



Health Policy Briefing

January 4, 2016

Congress Returns

The House and Senate will meet in pro forma session at 12 noon today for the convening of the second session of the 114th Congress.

State of the Union

President Obama will deliver his 2016 State of the Union address on Tuesday, January 12 at 9 p.m. ET. To date, there have been a total of 93 in-person Annual Messages/State of the Union Addresses. The U.S. Constitution provides the formal basis for the State of the Union Address: The President “shall from time to time give to the Congress Information of the State of the Union, and recommend to their Consideration such measures as he shall judge necessary and expedient.” [Article II, Section 3, Clause 1] The longest spoken State of the Union address was given in 1995 by President Bill Clinton: 9,190 words. The shortest, in 1790, was given by President George Washington: 1,089 words.

White House Conference on Aging Report Released

The 2015 White House Conference on Aging **final report** was released last week. The sixth White House Conference on Aging was held in July of 2015, and provided an opportunity for older Americans, their families and caregivers, advocates, and leaders in the field of aging to provide input on the four themes that emerged as particularly important to older Americans: Retirement Security, Healthy Aging, Long-Term Services and Supports, and Elder Justice. Based on the participant input received, the report defined the new goals for the conference in the future. The report stresses the need to acknowledge the demographic reality currently facing the country – over 10,000 baby boomers turn 65 every day, and this age wave will continue into the next decade. The second goal identified is the need to further support caregivers, both paid and

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unpaid. The report also identifies the importance of collaboration across the sectors of housing, transportation, health care, and long-term services and supports in order to further healthy aging. The need to take advantage of technology to help older Americans access the services they need was also outlined. Finally, the report concludes that the perception of aging must be changed from one that assumes the age wave will overwhelm to one that engages the challenges and embraces the possibilities that are inherent in the country's aging population.

Affordable Care Act News

Administration Announces Employer Reporting Delay

The Obama Administration announced last week that employers would have an extra two months past the February 1 deadline to give individuals forms for reporting on their offers of health coverage options they will provide. The decision was reportedly made following feedback received by the Treasury Department from the business community. Employers will also receive an extra three months to share their plan information with the Internal Revenue Service (IRS) past the previous February 29 due date for paper filings and the March 31 due date for electronic returns. The announcement was met with criticism from some Republicans, who believe that delaying the requirements of the health care law will not remedy what they believe are the fundamental flaws of the Affordable Care Act (ACA).

Food and Drug Administration News

FDA Proposes to Notify Consumers of Medical Device Reviews

In a draft guidance released last week, the Food and Drug Administration (FDA) proposed to let the public know when the agency is reviewing potential problems with medical devices. The proposed policy on what the FDA terms "emerging signals" would educate consumers about potential health concerns before the evidence surrounding the medical devices is actually examined. Currently, the FDA only raises concerns about medical devices such as surgical instruments and diagnostic equipment after they have completed an analysis of the data. This analysis is then usually followed by new recommendations for consumers or product recalls. Emerging signals that could be communicated to the public include device malfunctions, newly reported adverse events, an increase in the severity or frequency of previously known problems, or recently discovered interactions with other products. Sharing this information with consumers would be a means of protection from any device problems while the FDA is conducting its review, but would have the potential to unnecessarily halt the use of beneficial devices because of unevaluated risks.

FDA Seeks Feedback on Testing Drugs for Deadly Infections

The Food and Drug Administration (FDA) has opened a public docket to gather information on how to test experimental treatments for emerging infectious diseases such as Ebola. The docket was opened for suggestions on how to test medicines specifically designed to fight these infections when outbreaks pose such special hurdles to designing studies and recruiting patients. Other deadly infections to be targeted include Middle East Respiratory Syndrome. In the case of Ebola, researchers have faced the question of whether it is ethical to use placebos in order to compare the effectiveness of an experimental drug. It was also difficult to gather enough patients to test the experimental Ebola drug known as ZMapp due to the waning of the outbreak in Liberia, where the formal study was started. The FDA will accept submissions to the docket through January 28. Last week, the World Health Organization (WHO) announced the end of the Ebola outbreak in Guinea, the site of the original Ebola transmission. The outbreak ultimately killed more than 11,000 people, according to WHO.