

SINCE PRESIDENT OBAMA TOOK OFFICE, the Administration and Congress have maintained a focus toward passing some version of health care reform legislation. Because many Americans would argue that the United States' health care system—from coverage to delivery—is fundamentally broken, the nation's capital has been focused on little else since the summer. Congress has been resolute in its efforts to craft legislation that includes a sweeping system wide change intended to cover the approximately 46 million uninsured, end discriminatory practices of the insurance industry and overhaul the delivery system.

CONGRESS CONTINUES ITS PATH TOWARD

America's escalating trillion dollar deficit is unsustainable, and President Obama has been clear—health care expenditures that are climbing nearly 20 percent annually must be brought under control in order to attain a meaningful chance of economic recovery. The goals are laudable. Pass a bill that will achieve cost savings; provide meaningful coverage; result in high quality health care; eliminate waste; improve patient access; and improve affordability—and the funding must be sustainable.

House Passes Landmark Health Reform Bill

The efforts of Congress and the Administration have resulted in a historical outcome—on Saturday, November 7, 2009, the U.S. House of Representatives passed comprehensive health care reform legislation that would achieve many of President Obama's chief goals that he highlighted during his Presidential campaign, and has reinforced in recent months.

The legislation, H.R. 3962, which narrowly passed by a vote of 220-215, includes the heavily debated "public option" that proponents believe will help provide meaningful coverage for those currently without insurance. The Republican victories in recent gubernatorial elections in Virginia and New Jersey caused many Congressional Democrats take stock of their own reelection challenges, as evidenced when 39 Democrats choose to vote against H.R. 3962. Only one Republican, freshman Joseph Cao, voted in support of the bill.

Senate Moves Forward; Challenges Remain

The Democrats are attempting to take full advantage of their power position of controlling the House, Senate, and the White House for the first time since early in President Clinton's first term more than 16 years ago and are optimistic that something similar to the House bill will ultimately become law. Late

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HEALTH CARE REFORM

BY JULIE BIRKOFER



in the evening on November 18, Senate Majority Leader Harry Reid (D-NV) released the health reform bill, Patient Protection and Affordable Care Act, filed as a substitute amendment to the House-passed legislation. The following Saturday, the Senate voted along party lines to begin full debate. The bill intends to extend health benefits to 31 million Americans who currently are not insured at a cost of \$848 billion over 10 years. Now that the Democrats have sidestepped a Senate filibuster, it will take 51 votes to pass the bill out of the chamber. Once the Senate passes

its version of health care reform, it is likely a conference committee will convene to reconcile the differences between the two bills. Hurdles remain, however.

Notwithstanding the incredible achievements of the passage of House and Senate bills, the political realities in the Senate, the lack of full Democratic Caucus support in the House, and the incredibly contentious issue of whether federal funds should cover abortions indicate that much work remains for lawmakers in order to present President Obama with a bill that he can sign into law.

Industry Advocates to Preserve Patient Access

There are provisions within health care reform that would cause a sea change in how Americans receive health care. PPTA and its member companies have been focused on several aspects of the legislation that would directly affect the industry as a whole. In addition to PPTA, several recombinant manufacturers outside of the PPTA membership also have a stake in how the legislation would affect patient access to blood clotting factors. PPTA's membership is

TOP ISSUES AFFECTING THERAPIES AND PATIENT ACCESS

340B Drug Pricing Program

Designed to support federally funded clinics and hospitals that serve a large percentage of low income or uninsured patients, the 340B program offers covered entities the opportunity to purchase pharmaceuticals at steep discounts based on the minimum Medicaid outpatient drug rebate percentage. These hospitals and clinics are then able to resell these drugs to patients at or near market value, so the patients do not directly benefit from the discount. PPTA is concerned that expanding this program, which has already grown by more than 1,000 percent in the last decade, without an equitable improvement of program integrity could create both short-term and long-term patient access impediments.

Legislation in the Senate would expand the 340B program by increasing the types of entities eligible to qualify for 340B pricing, mandating that manufacturers sell product to 340B covered entities, extending 340B pricing to inpatient sales, and relaxing in certain instances the current prohibition against disproportionate share hospitals (DSH) using group purchasing organizations (GPOs) to purchase covered outpatient drugs. The bill would also require a study of the 340B program by the Government Accountability Office (GAO) within 18 months



of enactment. The proposed study would examine, among other things, whether mandatory sales of certain products to 340B covered entities could hinder patient access to these therapies through any provider.

Like the Senate bill, H.R. 3962 also would add new covered entity types and mandate sales. The House bill would not, however, extend 340B pricing to inpatient sales, nor would it create exceptions to the DSH GPO prohibition. The GAO study also is not included in H.R. 3962.


Comparative Effectiveness Research (CER)

Because an interoperable health information technology system will soon be a reality in the U.S. as a result of provisions in the economic stimulus bill signed into law earlier this year, there is unlimited potential for CER as a key component of a rapid learning network tool for physicians. While federally funded CER has been occurring for more than a decade, the creation of an independent CER entity has been a top priority for both the Administration and Congress. CER, however, has the potential to affect access to plasma protein therapies if study outcomes are used to support national coverage determinations or restrictive formularies.

Fortunately, the Senate bill, would help preserve patient access by requiring the new CER institute, each time there



dynamic and includes both plasma-derived and recombinant manufacturers. With health care reform legislation having an effect on all therapy producers and poised to change how patients access lifesaving plasma protein therapies, now more than ever it is imperative for all stakeholders to advocate for patient access.

The accompanying sidebar highlights key health care reform provisions on which PPTA has been advocating, and includes their current status. 

is a proposed CER study on a rare disease, to appoint an “expert advisory panel for rare diseases” to assist in the design of such research study and determine “the relative value and feasibility of conducting such research study.” The panel would include practicing and research clinicians, patients and patient representatives with experience in the relevant topic, project, or category for which the panel is established. Additionally, this panel would be permitted to include a representative of each manufacturer of each medical technology that is included in the relevant research topic project or category for which the panel is established.

The House bill, however, does not include a similar protection for patients with rare diseases.

Pathway for Biosimilars

Both the House and Senate health care reform bills include a provision creating an abbreviated Food and Drug Administration (FDA) approval pathway for biologicals that can prove biosimilarity to an innovator product. Such a pathway obviously raises considerable patient safety concerns. Interestingly, the European Medicines Agency (EMA), which already has a process for biosimilars in place, has stated that it will not accept an abbreviated application for a biosimilar referencing IVIG or blood clotting factors (both plasma-derived and recombinant). Congress has unequivocally indicated, however, that it will not carve out any product classes in legislation.

Of significant concern to PPTA is that neither bill would require FDA to promulgate product class-specific guidance on biosimilarity, interchangeability, and immunogenicity prior to consideration and approval of an abbreviated BLA. The key point of contention among stakeholders in the overall debate

surrounds the number of years of non-patent market exclusivity to which the innovator product should be entitled. Both the House and Senate bills contain 12 years of such exclusivity.

Congress will optimize its cost savings from biosimilars by modifying Medicare reimbursement to create new classes of reimbursement for interchangeable biosimilars and non-interchangeable biosimilars. Generally, under the House bill, interchangeable biosimilars would be reimbursed according to the volume-weighted ASP plus six percent of it and the reference product, while non-interchangeable biosimilars would be reimbursed according to their own volume-weighted ASP plus six percent of the reference product’s ASP.

LEARN MORE: *If you would like to join PPTA’s advocacy for patient access to plasma protein therapies, contact Kym Kilbourne at 443-458-4682 or via email at kkilbourne@pptaglobal.org.*

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