OF NOTE

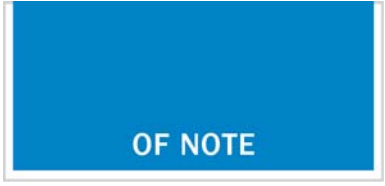
A student from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, associate director, supervised the contributions of Drew Canning (J.D. anticipated Dec. 2018).

Health Exchange Subsidies and Lawsuit Continue

The Trump administration will continue $7 billion cost-sharing subsidy payments to insurers while also appealing a 2016 Federal District Court ruling that stated without an appropriation bill from Congress, the payments are unconstitutional and should cease. The announcement arrives right as insurers prepare their Qualified Health Plan applications to participate in the 2018 exchange marketplace. Different from the tax credits marketplace members receive, these subsidies compensate insurers for lowering out-of-pocket cost for certain low-income consumers. Filed in 2014, the suit aimed to stop these cost-sharing payments because Congress had not authorized the funds but insurers continued to be reimbursed through the U.S. Department of Health and Human Services. If the appeal is dropped, the District Court's decision would stand and potentially allow future political disputes between the legislative and executive branches to be heard. The American Health Care Act that was withdrawn from a vote in the House on March 24 would have eliminated the cost-sharing subsidies. Robert Pear, *New York Times,* April 10th, 2017 https://www.nytimes.com/2017/04/10/us/politics/affordable-care-act-trump-subsidies.html?_r=0

FDA Delays Intended Use Rule

The Food and Drug Administration (FDA) has delayed a final rule concerning "Intended Use" at the behest of drug and device manufacturers. Delayed until March 19, 2018, the regulation impacts how manufacturers may speak about off-label uses of their products as well as what evidence may be shown in determining off-label use. Of issue to drug and device manufacturers is how the FDA released the regulation. In the proposed rule, the FDA had indicated off-label use would not be "based solely on [manufacturer's] knowledge", however the final rule added a "totality of the evidence" standard which manufacturers fear limits their due process and free speech rights. Additionally, drug and device manufacturers contend the additional language violates the Administrative Procedure Act and did not provide fair notice or an opportunity to comment. The FDA is now seeking comments through June 18, 2017. Dana A. Elfin, *BNA*, March 20th, 2017 https://www.bna.com/drug-device-industries-n57982085440/



Removal of Health Insurance Antitrust Exception Passes House, Needs Senate

The House of Representatives passed H.R. Bill 372 overwhelmingly, 416-7, in an effort to increase competition within health insurance. The Bill would remove an antitrust exemption that protected health insurers from prosecution due to sharing data. Currently, health plans can share data to help set premiums with no fear of antitrust prosecution. The fear is this interaction among health plans allows premiums to be set higher and negatively impacts consumers. However, the Congressional Budget Office estimates no significant effect on premiums or federal revenue due to the bill. The protection stems from the 1945 McCarren-Ferguson Act with the goal of allowing companies entering the insurance market to access other firm's data without fear of antitrust violations. Safe harbors would continue to exist for insurers that share historical loss data, performance of actuarial services, determination of loss development factors, and use of common forms. Alexei Alexis, *BNA*, March 23, 2017 https://www.bna.com/house-votes-lift-n57982085581/

ACA Provision Cuts 65,000 Medicaid Providers from State Databases

An Affordable Care Act provision aimed at reducing fraud, waste, and abuse, required providers to revalidate or recertify their Medicaid reimbursement eligibility before September 25, 2016. *Modern Healthcare* assembled data from 15 Medicaid agencies and determined 65,000 providers have been stripped from the federal program thus far. The impact is focused on providers who had enrolled in Medicaid prior to March 25, 2011. As states review provider's revalidation notices they are finding letters are returned due to wrong addresses, providers no longer wish to be part of the program, or they initially enrolled because of one patient. Medicaid has been criticized for low reimbursement to providers, roughly 60 percent of Medicare rate. However, improper Medicaid payments totaled $30 billion in 2015. Virgil Dickson, *Modern Healthcare*, February 22, 2017 http://www.modernhealthcare.com/article/20170222/NEWS/170229978

Potential Future of Children's Health Care Coverage – CHIP, ACA, Medicaid

The uninsured rate for children through age 17 is at an all-time low of 5 percent, nearly half of where it was ten years ago, due to expanded coverage and

funding from Medicaid, Children's Health Insurance Program (CHIP), individual exchange plans, and private family plans. Of the four million uninsured children, most qualify for Medicaid and CHIP but are not enrolled and thus miss the positive outcomes of health, school, and economic success associated with access to health care. Currently, 48 states have expanded Medicaid/CHIP eligibility to more than 200 percent of the Federal Poverty Limit. Additionally, CHIP and CHIP-Funded Medicaid programs receive federal matching funds between 88 percent and 100 percent, 23 percent of which is mandated by the ACA. Unfortunately, CHIP funding is set to end September 30, 2017 unless Congress renews funding. If funding is lost, 1.1 million children would become uninsured, others would shift to parents' plans or exchange plans, and states would have to cover the loss in federal matching to CHIP only programs. Accordingly, the Medicaid and CHIP Payment and Access Commission (MACPAC) has recommended extending CHIP funding through 2022 as well as keeping mandated ACA increase in matching funds. Should the ACA be repealed, it is estimated 4.4 million additional children would become uninsured. Likewise, changes to Medicaid such as proposed block grants will impact children's coverage since the size and scope of Medicaid is much broader than CHIP and states would have to contribute more to maintain existing benefits. Samantha Artiga and Petry Ubri, *Kaiser Family Foundation*, February 17, 2017 http://kff.org/medicaid/issue-brief/key-issues-in-childrens-health-coverage/

Medical Malpractice Reforms Quietly Progress

A series of bills aimed at changing the civil justice system's treatment of medical malpractice suits (Lawsuit Abuse Reduction Act, Innocent Party Protection Act, and Fairness in Class Action Litigation Act) have passed the House of Representatives and now await the Senate. The proposed changes supported by doctors, corporations, and the U.S. Chamber of Commerce include: limiting monetary awards to $250,000 for noneconomic damages such as pain and suffering; allowing class action lawsuits only if every person had an injury of the same type and scope; shifting claims to federal courts from state courts; and allowing federal judges to sanction attorneys. Opponents worry about a possible chilling effect on cases as well as the speed with which Congress would change the civil court system. Kimberly Kindy, *Washington Post*, March 9, 2017 https://www.washingtonpost.com/national/house-gop-quietly-advances-key-elements-of-tort-reform/2017/03/09/d52213b2-0414-11e7-b1e9-a05d3c21f7cf_story.html?tid=ss_mail&utm_term=.438607c658af