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HEALTH CARE REFORM UPDATE January 21, 2011

Implementation of Health Care Reform Law

On January 12th, the Committee on the Determination of Essential Health Benefits at the Institute of Medicine (IOM) began a three-day series of meetings to begin determining what constitutes an "essential health benefit" under the Affordable Care Act (ACA). The IOM research will play a key role in helping HHS determine which benefits will be required in health insurance plans offered on the future insurance exchanges. More information on the meeting can be found <u>here</u>.

The recently-elected Republican attorney general in Kansas announced on January 12th that the state intends to join a lawsuit challenging the ACA being led by Florida Attorney General Pam Bondi (R). On January 18th Bondi filed a motion adding Kansas and 5 other states, Iowa, Ohio, Wyoming, Maine, and Wisconsin, to the lawsuit, bringing the total number of states on this particular lawsuit to 26.

On January 14th lawyers for the Justice Department filed a brief requesting oral arguments in another lawsuit against the ACA that a conservative law center is appealing in Michigan. The Thomas More Law Center in Ann Arbor, MI is appealing a lower court's decision upholding the individual mandate as constitutional.

After a week-long postponement in legislative business in the wake of the shootings in Tucson, AZ, the House of Representatives reconvened on January 18th to begin debate on H.R. 2, the "Repealing the Job-Killing Health Care Law Act," and a House Resolution instructing House Committees to report legislation replacing the ACA with different proposals. The same day HHS released a new analysis of the ACA noting that as many as 129 million Americans could be denied coverage due to pre-existing conditions if the law is repealed. A press release on the study can be found <u>here</u>. The House ultimately voted and approved H.R. 2 on the evening of January 19th by a vote of 245-189. Three Democrats voted in favor of repeal. The House then voted on January 20th and approved the resolution instructing House Committees to report bills replacing the ACA by a vote of 253-175.

On January 18th CMS Chief Actuary Rick Foster, a man who throughout the health care reform debate repeatedly questioned Democrats' projections of savings of the ACA, sent a letter to House Ways & Means Health Subcommittee Ranking Member Pete Stark (D-CA) noting that the GOP repeal of the new law would exhaust the Medicare trust fund 12 years earlier than expected. A copy of that letter can be found <u>here</u>.

In a letter released on January 20th, Sens. Ben Nelson (D-NE), Amy Klobuchar (D-MN), and Maria Cantwell (D-WA), all Democratic Senators up for re-election in 2011, are cited as asking House Speaker John Boehner (R-OH) to take up and quickly pass H.R. 4, a bill sponsored by Rep. Dan Lungren (R-CA) to strike the 1099 tax filing requirement in the ACA. The portion of the bill has been criticized by business groups as being too onerous, and Democrats have signaled a willingness to compromise on the issue.

On January 20th a group of generic pharmaceutical manufacturers, pharmacy benefit managers, and the AARP sent a letter to FDA Commissioner Margaret Hamburg claiming that brand-name pharma companies and biotech manufacturers are intentionally twisting the new provisions in the ACA to prevent generic companies from making biologic products that are already on the market. The question revolves around whether the 12-year period before a generic biosimilar product can be approved provides market exclusivity or data exclusivity. A bipartisan group of lawmakers sent a letter earlier this month taking the side of the brand-name companies.

Secretary Sebelius announced on January 20th that states will be able to apply for federal grant money that is not subject to the annual appropriations process to help them establish the insurance exchanges required under the ACA. States that are further along in the process will be able to apply for multi-year funding and receive larger amounts up front.

On January 21st Secretary Sebelius announced that 3 million Medicare beneficiaries had so far received prescription drug relief under the ACA. The beneficiaries received a tax-free rebate check of \$250 as part of the closure of the "donut hole." A copy of the press release can be found <u>here</u>.

Other HHS and Federal Regulatory Initiatives

The Nationals Institutes of Health (NIH) reported on January 12th that medical expenditures related to cancer treatment in the U.S. are expected to soar over the next ten years. NIH reported that the increase in costs will primarily be contributed to the costs of new technologies and therapies associated with the disease. More detailed information can be found <u>here</u>.

On January 12th the Health IT Policy Committee released recommendations and directions for submitting comments on potential stage 2 'meaningful use' objectives under the electronic health record (EHR) incentive program established by the American Recovery and Reinvestment Act (ARRA). The comment period will last 45 days beginning this week. A copy of the recommendations can be found <u>here</u>.

HHS released on January 13th a recent survey showing that four-fifths of the country's hospitals and 41 percent of office-based physicians currently intend to take advantage of the ARRA EHR incentive program. Dr. David Blumenthal, the National Coordinator for Health IT, praised the numbers. A copy of the press release can be found <u>here</u>.

On January 13th the Medicare Payment Advisory Commission (MedPAC) voted to send two significant recommendations to Congress. The first was for Congress to set a co-pay for the use home health services, a proposal which has been floated before and rejected by Congress previously. The second was for Congress to raise inpatient and outpatient hospital payments by one percent in FY2012. Both proposals were largely rebuffed by industry representatives. More information on MedPAC's meetings can be found <u>here</u>.

The Department of Defense announced on January 13th that military families will now receive a benefit similar to one in the ACA extending insurance coverage to dependents up to the age of 26. The Tricare Young Adult Program was included in the 2011 defense authorization package that the President signed in early January.

On January 18th the Supreme Court announced that it would hear arguments on three consolidated California court cases over whether the California Department of Health Care Services could cut the amounts they pay medical providers under the Medicaid program. In each case, providers sued the California Department over proposed cuts. The debate will be closely watched by other cash-strapped states as governors struggle to solve budget woes in light of decreased revenues and an expanded Medicaid program.

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Norman, Oklahoma physician Cynthia Taylor became the nation's first provider on January 18th to receive money from the ARRA incentive program for EHR adoption. In her office, Dr. Taylor received a large ceremonial check worth \$21,250, an occasion that officially kicks off a much-anticipated \$19.2 billion in projected payouts.

On January 19th the FDA announced an implementation plan for 25 major changes to the 510(k) program, the most common process used to approve medical devices. The changes are part of the agency's efforts to streamlining the process and clarifying compliance requirements, but the changes still come with controversy as various stakeholders have pushed back. More information can be found <u>here</u>.

Other Legislative Initiatives

Living up to their campaign promises, House Republicans have introduced numerous bills and resolutions h over the past week to repeal, derail, and replace the ACA. Among them were a House resolution sponsored by Rep. John Carter (R-TX) disapproving of the new medical-loss ratio (MLR) rule for insurers and a bill sponsored by Rep. Paul Broun (R-GA) to repeal the 7.5 percent threshold on the deduction for medical expenses, provide for increased funding for high-risk pools, allow acquiring health insurance across State lines, and allow for the creation of association health plans.

According to a memo prepared by the majority staff of the Energy & Commerce Committee dated January 18th, the Committee may act to reorganize HHS. The "backgrounder" document, apparently prepared by the Committee's majority staff, lays out a reshuffle of the Department as a top priority on the Committee's agenda and notes that many of HHS' discretionary programs "have overlapping programs and duplicative programs." The memo also places a large emphasis on overhauling the rules surrounding the Medicaid program that the Committee claims "is on a trajectory to be the largest Medicaid health care program" as well as targets FDA oversight claiming that "FDA regulated products account for 25 cents out of every dollar spent by our nation's consumer."

On January 20th the House Judiciary Committee led by Chairman Lamar Smith (R-TX) held a hearing on medical liability reform. Proposals to reform our medical malpractice liability system are thought to be first on the GOP agenda to "replace" the ACA with more conservative alternatives.