills to street

drug dealers. U.S. Attorney Lynn Helland states “He contributed in a very large way [to Michigan’s opiate epidemic] for a period of at least two years...he did that as a doctor with a license, who, of all people, should have known the impact his prescribing was having on a broader community.” Disturbingly, once Awada is released from prison, he can try to get his license reinstated. He did, however, voice his shame during the sentencing hearing, saying, “I assume full and complete responsibility for my actions. I deeply regret the shame I have brought to my family...I apologize for the patients who I may have caused harm and who I have hurt by these actions.” Attorney General Loretta Lynch spoke about the urgency of the opioid epidemic. “What we face is not just...a public health crisis. We have a moral crisis—a test of whether we...can protect our children, our friends, our neighbors...from the scourge of addiction.” A federal study found that 1 in 3 American adults were prescribed painkillers by medical providers last year. Substance Abuse and Mental Health Services Administration stated in 2015 that “prescription painkillers are more widely used than cigarettes, smokeless tobacco or cigars, combined.” Kristine Guerra, *The Washington Post*, September 22, 2016
<https://www.washingtonpost.com/news/to-your-health/wp/2016/09/22/deceitful-pill-mill-doctor-who-prescribed-thousands-of-opioids-and-billed-dead-patients-settles-civil-lawsuit/>

Federal Drug Testing Rules Race to Catch Up to Illegal Prescription Drugs

Due to a locomotive accident caused by illegal drug use by operators, Congress ordered in 1991 that public transportation operators and Coast Guard members be drug tested for five critical drugs: marijuana, cocaine, amphetamines, natural opiates, and PCP. With the significant rise in the addiction to prescription painkillers in recent years, the federal drug-testing program is currently developing a new panel of testing for the common synthetic drugs being abused. Of most concern is the staggering increase in deaths from illegal use of prescription drugs. At the turn of the century, these deaths were synonymous with the deaths from cocaine at about 4,000. By 2013 these deaths have nearly quadrupled for synthetic prescription drugs, defining the abuse as an epidemic. Most recently, “the largest increase in the rate of drug overdose deaths involved synthetic opioids...A record 28,647 people died from heroin and prescription opioid use in 2014,” the Centers for Disease Control and Prevention reports. Because of these devastating facts, the Substance Abuse and Mental Health Services Administration (SAMHSA) is pushing for change in rules as soon as possible. It is projected that the transportation workers will be required to be tested for illegal prescription drugs by 2017. Ashley Halsey III, *The Washington Post*, September 19, 2016

https://www.washingtonpost.com/local/trafficandcommuting/federal-drug-testing-rules-race-to-catch-up-to-illegal-prescription-drugs/2016/09/19/6980ab1a-7b6f-11e6-ac8e-cf8e0dd91dc7_story.html

Clinton Just Made a Very Important Announcement—and Hardly Anyone is Talking About It

On August 29, Hillary Clinton proposed a wide-ranging mental-health strategy that many find to have a substantial chance of becoming law. The most pressing issue addressed in Clinton’s announcement is treating mental health with the same precedence as physical health, first by abolishing “old payment systems that shortchanged mental-health care and using the federal government’s role as a major payer in the health industry to encourage integrating mental-health care into medical practice.” The plan proposes \$5 billion allocated to community health centers offering mental-health and substance abuse treatment in addition to traditional medical care. Mindful of the shortage of mental-health professionals, Clinton encourages telemedicine, and other alternatives. The proposal includes expanding the budget for basic scientific research, such as studying the brain. A significant hurdle in passing mental-health reform law is the disagreement over the source of funding. Clinton also avoided some of

the most controversial issues, like requiring seriously mentally ill people to get care through so-called assisted outpatient treatment. It is thought that requiring the treatment would serve those most in need, and best use the funding for community health centers. Overall, Clinton’s focus on mental health is “warranted and welcome” as it is predicted to “do some real-world good.” Editorial Board, *The Washington Post*, August 31, 2016

https://www.washingtonpost.com/opinions/clinton-just-made-a-very-important-announcement--and-hardly-anyone-is-talking-about-it/2016/08/31/5379ddfe-6ef5-11e6-9705-23e51a2f424d_story.html