OF NOTE

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

The Opioid Crisis Is at Its Worst in Rural Areas. Can Telemedicine Help?

The White House's declaration of the opioid epidemic as a public health emergency on Oct. 26 is stimulating conversation on how to deliver opioid treatment to rural communities in America who are among the hardest hit by this epidemic. Jamey Lister, assistant professor of social work at Wayne State University, in a recent article for *The Conversation*, writes about the prospect of using telemedicine for opioid treatment.

Opioid treatment usually combines medication and behavioral therapy but there is growing concern about the numerous barriers to accessing opioid treatment in rural areas of America. Dr. Lister notes, "Many rural populations have a limited number of clinics that provide opioid treatment and behavioral therapy, as well as a shortage of providers who prescribe opioid treatment medications. People living in rural areas frequently travel long distances to their opioid treatment provider. Moreover, many may feel ashamed or stigmatized if they seek out opioid treatment in their local community." Telemedicine may play a crucial role in helping to overcome some of the barriers particular to rural areas. Jamey Lister, *The Conversation*, Nov. 9, 2017, https://theconversation.com/the-opioid-crisis-is-at-its-worst-in-rural-areas-can-telemedicine-help-86598

F.D.A. Speeds Review of Gene Therapies, Vowing to Target Rogue Clinics

The Food and Drug Administration (F.D.A.) issued new guidelines on Nov. 16 to speed the approval process of medical treatments involving human cells and tissues, including gene therapy. Included in these guidelines are measures to crack down on clinics that offer versions of these treatments that have not been approved by the F.D.A. and are potentially dangerous for patients.

The new guidelines are meant to expedite the review of some gene and cell therapies that demonstrate potential to treat unmet medical needs and serious illnesses. While these treatments will still be required to go through clinical trials the hope is that a faster process will more quickly put effective treatments on the market.

Currently only two gene therapy treatments - Kymriah from Novartis, and Yescarta made by Kite Pharma – have been approved by the F.D.A. with a cost in the hundreds of thousands of dollars. A third product designed to correct a gene defect that causes a blinding hereditary eye disease has been sent to the F.D.A. with a recommendation for approval by an advisory panel.

While the F.D.A. is trying to speed the approval process for treatments that show promising results, it is also vowing to crack down on stem-cell clinics that treat ailments through fat-derived stem cells that are injected back into the patient. These clinics claim to treat ailments such as arthritic knees, back pain, and heart disease but use largely unregulated and unapproved treatment methods. The F.D.A.'s goal is to "make clear to regenerative medicine developers that they will be held to the same standards as other drug and device makers." Sheila Kaplan and Denise Grady, *The New York Times*, Nov. 16, 2017, https://www.nytimes.com/2017/11/16/health/fda-gene-cell-therapy.html

Massachusetts Grabs Spotlight by Proposing New Twist On Medicaid Drug Coverage

A new proposal is being put forth to the U.S. Department of Health and Human Services by Massachusetts' Medicaid program that would give them "the power to negotiate discounts for the drugs it purchases and to exclude drugs with limited treatment value." The proposal is considered a step towards improving efficiency. With Medicaid spending on prescription drugs increasing nationally by 25 percent in 2014 and nearly 14 percent in 2015 other states are closely watching whether the Massachusetts Medicaid proposal is approved.

Currently, Medicaid covers most prescription drugs approved by the Food and Drug Administration. In turn, pharmaceutical manufacturers are required to discount the drugs for Medicaid according to a fixed percentage established through federal law. The problem, according to many states, is that the established percentage discount is no longer sufficient to defray the rising cost of drugs.

Luthra reports, "Massachusetts wants to go a different route, requesting a federal exemption known as a Section 1115 waiver, which is meant to let states test ways of improving Medicaid. It wants to pick which drugs it covers based on most beneficiaries' medical needs and which medicines demonstrate the highest rates of cost effectiveness."

Massachusetts argues that its Medicaid proposal provides the opportunity to better negotiate prices and therefore save public dollars while still providing patients with access to needed therapies because they guarantee coverage of "at least one medication per therapeutic class — that is, per specific medical need." The proposed plan also contains an appeals process for patients who need a medication not covered by Medicaid. But critics are concerned that the proposed plan will limit accessibility to medication for low-income people.

The proposal will be reviewed by the Centers for Medicare & Medicaid Services. There is no deadline for the decision but other states are paying close attention to whether this proposal is approved. Shefali Luthra, *Kaiser Health News*, Nov. 21, 2017, https://khn.org/news/massachusetts-grabs-spotlight-by-proposing-new-twist-on-medicaid-drug-coverage/

New 'Instructions' Could Let Dementia Patients Refuse Spoon-Feeding

End of Life Washington (EOLWA), a group that assists residents of the state of Washington with the state's 2009 Death with Dignity Act, recently created guidelines for dementia patients to refuse being spoon fed. The guidelines are titled, "Instructions for Oral Feeding and Drinking," and were recently posted on their website.

The document gives instructions for caregivers of Alzheimer's and other progressive dementia patients to withhold oral food or fluids under certain circumstances, namely, "the person appears indifferent to eating, or shows other signs of not wanting food — turning away, not willingly opening their mouth, spitting food out, coughing or choking."

"The new guidelines won't be binding — legally or ethically, experts say. Nearly two dozen states have laws that address assisted feeding, including many that prohibit withdrawing oral food and fluids from dying people." Proponents suggest the document is a step in the right direction with some proponents claiming the document doesn't go far enough. In contrast, critics are concerned that the document puts the vulnerable at risk for mistreatment with the possibility of starving the elderly or incapacitated. JoNel Aleccia, *Kaiser Health News*, Nov. 3, 2017, https://khn.org/news/new-instructions-could-let-dementia-patients-refuse-spoon-feeding/

First Digital Pill Approved to Worries About Biomedical 'Big Brother'

On Nov. 13 the Food and Drug Administration (F.D.A.) approved for the first time a digital pill - "a medication embedded with a sensor that can tell doctors whether, and when, patients take their medicine." The newly approved pill, called Abilify MyCite, is a digital version of the antipsychotic Abilify. Patients who agree to Abilify MyCite can sign consent forms that give their physicians and up to four other people (including family members) access to electronic data that shows the date and time the pills are taken. The patient can remove any person from having access to their data through a smartphone app.

The sensor in the digital pill, contains the safe ingredients (also found in food) of copper, magnesium, and silicon, which "generates an electrical signal when splashed by stomach fluid." A few

minutes after ingestion the signal is picked up by a Band-Aid-like patch that is placed on the left rib cage (this patch must be replaced every seven days). The patch then transmits the date and time of pill ingestion via Bluetooth to a cellphone app. The app allows the patient to also record their mood and hours of rest. This data is then made available to those whom the patient has given permission to access the data. The pill is slated to be released sometime next year; a price has currently not been released.

Proponents point to the ability of digital medication to remind patients when they forget to take their medicine and the potential to reduce the estimated $100 billion annual cost attributed to nonadherence and noncompliance with medication. But whether the digital pill improves compliance remains to be seen.

Critics of the digital pill are concerned that instead of fostering trust the digital pill could lead to mistrust of physicians and medicine, especially with patients taking antipsychotics like Abilify. Furthermore, there is concern that digital pills will become coercive tools used by physicians, families, insurance companies, public health agencies, etc. Dr. Eric Topol, director of Scripps Translational Science Institute, said, "Insurers might eventually give patients incentives to use them [digital pills], like discounts on copayments." Other companies are also developing digital medication technologies and some digital pill technologies that do not need clearance from the F.D.A are already in use or are currently being tested with patients who have heart problems, stroke, H.I.V, and diabetes. What remains to be seen is whether the majority of patients will freely consent to digital medication. Pam Belluck, *The New York Times*, Nov. 13, 2017, https://nyti.ms/2hAXsLz

New Gene-Therapy Treatments Will Carry Whopping Price Tags

In fall 2017, the Food and Drug Administration (F.D.A.) approved the first gene therapy treatment called Kymriah, which is used to treat rare forms of leukemia at a price tag of $475,000. There are currently 34 gene therapy treatments in the final stages of testing for F.D.A. approval and another 470 treatments in initial clinical trials. Most of these gene therapies target rare diseases that reach only a few patients and are designed to cure a patient with one procedure or injection. According to Gina Kolata, in an article in the New York Times, Sept. 11, 2017, the high cost is alarming medical researchers and economists. For example, Kolata reports that one drug in development to prevent blindness occurring from a rare genetic disease is projected to cost between $700,000 and $900,000 dollars.

Bluebird Bio, a company developing several gene therapies, recognizes that high treatment costs present many challenges. Elizabeth Pingpank, a spokeswoman for Bluebird Bio said, "We recognize that most payers in the U.S. are not currently set up to support one-time therapies that generate long-term transformative benefits." In response, Bluebird Bio has put together a consortium with academics to develop novel ways for insurance companies to pay the high price treatments. Bluebird Bio is not the only one trying to address the future high cost of gene therapy, as many health care executives are rushing to develop new payment models. Gina Kolata, *The New York Times,* Sept. 11, 2017, https://nyti.ms/2xW5yRG

Message of the Holy Father to the President of the Pontifical Academy for Life on the occasion of the European Regional Meeting of the "World Medical Association" on "end-of-life" issues (Vatican, 16-17 November 2017), 11/16/2017

On November 16, Pope Francis sent a message to the president of the Pontifical Academy for Life, Archbishop Vincenzo Paglia, and to all participants attending the European Regional Meeting of the World Medical Association on "end-of-life" issues. Pope Francis reaffirmed the Catholic tradition on end-of-life care, writing, "To determine whether a clinically appropriate medical intervention is actually proportionate, the mechanical application of a general rule is not sufficient. There needs to be a careful discernment of the moral object, the attending circumstances, and the intentions of those involved."

Pope Francis, citing the *Catechism of the Catholic Church*, stresses that the patient, if able, should have the primary role in evaluating and making decisions about treatments.

In the message Pope Francis calls attention to the growing gap in healthcare possibilities, noting that, "increasingly sophisticated and costly treatments are available to ever more limited and privileged segments of the population, and this raises questions about the sustainability of healthcare delivery and about what might be called a systemic tendency toward growing inequality in health care." He points out that this tendency is clearly visible at a Global level but inequalities also exist within wealthy countries.

Pope Francis also called caregivers to avoid the temptation to step back from patients when a cure is no longer possible. Instead he urged that "the supreme commandment of *responsible closeness*, must be kept uppermost in mind, as we see clearly from the Gospel story of the Good Samaritan (cf. *Lk* 10:25-37). It could be said that the categorical imperative is to never abandon the sick." He also pointed to the importance of palliative care in caring for the dying patient as it "opposes what makes death most terrifying and unwelcome—pain and loneliness." Pope Francis, *Message of the Holy Father to the President of the Pontifical Academy for Life on the occasion of the European Regional Meeting of the "World Medical Association" on "end of life" issues*, Nov. 16, 2017, http://press.vatican.va/content/salastampa/en/bollettino/pubblico/2017/11/16/171116d.html

Health Care & The Law

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 Madhav Bhatt (J.D. anticipated 2019) and Aria Suek (J.D./M.P.H. expected 2020).

States Expand Medicaid Benefits Despite GOP Efforts to Cut Medicaid Funding

Medicaid is one of the largest state-federal insurance programs that covers at least seventy-five million people in the country. The congressional Republicans and President Trump have been attempting to cut major federal funding to Medicaid. Despite their efforts, 26 states expanded or enhanced benefits in 2017 and at least 17 states plan to do so in 2018. These increased benefits were largely for mental health and substance abuse treatment, but some states have also added telemedicine and dental care. Four states—Louisiana, Virginia, South Dakota and New York—added cancer screening benefits such as genetic testing for the BRCA breast cancer gene mutation. The number of states adding benefits in 2017 was highest in at least a decade. Medicaid continues to face uncertainty as the Trump administration weighs whether to allow states to require non-disabled, adult enrollees to work in order to qualify for benefits. At least six states have such a request pending, and a decision is expected before end of the year. Phil Galewitz, *Kaiser Health News*, Oct. 19, 2017, https://khn.org/news/despite-gop-efforts-to-corral-medicaid-spending-states-expand-benefits/

The Trump Administration Proposes Drastic Changes to the Way Doctors Are Paid

A consensus developed over the past several decades is that the United States' annual medical cost can be controlled by changing the payment method for doctors. Instead of fee-for-service payment, that is, paying doctors for every appointment or procedure, they should be paid for their quality of care. The Obama administration supported this consensus through Affordable Care Act (ACA) which mandates large experiments to test new methods of payment. Some in the health care field have supported moving away from fee-for-service payment, while many have criticized ACA mandates as overly prescriptive. The Trump administration is making several regulatory changes that drastically affect these initiatives. It has proposed to cancel or reduce Medicare initiatives that

required doctors to accept lump sums fees for joint replacement and cardiac care, two of the biggest cost drivers of Medicare. The Department of Health and Human Services (HHS) has exempted doctors from a provision of a bipartisan law that created merit-based pay depending on quality of care. Also, the HHS now encourages smaller, voluntary programs instead and has proposed to enable doctors to determine their own prices by allowing them to contract directly with Medicare patients, a long-held Republican goal of so-called premium pricing. Abby Goodnough & Kate Zernike, *New York Times*, Nov. 12, 2017, https://www.nytimes.com/2017/11/12/health/doctor-pay-trump.html

Hospital Groups Sue to Stop Reduction of 340B Program Reimbursement Rates

Hospital groups, including the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals, sued HHS alleging that its rule released on Nov. 13, 2017, violated the Administrative Procedure Act and the Social Security Act. The rule lowers reimbursement rates offered by the 340B program from 106 percent of the average sales price of the drugs to 78.5 percent. The 340B program is a separate program from Medicare, and offers drug at low costs to public and not-for-profit hospitals and federally funded clinics serving large numbers of low-income patients. Under this program, hospitals purchase drugs at discounted rates, but are reimbursed by Medicare. The plaintiff organizations have also asked the court to grant a preliminary injunction against the rule. Matthew Loughran, *BNA*, Nov. 16, 2017, https://www.bloomberglaw.com/document/X7G4TPIC000000?bc=W1siU2VhcmNoIFJlc3VsdHMiLCIvc2VhcmNoL3Jlc3VsdHMvOTk0MjQ3MzJlMGQ2MGMyNDY1Y2ZmMDgzMmU3MTc3YzkiXV0--070db35a7dffcbf1b209298f3d059cbe5bc10652

N.Y. High Court: "Wrongful Birth" Claims Start at Birth

Most medical malpractice claims begin running on the date of the alleged negligence, but New York's highest court has carved out an exception to this rule. In this case, two couples claimed that they would not have had children through a fertility clinic had they known the egg donor was a carrier of a genetic defect. They alleged that Dr. Alan Copperman and Reproductive Medicine Associates of New York LLP failed to timely screen the egg donor for a genetic defect known as Fragile X or to notify the couples that they had not screened for this trait. The issue was whether New York's two-and-one-half-year statute of limitations for medical malpractice began running at the time the embryos were implanted or when the children were born. The majority held that wrongful birth claims begin at birth because it is impossible to determine whether the parents will incur extraordinary expenses for a child prior to birth, and from public policy standpoint, it gives parents a reasonable opportunity to bring suit. The dissenting judge argued that the majority has improperly carved out this exception. Y.Peter Kang, *Law360*, Dec. 14, 2017, https://www.law360.com/articles/994968/ny-high-court-says-wrongful-birth-claims-start-at-birth

The Regulatory Accountability Act of 2017 Imposes Substantial Requirements on Rule Making

The proposed Regulatory Accountability Act of 2017 would substantially revise the 1946 Administrative Procedure Act, a law that established rules for federal agency regulation, to impose onerous requirements on rule making. The proposed bill increases procedural requirements for rulemaking by expanding the extent to which businesses or other interested parties could intervene in the rulemaking process and imposes prohibitions on agencies from explaining how new regulations are beneficial. The bill promotes "formal rulemaking," an expensive and cumbersome procedure, where anyone could petition the agency to conduct a trial-like hearing for proposed major or

high-impact rules, which include most health and safety regulations. While the proponents of the bill claim that it will minimize unnecessary regulatory burdens that harm the economy, it is likely that this Act will make rule-making time-consuming and costly, inhibit agencies from responding to emergencies and new scientific evidence, and deprive the public from formal guidance on rules. Jonathan J. Darrow, Erin C. Fuse Brown, and Aaron S. Kesselheim, *New England Journal of Medicine*, Dec. 20, 2017, http://www.nejm.org/doi/full/10.1056/NEJMp1711643#t=article

I.R.S. Says It Will Reject Tax Returns That Lack Health Insurance Disclosure

Beginning 2018, the Internal Revenue Service (I.R.S.) will reject tax returns filed electronically for those who do not complete the information required about health care coverage, regardless of whether the individual is exempt from the individual mandate or must pay the penalty. For those filing on paper, the I.R.S. could also suspend processing and delay refunds. This guidance strays from President Trump's first executive order, which instructed various agencies to scale back the regulatory reach of the federal health care law. The I.R.S.'s choice in strict implementation makes it clear that taxpayers cannot ignore the Affordable Care Act, stating all taxpayers are required to disclose coverage information. Nicole M. Elliott, a tax lawyer for Holland and Knight and a former I.R.S. official involved in putting the ACA into effect, said the I.R.S.'s levy of the penalty could still be lenient towards those did not sign up for insurance during the previous year, but suggests this requirement helps to ease the burden for those that have insurance or are exempt from the penalty. Gary Claxton, an executive with the Kaiser Family Foundation, suggested this was the best way to enforce the mandate. Reed Abelson, *New York Times,* Oct. 20, 2017, https://www.nytimes.com/2017/10/20/health/irs-obamacare-mandate.html?rref=collection%2Ftimestopic%2FHealth%20Care%20Reform

ACA Enrollment for 2018 Nearly Matches Last Year's, Despite Trump Administration Efforts to Undermine It

For the 2018 insurance year, in addition to cutting the enrollment period in half, the Trump administration reduced 90 percent of federal spending for advertising and other outreach activities that were utilized to help consumers sign up for health insurance. The enrollment navigator funding was also cut by two-fifths. These efforts were seen as undermining actions by the administration to reduce the number of enrollees for the upcoming year. However, by the end of the enrollment period, more than 8.8 million Americans in 39 states signed up for 2018 health plans through the federal HealthCare.gov website. These astonishing numbers come close to nearly 95 percent of those enrolled during a three-month period during the 2017 enrollment period. The final tally on those enrolled does not include those who signed up for plans individually or those affected by recent natural disasters. Robert Restuccia, the executive director of Community Catalyst, a large grassroots health-care advocacy group commented on the enrollment numbers suggesting they "make it clear that Americans demand and support the quality, affordable health insurance and consumer protects the ACA offers." Amy Goldstein, *The Washington Post,* Dec. 21, 2017, https://www.washingtonpost.com/news/to-your-health/wp/2017/12/21/aca-enrollment-for-2018-nearly-matches-last-years-despite-trump-administration-efforts-to-undermine-it/?utm_term=.66de036998b6

Requiem for the Individual Mandate

The individual health insurance mandate began as a conservative tool, transformed into a bipartisan effort, and was eventually branded as a Democratic policy for presidential platforms. As a central element

of the Affordable Care Act, the mandate was intended to get healthier, less expensive individuals into the market, therefore lowering the average price of insurance. On Dec. 20, 2017, the individual mandate was eliminated in the newly passed tax bill. Some experts have suggested that the elimination will likely increase insurance prices and lower health coverage. The Congressional Budget Office has estimated that over the next 10 years as many as 13 million Americans could become uninsured and insurance premiums could rise by an additional 10 percent. However, it is unlikely to see the effect of the mandate elimination until 2019, when the tax penalties will no longer be collected for those uninsured. Other mandate enthusiasts have gone as far to suggest that the elimination of the mandate provision will lead to a death spiral of ever-escalating insurance premiums, eventually resulting in market collapses. In response, many Blue States have begun considering a state-level mandate to subsidize the effects of the mandate elimination. Margot Sanger-Katz, *New York Times,* Dec. 21, 2017, https://www.nytimes.com/2017/12/21/upshot/individual-health-insurance-mandate-end-impact.html?rref=collection%2Ftimestopic%2FHealth%20Care%20Reform

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 Scott Vermeer (J.D. anticipated 2018) and David Bird (J.D. anticipated 2019) The content was developed for the Of Note section of the fall 2017 issue and was inadvertently omitted.

Trump Threatens Obamacare Chaos as He Cuts Off Insurer Subsidy

President Trump signed an Executive Order on Oct. 12 to immediately halt payments on cost-sharing reduction subsidies provided to health insurers participating in the Affordable Care Act's marketplace. These payments helped to reduce insurance costs for low-income enrollees. In 2017, around 58 percent of all marketplace enrollees received cost-sharing reductions, resulting in roughly $7 billion in reimbursements to marketplace insurers by the federal government. The White House based the order on the premise that Congress never actually appropriated the CSR payments. The administration's actions came after numerous unsuccessful attempts by Republicans in Congress to repeal the ACA. Trump's actions were unsurprising to most insurers, as many had adjusted and raised their premiums accordingly for 2018 amid the uncertainty over the future CSR payments. The Executive Order also contained language asking regulators to "craft rules that would allow small businesses to band together to buy insurance across state lines, let insurers sell short-term plans curtailed under Obamacare, and permit workers to use funds from tax-advantaged accounts to pay for their own coverage." The anticipated result of this order will create alternative forms of coverage that will likely be cheaper, but less comprehensive. However, the order was a considerable political risk by the Trump administration, as a Kaiser Family Foundation poll in August found that 78 percent of those surveyed wanted the administration to work with Congress to improve and make the current ACA work. Zachary Tracer, *BNA*, Oct. 13, 2017, https://www.bloomberglaw.com/document/XFCCNUH0000000?jcsearch=bna%25200000015f1548d3f9ad5fdd4d935f0000#jcite

California Legislature Turns Up Pressure on Big Pharma

A bill was that re-introduced to the California state assembly in early 2017 is nearing implementation and, if successful, would require the pharmaceutical industry to give notice anytime they plan to raise drug prices by at least 16 percent over the following two-year span. More than just giving notice, however, the new law would also require pharma companies to give

justification for increases and note what percentage of the increase was caused by internal corporate spending. According to the bill's sponsor, support for this legislation came from numerous sociopolitical groups in many different industries and, although the bill failed to obtain enough votes in the state assembly when it was first introduced in 2016, it passed the 2017 vote with 15 votes more than required. Pharmaceutical advocates' argument that the bill will burden their research and development has largely fallen on deaf ears. California is not the first state to create these types of requirements but is the first that is large enough to make the pharmaceutical industry take notice. When smaller states tighten reporting structures, pharmaceutical companies can just pull out of the market, but when a state the size of California enacts such rules, market excision is not a viable option and companies are forced to comply or find viable legal counter attacks. Numerous other state legislatures are tracking these new regulations and if successful in California, will not be far behind in creating similar rules. April Demborsky, NPR, Oct. 4, 2017, http://www.npr.org/sections/health-shots/2017/10/04/551013546/california-bill-would-compel-drugmakers-to-justify-price-hikes

Insurance Expires for Nine Million Children

The Children's Health Insurance Program (CHIP) is a program which provides health insurance for low-income children and pregnant women. It was a product of the Clinton administration which was primarily funded by the federal government and which, during its two decades that it was in force, decreased the rate of uninsured individuals in the target population by nearly ten percent. To ensure that the program continued to operate CHIP needed congressional renewal no later than the end of Sept. 2017. However, due to the congressional focus on repealing and replacing the Affordable Care Act it was allowed to lapse. Although the federal government will recognize a roughly $16 billion savings by eliminating the program, those costs will now be put back on the shoulders of the at-risk population which the program was designed to support. The maximum payments which an insured mother or child could be billed under CHIP was capped at five percent of their annual family income. Without the program's protection and financial support these families are no longer shielded from ever-rising costs of modern medicine. Valerie Strauss, Washington Post, Oct. 1, 2017, https://www.washingtonpost.com/news/answer-sheet/wp/2017/10/01/9-million-kids-get-health-insurance-under-chip-congress-just-let-it-expire/?utm_term=.dc62637be5bc

Senate's Three Health Care Proposals: A Guide

There have been three major efforts to find a path forward since Republicans were unsuccessful at repealing and replacing the Affordable Care Act in July: the Graham-Cassidy Bill; insurance stabilization; and a single-payer plan. Sponsored by senators Lindsey Graham of South Carolina and Bill Cassidy of Louisiana, the Graham-Cassidy Bill would take money earmarked for Medicaid and insurance subsidies by the ACA and transform them into block grants for states. States would then be able use those grants to design their own health-care systems. On Sept. 26, Majority Leader Mitch McConnell announced that the bill would not be brought for a vote. Insurance stabilization is a rare bipartisan health-care push to repair and strengthen the individual insurance market. This plan would officially appropriate the funds necessary for payment of ACA subsidies that lower out-of-pocket costs for low-income consumers. This would allow stability in the market by eliminating the uncertainty factor regarding subsidy payments which should result in controlled premium increases. This plan faces significant opposition and it is unclear whether it will be voted on in the near future. Finally, the single-payer plan would create a national government-sponsored health care system. This plan would effectively supplant private insurance by extending Medicare-like health coverage to all Americans, except the medical benefits included would be the same as those provided under the ACA, eliminating the majority of out-of-pocket costs. This plan is also has an uphill battle as it is not universally supported

among Republicans or Democrats. Michelle Hackman, *The Wall Street Journal*, Sept. 19, 2017, https://www.wsj.com/articles/senates-three-health-care-proposals-a-guide-1505813402

Senator Pushes for Hospital Inspections to Be Made Public

Sen. Chuck Grassley (R., Iowa), chairman of the Senate Judiciary Committee, is pushing for hospital inspection reports to be made available to the public. This issue came about amid complaints against the Joint Commission, a non-profit organization based in Oakbrook Terrace, Ill., which stated that one of the nation's largest hospital accreditation groups was not rigorously enforcing health and safety standards. An investigative report by the *Wall Street Journal* prompted Grassley's request as it found that the Joint Commission was not revoking or modifying the accreditation of hospitals when serious safely violations were found. The Joint Commission has previously held that confidentiality in the process encourages hospitals to be candid with the commission. It went on to say that making the reports public would lead to increased costs. However, this has drawn harsh criticism from consumer groups and physicians who worry that the serious problems being found are also being kept from the patients who use the facilities. CMS has said it has become increasingly concerned about accreditors' performance, specifically noting their inability to identify problems later found by government inspectors. In more than 30 instances, hospitals retained their full accreditation even though their violations were deemed by CMS so significant that they had caused, or were likely to cause, a risk of serious injury or death to patient. Accordingly, it issued a draft rule to make these accreditor inspections public; however, it withdrew the rule citing fears that the proposal was an attempt by CMS to circumvent the law. Stephanie Armour, *The Wall Street Journal,* Sept. 19, 2017, https://www.wsj.com/articles/senator-pushes-for-hospital-inspections-to-be-made-public-1505843279

The Affordable Care Act Remains as Polarizing as Ever

Two opposing factions in the Senate are trying to make changes in the Affordable Care Act. On the left is a group led by Sen. Bernie Sanders which proposes a single-payer plan which would expand Medicare's current coverage to eventually include all Americans. Sanders proposes paying for this expansion by, among other options, increasing taxes on wealthy Americans. On the other side are Sen. Lindsey Graham and Sen. Bill Cassidy who are lobbying for a dismantling of the ACA in favor of a financial formula which would re-allocate the ACA's funding into a federal block grant for each state. Republicans are still shaky in their support for such a drastic measure while most Democrats are focused on simply protecting the ACA and the coverages which it provides. While the ACA could use some refinement, the path toward revision is as murky as ever. Robert Pear, the *New York Times*, Sept. 13, 2017, https://www.nytimes.com/2017/09/13/us/politics/health-care-obamacare-single-payer-graham-cassidy.html

IRS Yanks Hospital Tax Exemption, Sends Strong Compliance Message

An unidentified hospital was notified last year that its non-profit tax-exempt status had been stripped due to a failure to comply with 501(r) requirements. This revocation was the first of its kind by the IRS. As a dual status hospital, it is a government-run hospital that also obtained tax-exempt status under section 501(c)(3). This particular hospital was cited for its failure to submit a Community Health Needs Assessment report or to adopt a plan which would address the health-care needs of the community discussed in said report. The hospital declined to contest the IRS' determination, as the hospital's administrators explained it was a "small rural facility" and "had neither the financial wherewithal nor the staffing to devote to the specific requirements of

Treasury Regulation § 1.501(r)-3." While the unnamed hospital was still able to fall back on its dual status as a partially government-run organization for exemption from federal taxation, this revocation should serve as a wake-up call for charitable hospitals, especially non-governmental hospitals, to comply with Section 501(r). It should also be noted, that the bar for revocation is very high, and if a hospital is making a good faith effort to comply with Section 501(r) requirements, it is unlikely that the IRS will make a case for revocation against them. However, a hospital's inability to comply completely and openly with the CHNA requirements could lead to an exceptionally more invasive audit of the hospital by the IRS. Matthew Loughran, *BNA*, Aug. 30, 2017, https://www.bna.com/irs-yanks-hospital-n73014463912/

Medicare to Narrow Scope of Health-Care Provider Audits

CMS announced that The Centers for Medicare & Medicaid Services' Targeted Probe and Educate Program will roll out nationally to all 12 Medicare administrative jurisdictions by the end of 2017. This program involves reviewing fewer claims per provider. It also adheres to the Trump administration's goal of reducing provider burdens and educates providers on proper claims billing. The audits were never intended to punish providers for improper payments, but rather to reduce the number of improper Medicare claims appeals. The program will target and focus on providers with higher claims error rates. These TPE audits are expected to be more persuasive in encouraging better billing habits because they will single out specific providers as potential problems instead of an entire industry sector billing for a particular code, forcing those providers to take the inquiry seriously. James Swann, *BNA,* Aug. 22, 2017, https://www.bna.com/medicare-narrow-scope-n73014463501/