



President Obama Signs SEMINAL HEALTH CARE REFORM LEGISLATION

BY JULIE BIRKOFER AND JAY GREISSING

Highlights of the New Health Reform Law Insurance Reform

Many stakeholders within the plasma protein therapies user community worked hard to secure the PPACA's elimination of lifetime limits on insurance benefits and of the practice of insurers denying coverage based on preexisting conditions. These insurance reforms will help all Americans access and maintain the medical care they need.

Specifically, within six months of enactment, group health plans and health insurers offering group or individual coverage may not establish lifetime limits on the dollar value of benefits for any participant or beneficiary. Beginning January 1, 2014, such plans and insurers may not impose any preexisting condition exclusion with respect to such plan or coverage.

In order to provide immediate health insurance coverage to those uninsured

individuals with pre-existing conditions, the new law requires the Secretary to establish, within 90 days of enactment, temporary national high risk health insurance pools. These risk pools will exist until 2014, when the insurance exchanges will be operational.

Annual limits on coverage are also banned, beginning January 1, 2014. Prior to that date, group health plans and health insurers offering group or individual coverage may impose annual limits on coverage, but only to the

IN LATE MARCH, President Barack Obama signed into law the Senate health care reform bill, H.R. 3590, the Patient Protection and Affordable Care Act (PPACA), and the bicameral reform budget reconciliation package H.R. 4872. This action is, without question, an historical achievement because of the sweeping changes to America's health care system amongst the back drop of deep partisanship and the economic recession.

extent necessary to preserve participant or beneficiary access to needed services with a minimal impact on premiums.

Other insurance reform provisions of note include: (1) an extension of health insurance coverage for adult child dependents that are not married, allowing such individuals to remain on a parent or guardian's insurance plan until age 26; (2) a prohibition against coverage rescissions by group health plans and health insurers offering group or individual coverage; (3) fair premiums; (4) guaranteed coverage and renewal; and (5) a prohibition against discrimination based on health status of covered individual.

Follow-on Biologics (Biosimilars)

The follow-on biologics provisions signed into law provide innovators with four years of data exclusivity and 12 years of market exclusivity. These exclusivity provisions were favored not only by the entire biologics industry, including PPTA, but also by the majority of lawmakers. Despite speculation in recent months that a more generic friendly exclusivity provisions would be in the final bill at the President's desk, a scaled back biosimilar bill never came to fruition.

Comparative Effectiveness Research (CER)

As part of its section establishing an independent patient-centered CER body, the PPACA

includes a rare disease advisory panel, which PPTA championed. This provision requires the appointment of an expert advisory panel during each instance a rare disease is being considered for a CER study for the purpose of assisting in the design of the research study and determining the relative value and feasibility of conducting the research study. Because patients and physicians with relevant experience in the rare disease must serve on such a panel, PPTA believes this provision successfully empowers patients and physicians to contribute to the CER process. PPTA looks forward to working with consumer organizations as the new CER institute is implemented and engaging appropriately as CER studies are proposed.



A History of OVERHAULING HEALTH CARE IN THE UNITED STATES



1934
President Franklin D. Roosevelt's
New Deal omits health insurance plan



1945
President Harry S. Truman
calls on Congress for health care overhaul



1988
Medicare Catastrophic Coverage Act
overwhelming approved by Congress and signed into law by **President Ronald Reagan**



1989
Catastrophic Coverage Act
repealed

1993
President Bill Clinton
starts a reform effort which would provide universal coverage based on the idea of "managed competition"


1994
President Bill Clinton's Health Security Act
fails to pass in Congress

Independent Medicare Advisory Board (IMAB)

While the CER provisions have strong safeguards for patient access, the IMAB provisions fail to protect patients in a similarly adequate manner. The purpose of the IMAB that will be created as a result of the passage of health care reform is to reduce the per capita rate of growth in Medicare spending. Beginning in 2014, the IMAB would submit to Congress and the President recommendations to this effect if the Chief Actuary of the Centers for Medicare and Medicaid Services (CMS) determines in the previous year that such growth rate will increase faster than an established inflation rate. These recommendations would automatically go into effect

the following year unless subsequent legislative action is taken by a certain date.

Some of the structure of the IMAB is controversial; such as, its ability to require the Secretary of the U.S. Department of Health and Human Services to unilaterally promulgate new Medicare policies with limited Congressional oversight. One hundred Members of the House of Representatives—both Democrats and Republicans—have expressed opposition to the IMAB. In a January 15, 2010 letter to Speaker of the House Rep. Nancy Pelosi (D-Calif.), the concerned lawmakers contend that the “unelected, unaccountable Medicare commission as envisioned in the Senate’s IMAB proposal... would end Congress’s ability to shape

Medicare to provide the best policies for beneficiaries in [their] communities around the country.” Because of the opposition to it, one could certainly see this provision modified before it goes into effect in 2014. While this board will have a consumer advisory panel, the IMAB is generally bad policy that has the potential to not only adversely affect patient access to the complete range of plasma protein therapies in each therapeutic class, but also hinder the ability of patients to follow the most appropriate treatment plan developed with their physician. 

JULIE BIRKOFER is PPTA’s Senior Vice President, North America and JAY GREISSING is PPTA’s Director, Federal Affairs



1962
President John F. Kennedy takes up the issue of health benefits for Social Security recipients



1971
President Richard M. Nixon backs plan requiring employers to provide a minimum level of insurance to employees



1976
President Jimmy Carter calls for a comprehensive national health insurance system with universal and mandatory coverage



1986
Congress signs the **Consolidated Omnibus Budget Reconciliation Act** or COBRA into law



1996
The **Health Insurance Portability and Accountability Act** (HIPAA) establishing medical record privacy and protecting people from being barred for preexisting conditions is signed into law

1997
The **State Children’s Health Insurance Program** (S-CHIP) is enacted

2003
Medicare is expanded to cover prescription drugs when **President George W. Bush** signs the **Medicare Modernization Act** into law



March 23, 2010
President Barack Obama signs the **Affordable Health Care for America Act** into law