Of Note

Lawmakers Push Increased Access to Emergency Contraception

The Emergency Contraception Access and Education Act of 2014 was introduced in the Senate by five Democratic senators: Patty Murray (D-Wash.), Elizabeth Warren (D-Mass.), Barbara Boxer (D-Calf.), Richard Blumenthal (D-Conn.), and Cory Booker (D-N.J.). The act states that any hospital receiving Medicaid or Medicare funding must provide information and access to emergency contraception for survivors of sexual assault regardless of their ability to pay for the treatment. Senator Murray told *Time*, "Emergency contraception is a critical part of these family planning choices and it's time Republicans join us in supporting this safe and responsible means of preventing unintended pregnancies." It is likely the bill will face opposition from congressional Republicans. Charlotte Alter, *Time*, September 24, 2014

Too Many People Die in Hospital Instead of Home. Here's Why.

Patients in the New York metropolitan area choose aggressive treatments more often than patients in other parts of the country. This means more doctor visits, more treatments, more expenses, and more people dying in the hospital. Why does this happen more in New York? Specialists at the Dartmouth Healthcare Atlas surfaced two possible reasons: the area has a lot of hospital beds and the medical "culture" consists of highly trained specialists who see it as their job to *cure* illness. At Mount Sinai Hospital, the chair of surgery requires staff to discuss hospice options with all terminally ill patients. Dr. Diane Meier, a geriatric specialist at Mount Sinai, added, "All of medicine needs to be willing to say, 'Why did this person with end-stage dementia have three or four hospitalizations in the last three months of life and die in the intensive care unit? This was a terrible experience for the patient and family. A lot of unnecessary suffering'". Fred Mogul, *Kaiser Health News*, Sept. 22, 2014

Transplant Providers Dispute Changes to Allocating Donated Livers

In the United States, 6,256 adults received liver transplants in 2012 but 3,002 patients died or were removed from the waitlist. The United Network for Organ Sharing (UNOS), a not-for-profit that contracts with the federal government to oversee the organ transplant system, wrote a preliminary proposal to address the geographic disparity of organ transplants. The proposal seeks to address the disparity by reducing the number of allocation districts from 11 to as few as four. Currently, doctors will advise more affluent patients to temporarily relocate to a state with higher transplant rates. A bipartisan group of more than 50 members of Congress criticized the proposal. They said if the new standards were implemented, "more organs for

transplant would travel significantly longer distances, areas with high organ-donation rates would be disproportionately affected, organs would experience longer cold ischemic times, and the proposal may not have the desired effect of lowering overall waitlist mortality." Sabriya Rice, *Modern Healthcare*, Sept. 22, 2014

Dying In America Is Harder Than It Has To Be, IOM Says

The Institute of Medicine released a report, "Dying in America", that offers a new "life-cycle model of advance care planning." The report suggests that end-of-life conversations begin when people receive their driver's license and make a decision regarding organ donation. As a person reaches other milestones in life, turning 18, getting married or having children, a counselor or social worker should continue the conversation. The report concludes that the American health care system is not equipped to properly care for patients at the end of life. There are not enough doctors proficient in palliative care. There is reluctance among doctors to have honest end-of-life conversations. There is not enough financial or organizational support for dying patients. The committee offers a recommendation to combat these systemic problems. Regardless of specialty, all clinicians "should be competent in basic palliative care, including communication skills, interprofessional collaboration, and symptom management." Jenny Gold, *Kaiser Health News*, Sept. 17, 2014

The Trials of Stem Cell Therapy, Stem Cells: Plenty of Hope, but Halting Progress

Progress in stem cell therapy research has been slow. Dr. Ellen Feigal, senior vice president of research and development at the California Institute of Regenerative Medicine, says that research has shown stem cell therapy can be safe so "Now what we want to know is: Will it work, and will it be better than what's already out there?" According to Dr. Charles Murry, co-director of the Institute of Stem Cell and Regenerative Medicine at the University of Washington, beyond bone marrow transplant, few therapies have been effective. In 2006, Shinya Yamanaka, a Japanese researcher and Nobel Prize winner, discovered a way to revert adult cells back into stem cells. This allowed new avenues of research including reproducing cells from patients with specific problems and studying the disease in a petri dish. The most cost-effective way to deliver therapy is still unknown. A recent study at the University of Miami found that patients using donor stem cells did just as well as patients injected with their own stem cells. This finding, if supported further, could mean that stems cells created in large batches could be used for multiple patients, lowering the cost of treatment. Dr. David Scadden, co-director of the Harvard Stem Cell Institute, warns that "progress comes in fits and starts," just like the "war on cancer" declared in 1971. Karen Weintraub, *The New York Times*, September 15, 2014

NIH Issues Finalized Policy On Genomic Data Sharing

The National Institutes of Health issued a final NIH Genomic Data Sharing (GDS) policy to promote data sharing. The policy is expected to assist researchers in turning data into knowledge, products and procedures to improve the health of patients across the country. A key to the new GDS policy is that researchers obtain informed consent of participants to share information for possible future studies. Along with verifying informed consent, the policy ensures that data was collected legally and in an ethically appropriate manner with personal identifiers removed. Kathy Hudson, NIH deputy director for science, outreach and policy, said "Everyone is eager to see the incredible deluge of molecular discoveries about disease translated into prevention, diagnostics, and therapeutics for patients. The collective knowledge achieved through data sharing benefits researchers and patients alike, but it must be done carefully. Aug. 27, 2014, www.nih.gov/news/health/aug2014/od-27.htm

Obamacare Has Reduced the Uninsured Rate for Virtually Everyone – Except Kids

According to the Urban Institute Health Reform Monitoring Survey, the rate of uninsured adults dropped 4 percent over the past year but the rate of uninsured children has barely changed. Fortunately the rate of uninsured children was low before the ACA implementation, about 7 percent, due to programs like the Children's Health Insurance Program (CHIP). Among enrollees in the new health insurance exchanges, only 6 percent are children. The Urban Institute and the Georgetown University Center for Children and Families see that increased Medicaid enrollment could cover more children who could not afford the high insurance premiums offered under CHIP. The researchers estimate that 55 percent of uninsured children are eligible for public coverage through Medicaid or CHIP. As the ACA continues to take effect, lawmakers have to decide how to fund CHIP after the 2015 fiscal year. Advocates of CHIP are concerned that lawmakers will cut or eliminate the program but advisors warn that a change would increase the rate of uninsured children. Jason Millman, *Washington Post*, Sept. 9, 2014

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Assistant Director, supervised the contributions of health law student Rachel A. Polzin (JD/MHA anticipated May 2015) and Kalle Deyette (JD/MPH anticipated May 2016).

Consumers Turn to Online Auction Site for Cheaper Medical Care

As many Americans use the Internet to book hotels and flights and even search for

a mate, some are now starting to go online to arrange medical care through an auction website called *Medibid*. Operating largely outside the confines of traditional health insurance, the four-year-old online service links patients seeking non-emergency care with physicians and facilities that offer what they need. To date, approximately 120,000 consumers or "seekers" have used *Medibid* and roughly 6,000 doctors, surgery centers and even some hospitals have registered as "bidders". The founder of *Medibid* contends that offering this type of service in the U.S. is long overdue and describes it as "disruptive innovation" that introduces transparency and competition.

The way *Medibid* works is seekers post requests for services on the website ($25/request or $60 for unlimited/year), wait for physicians to bid ($50/bid or $250/many) and once the seekers accept a bid, *Medibid* bows out and patients and physicians finalize the arrangement. Many bids are package deals that include the professional charge, facility fee and anesthesia services, yet complications are rarely covered under the terms of *Medibid*.

Despite lower prices, this unconventional option is not without its critics. A professor of surgery at John Hopkins Hospital expressed concern over the lack of good quality metrics and asks, "How do you know what you're getting?" *Medibid* does not verify credentials; rather physicians are required to send their license number to patients, who then have the option of checking the physician on their own through third-party services.

The head of the division of bioethics at NYU Langone Medical Center has similar concerns related to the lack of oversight in free-standing surgery centers, where many of *Medibid* services are performed. Compared to hospitals, these settings typically have to comply with lighter regulations, have fewer patient safeguards in place, and are often exempt from quality reporting requirements. Additionally, the lack of peer review is unsettling in that "it doesn't take a lot of qualifications to open one." Sandra G. Boodman, *The Washington Post*, Aug. 4, 2014
http://www.washingtonpost.com/national/health-science/like-priceline-for-patients-doctors-compete-for-business-via-online-bids-for-surgery/2014/08/01/030d3576-f7e4-11e3-a606-946fd632f9f1_story.html

Medicare Offers Settlement to End Battle Over Hospitals' Claim Appeals

Facing an 18-month backlog of an estimated 800,000 cases, Medicare recently—and quietly—offered to settle thousands of hospital appeals related to short-term care. The appeals stem from a disagreement over billing, where Medicare and its private audit contractors believe hospitals are inappropriately billing outpatient, short-stay care at the much higher inpatient rate. The difference between the inpatient and outpatient rate can add up to thousands of dollars per patient and hospitals argue they are

correctly billing short-term stays at the inpatient rate.
The disagreement has led to a stalemate between Medicare and hospitals and a lengthy wait before administrative law judges can hear cases. The proposed settlement has been described as an opportunity for hospitals to "alleviate the administrative burden of current appeals on both the hospital and the Medicare system" and could total several hundred million dollars. Hospitals have two months to decide whether to take the settlement, which would pay sixty-eight cents for every dollar billed and Medicare says it will pay them within sixty days of when they reach an agreement.

Congress and industry leaders recently denounced Medicare's lengthy delays in appealing claims. Thus, the proposed settlement represents considerable concession by Medicare, which has also been praised for "taking a big step forward to get[ing] rid of a major problem." Yet, the settlement offer has generated mixed reviews from hospitals. Ultimately, hospitals will have to decide on whether they want to gamble on getting paid in full, or take the deal while it is still on the table. Reed Abelson, *New York Times*, Aug. 29, 2014
http://www.nytimes.com/2014/08/30/business/medicare-will-settle-appeals-of-short-term-care-bills.html

Congress Urged to 'Catch Up With Technology' and Revamp Legislation

At a senate roundtable entitled, "Harnessing the Power of Telehealth: Promises and Challenges," participants identified reimbursement and licensure as key impediments to getting telehealth services to those who might benefit. Under current reimbursement, Medicare only permits payment for telehealth services in rural areas or ones with rural characteristics. Problems arise in that many areas in the country do not meet the regulatory definition of rural, but are still underserved by specialists. CMS officials noted, "There has been significant innovation since implementation of the agency's telemedicine restrictions," which supported the roundtable moderator's call for Congressional bipartisan action to ensure telemedicine laws "catch up with technology."

Medical licensure was also highlighted as an impediment. The current licensure laws create obstacles for telehealth by requiring the remote consulting physician be licensed in the state where the patient is located. Several options have been set forth to address this problem, such as the Federation of State Medical Boards' proposed Interstate Licensure Compact, where physicians would have a streamlined licensing process in states that adopt the compact. A member of the American Medical Association Board of Trustees said that "organized medicine" supports the licensure compact and wants it to move forward.

Yet, the AMA also warns that potential safety threats associated with telemedicine still loom, such as prescribing antibiotics without appropriate diagnostics testing. Mindy Yochelson, *BNA's Health Care Daily Report*, Sept. 16, 2014 http://www.bloomberglaw.com/search/results/c6334dec07d086a539f11365db0cac92/document/X13PKVSS000000?search32=C9P6UQR5E9FN6PB1E9HMGNRKCLP6QFAND5Q6SPBJEDIN682JC5SI0JB5CHKM6OBICKG4IRBGCLI6ASP085H6IR39EHSJMEREDTFMIRBGBTO6GSJ1EDIN6F9H7CTMCQBOBTH6URRCBTONAPBIFh

FDA Encouraged to Limit Male Use of the 'Foundation of Youth'

An expert panel recently voted 19-1 for the FDA to impose strict new limitations on testosterone drugs—a multibillion-dollar industry. Medical experts became concerned when what was once only taken to treat serious medical conditions turned into a drug that over two million American men are taking. The significant increase is driven in part by marketing that suggests the drugs are a solution for low energy, low libido and other ills, many of which are simply the result of aging. Since the early 2000s, testosterone usage by men in their 40s has quadrupled, reflecting what has been described as "people looking for the fountain of youth."

Experts also point to the vagueness in testosterone drug labels as being a critical problem because many physicians interpret them to include *any* man with low testosterone, but even then, a fifth to a quarter of men who are prescribed the drug have not had a baseline test of their testosterone level. Even more concerning is the lack of research on the effects of using the drug, which has led frustrated experts to ask why the F.D.A. allowed the "push for the creation and selling of 'aging is optional for men,'" especially when any benefit and potential harm in using it are unknown.

If the FDA adopts the panel's recommendations, it could significantly reduce the number of men prescribed the drugs, by limiting the label to men with serious medical conditions such as pituitary gland problems. The panel also voted to give the FDA more control over the marketing of the drugs, allowing the agency to draw a narrower definition of whom drug companies could target. The panel's primary aim was to "rein in the inappropriate advertising and use of [testosterone] drugs" and although the F.D.A. often takes the advice of such panels, changes will ultimately be up to the discretion of the agency. Sabrina Tavernise, *The New York Times*, Sept. 17, 2014 http://www.nytimes.com/2014/09/18/health/testosterone-drugs-fda.html?_r=0

RACs Recover for Medicare

Medicare's recovery auditor contractors, or RACs, found $3.75 billion of incorrect payments, almost all related to overpayments, made to doctors and hospitals in the fiscal year of 2013. Providers who appealed these audits won less than 20 percent of the time. RACs resulted in $3 billion going back into Medicare's trust fund, as RACs receive between nine percent and 12.5 percent of improper payments they find. While the RAC trade group and lobbying arm, the American Coalition for Healthcare Claims Integrity, feels this report shows the success of the RAC program, the health care industry said the figures are distorted. American Hospital Association data on RACs stated that in the first quarter of 2014 hospitals won 66 percent of their appeals of the RAC denials. The data also says hospitals appealed 50 percent of the denials. An attorney from Hall Render said hospitals generally have a good success rate in RAC appeals.

Part of the differences between what the two groups say may stem from the fact that the government may count appealed claims multiple times, based on decisions at different levels of appeals, while the AHA only reports final decisions from Medicare's appeals courts. Additionally, the RAC report sheds an interesting light on the CMS appeals settlement process, where hospitals have until the end of October to accept an offer of the government reimbursing 68 percent of their backlogged claims if they withdrew all of their appeals, which seems like a particularly favorable settlement if hospitals were winning under 20 percent of appeals. Bob Herman, *Modern Healthcare*, Sept. 29, 2014 http://www.modernhealthcare.com/article/20140929/NEWS/309299939,

More Hospitals Will Face Medicare Payment Reductions for Hospital Readmission at Higher Penalties

Medicare will fine a record number of hospitals for too many readmissions. Records show that 2,610 hospitals will receive a reduction in Medicare payments ranging from one-hundredth of a percent to three percent of Medicare payments, with an average reduction of 0.63 percent. This represents three-quarters of the hospitals subjected to the Hospital Readmission Reductions Program.

Under the Hospital Readmission Reduction Program, the Centers for Medicare and Medicaid Services (CMS) may reduce a hospital's payments if too many of the hospital's Medicare patients return within a month time period for additional treatments after initially being admitted for an elective knee or hip replacement, lung ailments such as chronic bronchitis, heart failure, heart attacks or pneumonia. A hospital may be fined if readmission rates for any category of illness are above the national standard set by CMS. The penalty may be as high as a three percent reduction in payments for every Medicare patient the hospital sees the following year regardless of

whether the patient is readmitted. The maximum penalty was raised from two percent last year and has reached the maximum the law provides.

These penalties are changing hospitals and administers' attitudes and behaviors. Some hospitals now report that they will do their best to care for returning patients without readmitting them as overnight patients, and thus avoid CMS, including the patient within its readmission rates. Others report assign nurses or pay private companies to visit patients at home to ensure the patient is following his or her discharge plan.
Jordan Rau, *Kaiser Health News*, Oct. 2, 2014
http://www.kaiserhealthnews.org/Stories/2014/October/02/Medicare-readmissions-penalties-2015.aspx?utm_source=khn&utm_medium=internal&utm_campaign=searched.

U.S. Doctors and Teaching Hospitals Were Paid $3.5 Billion from Drug and Device Makers. However, Concerns regarding the Data's Accuracy Remain.

The Sunshine Act, which was passed as part of the Patient Protection and Affordability Care Act (ACA), requires all drug and medical device manufactures to report payments or transfers of value made to providers and teaching hospitals. The Act's intention is to protect the integrity of medical judgment and research by making conflict of interests more transparent. The first round of data was disclosed by the Center for Medicare and Medicaid Services (CMS) on Sept. 30, 2014 and covered the five-month period from Aug. to Dec. 2013. The disclosures revealed that 4.4 million payments were made to approximately 550,000 doctors and 1,360 teaching hospitals totaling $3.5 billion.
Questions remain about the accuracy and usefulness of the data. First, the data include only five months of data and have no historical comparisons. Second, about 40 percent of the records released were "de-identified," removing the name of the physician or hospital the payment was made to. Without identifying the payment recipient, it is impossible to assess the conflict of interest and whether the payment unduly influenced the provider or hospital. Conflicts of interest need to be evaluated based on the totality of circumstances. Third, some physicians found payments were wrongly or unfairly attributed to them.

In addition, the roll out of the disclosure faced technical issues. Drug companies had trouble uploading data to the government's servers. In addition, the database was suspended for twelve days after CMS discovered that manufacturers were submitting intermingled data. For example, manufacturers would mix-up the wrong national provider identifier (NPI) number for physicians with the same first and last names. Despite the technical issues, Pharmaceutical Research and Manufacturers of America (PhRMA) continues to support the Sunshine Act and pledges to work diligently to ensure accuracy and timely submission of data. It

does ask for additional guidance from CMS in clarifying the reporting regulations. Bronwyn Mixter, Sept. 19, 2014 https://www.bloomberglaw.com/search/results/436fcc2ceeed13617e82df448ebca4f4/document/X6R1DNAS000000?search32=C9P6UQR5E9FN6PB1E9HMGNRKCLP6QFAJELN76Q39DPII0GB3EGTJMRJFBTKMQS2VE1K74OBJCLPJQC9R7DJ6IU2VC9NMUR2VE5QMASJP7KOG. Caroline Chen, Drug, Oct. 06, 2014, available at https://www.bloomberglaw.com/search/results/436fcc2ceeed13617e82df448ebca4f4/document/X32NG2N8000000?search32=C9P6UQR5E9FN6PB1E9HMGNRKCLP6QFAJELN76Q39DPII0GB3EGTJMRJFBTKMQS2VE1K74OBJCLPJQC9R7DJ6IU2VC9NMUR2VE5QMASJP7KOG.