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HEALTH CARE REFORM UPDATE

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Implementation of the Affordable Care Act

On October 31st the Department of Justice (DOJ) determined that it does not oppose the Supreme Court ordering the 4th Circuit Court to reexamine claims from Liberty University that the employer mandate is unconstitutional and that the individual mandate violates free exercise of religion. The brief from DOJ can be read [here](#).

On October 31st the U.S. District Court of the Eastern District of Michigan granted a preliminary injunction to Daniel Weingartz and the Weingartz Supply Company exempting Weingartz and his company from the contraceptive mandate of the ACA. The full ruling can be found [here](#).

On November 1st Health and Human Services (HHS) Secretary Sebelius announced a final rule implementing a requirement under the ACA that physicians caring for Medicaid beneficiaries must receive equal payment as those who care for Medicare beneficiaries. Secretary Sebelius said the rule ensures millions of Americans will get the health care they need to treat small health problems before they become larger issues. A release from HHS is available [here](#).

On November 1st Criswell College in Dallas filed a lawsuit in U.S. District Court claiming it is unconstitutionally being coerced to violate the Sixth Commandment (“thou shalt not murder”) because the college must pay heavy fines if it does not comply with the ACA’s contraceptive mandate. Criswell argues its First Amendment right to freely exercise its religion is being violated by the mandate. The lawsuit can be viewed [here](#).

On November 6th voters in Florida rejected a proposal that sought to amend the state’s constitution to block the ACA’s mandate that people buy insurance or pay a penalty. Voters in Alabama, Montana, and Wyoming chose to block implementation of ACA measures, although these votes were largely

symbolic, as the Supreme Court has already made its final decision regarding ACA approval. An article on Florida's vote can be read [here](#).

On November 8th Kansas Governor Sam Brownback (R) said he will not pursue a state-federal partnership insurance exchange. Calling the ACA an overreach by Washington, Brownback said he would not implement a partnership exchange because it would cost the state millions without offering benefits. The release from Brownback's office is available [here](#).

On November 8th Missouri Governor Jay Nixon (D) said he will notify the federal government that his state will not be running a state-based health insurance exchange. While Governor Nixon said a federal insurance exchange is not ideal, voters in Missouri passed a measure on November 6th that does not allow the governor to establish a state-run exchange without legislative or voter approval. An article on the governor's decision is available [here](#).

On November 9th HHS Secretary Sebelius sent a letter to governors across the country extending deadlines relating to the establishment of health care insurance exchanges. Secretary Sebelius said states must declare their intention to establish a state-based exchange by November 16th, but the exchange blueprint can be submitted through December 14th. States running a partnership exchange have until February 15th to submit a declaration letter and blueprint. The letter from HHS can be found [here](#).

Other HHS and Federal Regulatory Initiatives

On October 26th the Centers for Medicare and Medicaid Services (CMS) responded to a request from Maine to drop 30,000 people from the state's Medicaid program. CMS said more information is required on the situation, and it asked Maine to answer some additional questions. The information request means CMS has an additional 90 days to make a decision following a response. The letter from CMS to Maine can be read [here](#).

On October 31st the Center for Medicaid and CHIP Services (CMCS) instructed states to prepare for new prescription requests for voriconazole, an anti-fungal drug the Centers for Disease Control (CDC) has recommended to be used to treat meningitis caused by contaminated steroid injections from the New England Compounding Center. The notice from CMCS can be seen [here](#).

On October 31st the Government Accountability Office (GAO) released a report noting that increased self-referrals by physicians cost Medicare \$109 million in 2010. The GAO said the Centers for Medicare and Medicaid Services (CMS) should more closely monitor and identify the necessity of self-referrals. The report is available [here](#).

On October 31st the GAO issued a report highlighting the challenges the Food and Drug Administration (FDA) faces as it attempts to use foreign governments and other third parties to ensure the safety of imported food. The GAO suggested the FDA should revise its comparability approach to allow for the assessment of particular food products, such as seafood. The report can be read [here](#).

On October 31st the Food and Drug Administration (FDA) announced that Ameridose will voluntarily recall all of its non-expired products in circulation. No patient infections have been reported, but caution is being taken due to shared management between Ameridose and the New England

Compounding Center (NECC), which has been linked to the nationwide meningitis outbreak. The release from the FDA can be read [here](#).

On November 1st CMS released new rules on payment systems for Medicaid primary care physicians and the Medicare physician fee schedule. The filed rules are available [here](#).

On November 2nd CMS announced that 5.5%, or 85,000, of all medical records requested in the last year for review by contractors investigating improper payments in the Medicare program were sent using the Electronic Submission of Medical Documentation (esMD). CMS says that esMD provides an alternative to mail and fax. The release from CMS can be read [here](#).

On November 2nd CMS released regulations that update the end-stage renal disease prospective payment system and the home health prospective payment system rate update. Both regulations can be found [here](#).

On November 8th CMS sent a letter to the state of Texas indicating that funding for the state's Women's Health Program would end on Dec. 31. State lawmakers previously decided to remove Planned Parenthood and other abortion-affiliated clinics from the program, a move which CMS says limits the care options of women in the state. The letter from CMS is available [here](#). An article on the CMS decision can be read [here](#).

On November 9th the Centers for Disease Control (CDC) released updated case counts from the nationwide meningitis outbreak. As of the most recent update, 32 people have been killed from the outbreak, with over 400 cases reported. Updated case numbers from the CDC are available [here](#).

On November 12th CMS unveiled new features on the Medicare Prescription Plan Finder. CMS says the updated finder will provide beneficiaries with understandable comparisons of the costs and benefits of different plans. The new plan finder can be accessed [here](#).

Other Congressional and State Initiatives

On November 1st Representative Ed Markey (D-MA) announced he would introduce legislation that will strengthen federal regulations for compounding pharmacies, which he officially filed the following day. The Verifying Authority and Legality in Drug (VALID) Compounding Act will give the FDA authority to ensure the safety of drugs made at compounding pharmacies. A release from Rep. Markey is available [here](#). Text of the bill is available [here](#).

On November 1st Colorado Governor John Hickenlooper (D) wrote a letter to the state's general assembly addressing the budget for FY 2013-14. Hickenlooper has said in the past that he anticipates Medicaid expansion in the state through the ACA, although not enough guidance from the federal government is currently available to make a final determination. The letter from Hickenlooper can be read [here](#).

On November 5th New York Governor Andrew Cuomo (D) announced his state submitted a Section 1135 waiver request to the U.S. Department of Health and Human Services (HHS). Agreement of the waiver from HHS would relax certain administrative and record keeping rules that would help more

quickly deliver necessary health care services to New Yorkers. The release from Governor Cuomo is available [here](#).

On November 6th Florida voters rejected Amendment 6, a proposal that prohibited spending public funds on abortion or on insurance plans that cover abortion. Amendment 6 would have also eliminated a woman's right to privacy regarding abortion. Floridians also rejected Amendment 8, the Florida Religious Freedom Amendment, which opponents said could be interpreted as allowing religious organizations to refuse to provide reproductive health services. In Montana, voters passed an initiative requiring abortion providers to notify parents 48 hours in advance of a procedure given to a minor under 16 years of age. An article on the Florida rejections is available [here](#). The Montana decision can be read about [here](#).

On November 6th Massachusetts voters rejected a proposal that would have allowed physician-assisted suicide for terminally ill patients. The measure was struck down by a 51% to 49% margin. An article on the vote is available [here](#).

On November 6th Chairman Fred Upton (R-MI) of the House Energy and Commerce Committee issued a subpoena to Barry Cadden of the New England Compounding Center (NECC). The Committee issued the subpoena to bring Mr. Cadden to testify, who said he would not do so voluntarily. The press release from the Committee can be read [here](#). The subpoena to Mr. Cadden is available [here](#).

On November 9th the Guttmacher Institute released a study in which 40% of women throughout the country say their only source of health care was from a women's health center. About 60% of women surveyed said they used women's health centers in addition to another source. The study can be read [here](#).

Other Health Care News

On October 30th a survey from eHealthInsurance noted that many small businesses still lack a thorough understanding of the Affordable Care Act (ACA). Over one-third of the businesses with 50 employees incorrectly believed they were required to cover employees with insurance. Another 35% were not sure of the ACA's requirements regarding small businesses. The full survey is available [here](#).

On October 30th an article released in the journal *Cancer Epidemiology, Biomarkers & Prevention* noted that the quality of life of cancer survivors varies widely depending on the type of cancer experienced. Survivors of melanoma, breast, and prostate cancer had a mental- and physical-related quality of life similar to those who never had cancer. Survivors of cervical, blood, and colorectal cancers had a lower physical quality of life. An article on the study's findings is available [here](#).

On November 1st the Commonwealth Fund released a report finding that the number of small business workers offered, eligible, and covered by health insurance through their jobs declined over the past 10 years. In companies with fewer than 50 employees, less than 50% were offered and eligible for health insurance through their jobs in 2010. The full report can be read [here](#).

On November 1st the American Hospital Association (AHA) and four other hospital systems filed a lawsuit against HHS in U.S. District Court in the District of Columbia. The AHA says the federal

government refuses to reimburse hospitals for care which the AHA deems is reasonable and medically necessary. Government officials suggest many of the contested services could have been provided at an outpatient facility. The lawsuit can be found [here](#).

On November 2nd Orthofix International NV, a company which manufactures spinal implants and spinal surgery products, agreed to pay the United States \$30 million to settle a case involving Blackstone Medical Inc., an Orthofix subsidiary. Blackstone allegedly paid kickbacks to surgeons who used its products. The kickbacks included consulting agreements, royalty arrangements, research grants, travel, and entertainment. A release from the Department of Justice can be read [here](#).

On November 5th the RAND Corporation released a study that finds physicians with the least amount of experience spend significantly more money treating patients than physicians with the most experience. The study could have implications for young doctors as health care providers and the government look to provide higher quality health care at a lower cost. A release from RAND is available [here](#).

On November 5th the Federal Bureau of Investigation (FBI) announced that the Freeman Health System of Joplin, Missouri, agreed to pay \$9.3 million to settle allegations that the hospital system violated the Stark Law and the False Claims Act by knowingly providing incentive pay to physicians in a manner violating federal law. The FBI release is available [here](#).

On November 5th the FDA sent a letter to The Avalon Effect expressing concerns with claims being made by the Tennessee company that a special light therapy can treat or cure fungal meningitis and other diseases. The FDA warns consumers about opportunistic marketing following a nationwide meningitis outbreak. The FDA's release on the issue can be read [here](#).

On November 6th the National Eye Institute (NEI) issued a release expressing concern over increasing rates of diabetic retinopathy (DR), a common complication of diabetes that can lead to blindness. The number of Americans affected by DR is now at 7.7 million, up 3.7 million in the last decade. The NEI notes the rate is projected to reach 11 million by 2030. A release from NEI on the issue of DR is available [here](#).

On November 8th the Congressional Budget Office (CBO) released a report with choices for deficit reduction. Options include eliminating coverage-expansion under the ACA, which would save about \$150 billion through 2020. Other choices include reducing the floor on Medicaid match rates, raising the Medicare eligibility age, and increasing Medicare Part B premiums. The CBO's full report can be read [here](#).

On November 8th the National Coalition on Health Care (NCHC) released a plan that offers \$500 billion in health care deficit savings. Proposals in the report include a removal of barriers to competition for affordable generic drugs, a reform of Medicare post-acute and home health payments, and increased taxation on tobacco and sweetened beverages. The full report is available [here](#).

On November 8th the Retail Industry Leaders Association (RILA) sent a letter to President Obama expressing concern over a lack of regulatory guidance regarding the ACA. RILA asked for enforcement delays and encouraged the president to provide employers with ample time to comply with the ACA. A letter from RILA to the president is available [here](#).

Hearings and Mark-Ups Scheduled

Senate

On November 15th The Senate HELP Committee is holding a hearing titled the “Implications of the 2012 Meningitis Outbreak.” More information can be found [here](#).

House of Representatives

On November 14th the Energy & Commerce Committee is holding a hearing titled “The Fungal Meningitis Outbreak: Could It Have Been Prevented?” More information can be found [here](#).