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HEALTH CARE REFORM UPDATE

April 2, 2012

Special Report: Health Reform before the Supreme Court

Last week all eyes in the health policy world were tuned to the U.S. Supreme Court, which held much-anticipated oral arguments on constitutional merits of several portions of the Affordable Care Act (ACA). In the week leading up to the five and one-half hours of oral arguments – the longest span allotted since 1976 – C-SPAN conducted a poll which found that 91% of Americans were either “somewhat” or “very” closely following news coverage of the case. The considerable attention paralleled a renewed interest in televising the proceedings, with 74% of those polled arguing that the three days of arguments warranted such coverage. The full survey results are available [here](#).

Ultimately, the Court rejected the attempt at television coverage, but permitted the unprecedented release of audio recordings and transcripts on the same day as the oral arguments. Still, as could be expected from that demand for coverage, major news outlets issued numerous updates and did not shy away from making predictions about the result. The consensus that emerged held that Solicitor General Donald Verrilli, Jr., was the recipient of particularly piercing questions from the more conservative Justices on the Court, on the issue of whether the individual mandate is constitutional. While such questioning does not necessarily indicate the Supreme Court’s ultimate holding, it was enough to fuel speculation that the individual mandate might be struck down.

The oral arguments on Monday, March 26th focused on the Anti-Injunction Act and whether the case could be heard yet. Both sides supported having the case move forward, so the Court hired an outside attorney to argue the point that it should stop. The transcript from Monday is available [here](#), and the audio recording available [here](#). On Tuesday, the arguably most contentious aspect of the ACA was addressed – the individual mandate. The transcript is available [here](#), and the audio recording is available [here](#). Wednesday brought the issue of severability to the forefront – whether the bill could stand without the individual mandate, as well as the constitutionality of the Medicaid expansion. The arguments were divided into two sections, with the transcripts for parts one and two available [here](#) and [here](#), and the audio for parts one and two available [here](#) and [here](#).

Even as the Justices were expected to conduct an informal vote on the case last Friday, everyone – pundits and politicians alike, will have to wait until the decision is released in June.

Implementation of the Affordable Care Act (ACA)

On March 26th the Centers for Medicare & Medicaid Services' (CMS) Innovation Center reported that it would delay the announcement of the grant recipient winners from its Health Care Innovation Challenge. Selected applicants were supposed to be announced on March 30th, but the Center received a deluge of approximately 3,000 submissions and so notification will be delayed for several weeks. The Challenge can provide up to \$1 billion in grants to aid applicants implement strategies that will lower costs while improving the health and care of individuals enrolled in Medicare, Medicaid, and CHIP. The press release is available [here](#).

On March 29th CMS announced that it had awarded funding to three additional Consumer Oriented and Operated Plans (CO-OPs) in Maine, Oregon, and South Carolina bringing the total number of states with CMS-funded CO-OPs to ten. The funding opportunity was created as part of the ACA designed to inject competition into the health insurance marketplace. The CMS release announcing the awards can be found [here](#).

Other HHS and Federal Regulatory Initiatives

On March 27th the Food and Drug Administration (FDA) published a new guidance document for manufacturers navigating the medical device premarket approval process. It details the principal factors considered and systematic approach used by the FDA when making cost-benefit determinations of low to high risk device approval. Benefit considerations include the magnitude and probability of a patient experiencing one or more benefit, while risk considerations include the severity, likelihood, and duration of adverse affects. The guidance document is available [here](#). A press release can be found [here](#).

On March 27th the Presidential Commission for the Study of Bioethical Issues, which is part of HHS, issued a formal request for public comment on the privacy implications of individual human genome sequencing. The Commission was created in 2009 by President Obama to make recommendations for ethical guidelines for scientific research. This latest request comes as genome sequencing has become dramatically less expensive, with the prospects of individual sequencing spurring questions about its proper use for research and clinical care relative to the needs of personal privacy and societal benefit. Comments will be accepted through May 25th, and can be submitted [here](#). The notice in the Federal Register is available [here](#).

On March 29th CMS announced its intent to establish a Federally Funded Research and Development Center (FFRDC). Currently CMS relies on the Internal Revenue Service's FFRDC, which has focused on upgrading the agency's information technology capabilities. With a CMS-specific FFRDC, the agency will look to better facilitate small business participation and increase transparency in its awards process. It will develop metrics to measure agency performance and ensure that it complies with its statutory requirements. The notice in the Federal Register is available [here](#).

On March 30th the CDC's National Center on Birth Defects and Developmental Disabilities released a report which estimated that 1 in 88 children have an autism spectrum disorder. The estimate is derived

from data collected in 2008 on children who were eight years old. The finding marks a 23% increase since the last CDC report issued in 2009 and a 78% increase since the Center's first report in 2007. Improved diagnoses and earlier interventions were cited as the most likely reasons for the increase. The full report is available [here](#).

On March 30th CMS announced that it had paid a total of \$6.6 million in incentive payments to two separate programs: the Physician Quality Reporting System, and an electronic prescribing program. The CMS report can be found [here](#).

Other Congressional and State Initiatives

On March 29th the House of Representatives approved, by a vote of 228 to 191, the \$3.5 trillion budget plan introduced by Rep. Paul Ryan (R-WI). The plan passed with all but 10 Republicans in support and every Democrat opposed. Ryan claims that the budget will cut \$5.3 trillion from deficits over the next ten years, but policy uncertainty in the plan prevented the Congressional Budget Office from confirming that estimate. The CBO analysis is available [here](#). House Speaker John Boehner celebrated the proposal as representing a “blueprint for America’s future,” and for making the “tough decisions” to save Social Security and Medicare. For her part, Minority Leader Nancy Pelosi derided the budget, claiming that it did not represent the “national values” of the American people and for cutting social programs in favor of “big oil.” Read Boehner’s floor speech [here](#) and Pelosi’s floor speech [here](#).

Other Health Care News

On March 27th the Urban Institute released a report which claimed that only 6% of the population under age 65 would need to newly purchase health insurance or pay the penalty under the individual mandate requirement of the ACA. Most Americans subject to the mandate are estimated to already have coverage, while 33% of those under the age of 65 would be exempt from paying the penalty due in large part to incomes that are below the minimum threshold. The study was funded by the Robert Wood Johnson Foundation, and is available [here](#).

On March 29th The National Community Pharmacists Association, the National Association of Chain Drug Stores, and nine pharmacy companies filed a lawsuit to block the Express Scripts-Medco merger. The suit alleges that since the proposed merger is between two of the three largest pharmacy benefits management companies, the resulting firm will have sufficient market power to reduce reimbursements to retail community pharmacies – driving them out of business, so as to force individuals to subscribe to mail-order services or visit specialty pharmacies. The lawsuit was filed in the U.S. District Court for the Western District of Pennsylvania and is available [here](#).

Hearings & Mark-ups Scheduled

Congress is currently on recess for two weeks