

Health Policy Update

Federal Action

Medicare Patient Access

PPTA works with Congress, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) in communicating the importance of unfettered consumer access to all plasma derived and recombinant analog therapies (collectively plasma protein therapies) while at the same time educating policymakers on the unique, niche biologics industry that produce these lifesaving medicines.

Health Care Reform

Health care reform initiatives are extremely fluid, especially since the August recess brought more public fears and uncertainty about President Barack Obama's health care reform agenda in the form of confrontational 'town hall' style meetings in congressional districts across the country. Thus, to regain public confidence and to revitalize congressional support especially within his own party, the President addressed the nation on September 9, 2009 and articulated his vision of health care reform in attempts to dispel what the administration feels are inaccurate portrayals by the opposition to government run health care. Democrat Leadership is hopeful that the President's speech will encourage the caucus to compromise in order to pass a health care reform bill before the end of the year.

In his speech, the President suggested creating an insurance exchange for the uninsured and mandating coverage for pre-existing conditions. The President also

extended an olive branch to Republicans by proposing non-descript medical liability reforms. The majority of the proposals that President Obama laid out for the nation were, however, not new; both the House and the Senate have debated them extensively over the past several months.

With regard to his proposal for a public health insurance plan option that would begin in 2013, President Obama made it clear it could be one of many components of health care reform and that the House and the Senate have the flexibility to negotiate viable alternative approaches, including "triggers" for the public option and the Senate Finance Committee's ballyhooed non-profit insurance cooperatives for uninsured individuals and families. Additionally, this speech provided a forum for the President to commit to the controversial policies that would implement tax penalties on individuals who fail to obtain health insurance coverage and mid to large size businesses that fail to offer it to their employees.

To learn more about the President's health care reform plan, please go to http://www.whitehouse.gov/issues/health_care/plan/

The biggest obstacle for the President's plan is the ability to pass either chamber because resistance to a public option is coming from both Republicans and Democrats. In the House of Representatives, the moderate Democrats and the liberal Democrats have been firmly divided over the public option concept. Federally funded abortion is also an issue that will prohibit many Members of Congress from voting to support of health

care reform legislation in its current form. A public option would also not pass the Senate because of the filibuster -- 60 votes are necessary for passage. Although Democrat Leadership could avoid a filibuster if it uses the budget reconciliation process to pass legislation, the political consequences of doing so may be too great. Senate Finance Committee Chairman, Max Baucus (D-MT) has committed to drafting legislation that does not have a public option plan but would provide comprehensive insurance coverage through the cooperative health insurers, otherwise known as non-profit 'co-ops'.

Chairman Baucus has been working with a bipartisan group of five other Finance Committee members who are perceived as vital to drafting legislation that the committee can support. After months of closely negotiating, there appears to be a schism in "the gang of six." Specifically, Senators Chuck Grassley (R-IA) and Mike Enzi (R-WY) objected to some provisions in Baucus' recently released framework for the Finance Committee bill, including the anticipated "cooperative" alternative to a public insurance plan and at least \$400 billion in Medicare cuts and assessments on the insurance industry to fund health care system reforms. The draft outline of legislation, which reportedly comes in at less than \$900 billion over 10 years, does not include a "trigger" public plan option promoted by Senator Olympia Snowe (R-ME), but she is likely to offer the proposal as an amendment during markup.

Of particular interest to PPTA and the hemophilia community, Chairman Baucus' draft outline of the legislation proposes to increase the Medicaid outpatient drug rebate percentage paid by manufacturers as one of numerous ways to pay for the massive costs of health care reform. Baucus, however, recognizes the importance of patient access to life-saving blood clotting factor products and determined the rebate percentage should only be increased by two percentage points for the entire therapeutic class of blood

clotting factor products -- from the current 15.1% to 17.1% -- while the minimum rebate percentage for all other branded pharmaceuticals and biologicals, except drugs approved by FDA for only pediatric indications, will be increased to 23.1%.

Because such a high volume of blood clotting factors goes through Medicaid and 340B, Chairman Baucus realized that increasing the Medicaid rebate penalty so drastically may have an unintended consequence of patients having less ability to choose their provider of blood clotting factors and related services. PPTA, its member companies, and some stakeholder organizations have advocated for special consideration for blood clotting factors for several months and we view this development as an important step in preserving patient access to blood clotting factors. The Finance Committee is expected to begin marking up health care reform legislation the week of September 21st. The bill reported out of the Finance Committee will need to be reconciled with the bill ordered to be reported by the Senate Committee on Health, Education, Labor, and Pensions (HELP) on July 15, 2009.

Meanwhile, the House Committee on Energy and Commerce passed H.R. 3200, the America's Affordable Health Choices Act of 2009, on July 31, 2009 by a three vote margin, but Chairman Henry Waxman (D-CA) has agreed to consider as many as 70 amendments that were filed but not offered in July. Among those amendments of particular interest are those addressing the 340B Drug Pricing Program and comparative effectiveness research (CER).

Comparative Effectiveness Research

CER has been ongoing for more than a decade, but has received more attention from lawmakers in recent years as cost containment has become more of a priority.

The Senate HELP Committee bill and H.R. 3200 have included comprehensive CER legislative language. The Senate Finance

Committee has yet to release the full details of CER in its health care reform package, but has indicated it will be included as well. The language in the Finance Committee bill will likely be S. 1213, as introduced by Senators Max Baucus (D-MT) and Kent Conrad (D-ND) in June.

As reported in PPTA's June *Health Policy Update*, PPTA strongly supports S. 1213 because it incorporated PPTA's recommendation for a permanent advisory panel on rare diseases. PPTA offered this recommendation in a March 2, 2009 letter to Senators Baucus and Conrad. Specifically, when there is a proposed CER study for a rare disease, the new bill would require the Patient-Centered Outcomes Research Institute to "appoint an expert advisory panel for purposes of assisting in the design of such research study and determining the relative value and feasibility of conducting such research study." PPTA has been advocating that S. 1213 be the base from which comprehensive CER legislation is crafted in the health care reform debate.

PPTA greatly appreciates the efforts of Senator Mike Enzi (R-WY) as he attempted to improve the Senate HELP Committee's CER provisions. One of Enzi's amendments that the committee adopted would include a rare disease advisory panel. Although this language creating the rare disease advisory panel is not crafted as strongly as the panel in S. 1213, it was critical to get it adopted so the HELP bill is at least consistent with the approach for treating these types of patients in S. 1213 to make the reconciliation of these two bills easier.

The CER language in H.R. 3200 does not go far enough to ensure the recognition that all patients are unique. Although it does require stakeholder input in establishing research questions and study methodology, and creates a "Patient Ombudsman," who "shall serve as an available point of contact for any patients with an interest in proposed" CER studies and "ensure that any comments from patients regarding proposed" CER studies are reviewed by the

CER Commission, it fails to recognize that rare diseases must be given special consideration and that patients may react differently to the same treatment plan, so multiple treatment options must be preserved. On a positive note, two amendments offered by Republicans were adopted that may help limit national coverage determinations stemming from CER, but realistically CMS' authority will not likely be affected. Specifically, the Rogers Amendment would prohibit the government from using CER to deny or ration patient care and the Gingrey Amendment would prohibit the independent body responsible for CER to make recommendations based solely on cost effectiveness.

One of the pending amendments to H.R. 3200 in the Energy and Commerce Committee has been filed by Representative Donna Christensen (D-VI). It includes a number of patient safeguards, but again, no rare disease advisory panel.

PPTA continues to work with lawmakers and stakeholders to make sure that safeguards for rare diseases are implemented in any final health care reform package that may eventually cross the president's desk.

Follow-on Biologics

The Senate HELP Committee health reform legislation added biosimilars legislation very similar to S. 1695 of the 110th Congress, which the committee reported out in 2007. The new biosimilars language, which was added to the HELP Committee's bill through the Hagan-Enzi-Hatch Amendment, includes a robust data exclusivity period of 12 years for innovator products but it does not have additional patient safe guards, such as mandatory product class specific guidance, which PPTA strongly supports.

Moreover, on July 31, 2009 the House Energy and Commerce Committee added biosimilars language to H.R. 3200 through an amendment offered by Representatives Anna Eshoo (D-CA), Jay Inslee (D-WA),

and Joe Barton (R-TX). This amendment was quite similar to the Hagan-Enzi-Hatch Amendment as it also included an additional 12 year non-patent exclusivity period for innovators, but no mandatory product class specific guidance. This language is much weaker than H.R. 1548, which Eshoo, Inslee, and Barton introduced earlier this year. PPTA strongly supports H.R. 1548 because it would have required FDA to issue final product class specific guidance for the therapeutic class of the reference product in the abbreviated biologics license application (BLA) before it could approve the abbreviated BLA.

The politics behind the Energy and Commerce Committee action is quite interesting and further demonstrated the strained relationship between Chairman Waxman and Ms. Eshoo. Waxman had introduced and supports a competing bill, H.R. 1427, which is more generic friendly in the sense that an additional exclusivity period for innovator products would only apply to products new to the market after the new laws go into effect and would be nearly impossible to obtain, but if the innovator could receive it, it would be for no more than a five year period. New plasma protein therapies would likely never be eligible for this additional exclusivity period in the Waxman bill.

Eshoo's original bill dwarfs the Chairman's bill in number of cosponsors 142-14. H.R. 1548 also outpaced H.R. 1427 in support from committee members by a count of 24-6, including the lead sponsors. Although H.R. 1548 would have been adopted by the committee just as easily as the amendment she ultimately offered, which passed by a vote of 47-11, Eshoo interestingly offered language more similar to that which passed the Senate HELP Committee.

Of note during the Energy and Commerce Committee's consideration of the Eshoo amendment, she requested, much to Chairman Waxman's chagrin, a roll call vote even though she had clearly won a voice vote. Beyond the firm belief held by

Chairman Waxman and President Obama that 12 years of additional data exclusivity protection is excessive, the decision by Representative Eshoo to show up Chairman Waxman with the roll call vote will undoubtedly increase the chance that the Chairman removes the biosimilars language from any final negotiated bi-cameral health care legislation in conference committee, if and when both chambers pass health care reform legislation.

PPTA strongly supports the robust 12 years of data exclusivity encompassed in amendments passed both the Senate HELP and House Energy and Commerce Committees. It is, however, disappointed that Ms. Eshoo dropped many important provisions from H.R. 1548 in the amendment she ultimately offered.

340B Drug Pricing Program Expansion

The Senate HELP committee passed provisions in their health care reform legislation that will greatly expand the 340B Drug Pricing Program. If enacted, manufacturers will be selling an increased volume of drugs at a much lower price. For the plasma protein therapeutics industry, such a drastic change could negatively affect patient access to therapies like IVIG and blood clotting factors. Although PPTA successfully worked with Senator Orrin Hatch (R-UT) to add an amendment to the bill calling for a study by the Government Accountability Office within 18 months of enactment that would examine whether those patients served by 340B covered entities are receiving optimal health care services and make recommendations on (1) whether 340B expansion is even necessary with health insurance reform, (2) whether the new mandatory sales requirement is hindering patient access, and (3) whether income from the 340B program is being used by covered entities to further program objectives, PPTA remains concerned with the legislation.

Specific provisions of concern for PPTA in the Senate bill are a mandatory sales

requirement that would seemingly give 340B covered entities first priority in purchasing products, extending 340B pricing to inpatient sales, and relaxing the group purchasing organization prohibition for disproportionate share hospitals in certain instances. H.R. 3200 also includes the inpatient expansion and the relaxation of the DSH GPO prohibition. The mandatory sales language is expected to be added through Chairman Waxman's pending program integrity language.

PPTA member companies are committed to providing treatment for patients. Unfortunately, the added cost of mandatory sales of an unlimited volume of plasma-derived therapies (of which there is not an unlimited supply) to an increased number of 340B covered entities at a 46% to 53% lower 340B ceiling price is an unsustainable long-term business model that will impede patient access by curtailing the ability of manufacturers of plasma protein therapies to (1) continue the research and development of critical new therapies for rare diseases that are untreated or ineffectively treated; (2) improve formulations and modes of delivery for existing therapies; (3) develop technology to increase the protein yield from each liter of plasma to address growing demand, especially for immune globulin; and (4) preserve brand to brand competition in certain therapeutic classes as increased costs may affect the viability of producing some brands. The short-term ramifications on patient outcomes is also troubling because the policy will drive patients, including those with immune system disorders, to 340B covered entities for treatment, and disrupt supply to non-340B hospitals if there is a steep increase in orders from 340B providers.

Several plasma protein user stakeholder organizations have engaged both the House and the Senate on these issues. In July, the Immune Deficiency Foundation (IDF) and the Jeffrey Modell Foundation (JMF) sent joint statements to the Senate HELP Committee and the House Energy and

Commerce Committee urging lawmakers to recognize that forcing manufacturers to sell products to the expanding 340B program may lead to priority access for the 340B covered entities, which could have patient access consequences. According to the stakeholders, "If implemented, this policy [manufacturer forced sales to 340B] could force patients out of their current or preferred site of care (i.e., other hospitals, physician offices or their homes) into 340B eligible hospitals in order to gain access to products, such as IVIG, for which there is not an unlimited supply." PPTA is working with stakeholders to ensure that the provision forcing manufacturer unlimited sales to the 340B covered entities will not be in any final health care reform legislation.

Medicare Patient IVIG Access Act

As reported in June, The Medicare Patient IVIG Access Act is not incorporated in any of the health care reform draft proposals including the Senate Finance Committee and H.R. 3200 coming out of the House. PPTA along with the many of the interested stakeholders supporting the legislation will work with allied Members of Congress to include a possible amendment for this key piece of legislation in any negotiated health care reform proposal that may hit the House and Senate floors.

Limiting Life Time Private Insurance Capitations

In the House of Representatives, H.R. 3200 eliminates lifetime capitations; however, the implementation of this provision does not take effect until 2013 for new plans and 2018 for existing employer-based plans. In the Senate HELP Committee, the elimination of lifetime caps is effective in the next plan year for new plans. In addition, in Chairman Baucus' draft outline for health care reform legislation released this past week, mandates that "beginning January 1, 2013, health insurance plans in the individual market would be required to offer coverage on a guaranteed issue basis and would be prohibited from excluding

coverage for pre-existing health conditions. Limited benefit plans and lifetime limits would be prohibited, and health insurance companies would be prohibited from rescinding health coverage.” The draft outline also mandates that all plans sold in the non-group and small group market would be prohibited from applying annual or lifetime limits on benefits.

While the draft Senate Finance bill does prohibit lifetime insurance limits or caps, the elimination of these lifetime limits would not occur until at least 2013 and specific details of the draft bill have yet to be released. Therefore, although, PPTA and other stakeholders praise all the various committees’ elimination of lifetime caps, we believe that a three, five or even eight year delay in its implementation does not satisfactorily address the patients who are presently in danger of hitting their private lifetime insurance caps. PPTA along with other interested stakeholders will continue to advocate for the immediate elimination of lifetime limits for patients.

State Action

Market Access

The National Conference of State Legislatures held their Annual Legislative Summit in Philadelphia, PA in July. Many of the meetings focused on health issues and how to provide health care access to more people. The Massachusetts Health Care Reform Plan was mentioned in more than one session. Massachusetts passed an ambitious plan to provide health care to all its residents in April 2006. Unique in the Massachusetts plan is the mandate that uninsured adults must purchase health insurance if affordable coverage is available. As a result of this plan, the uninsured rate in Massachusetts is just 5%.

The many presentations on health care reform and universal health care show the interest legislators have in improving the

health care systems in their states. Since there will not be meaningful health care reform without addressing the chronically ill who account for a large percentage of health care costs, it is important that individuals with chronic conditions educate state decision-makers about their healthcare needs. This is especially true of individuals that need open access to their appropriate plasma protein therapy. Very few state decision-makers know the first thing about conditions that need plasma protein replacement.

The fall is a good time to visit your legislators. If you need assistance finding your elected officials or setting up an appointment, please contact Bill Speir or Chip Riddleberger.

Calendar

The Advisory Committee on Blood Safety and Availability (ACBSA) meeting has been tentatively scheduled for **November 19-20** (from October 1-2) at the Universities at Shady Grove (9630 Gudelsky Drive, Rockville, MD 20850).

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Visit: <http://www.donatingplasma.org/>

This PPTA publication aims to keep Stakeholders apprised of evolving state and federal health policy developments. **To provide feedback or to add colleagues to the distribution list, please contact Diana Krueger at the Association.**

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PPTA Staff is always available to attend consumer organization functions, make presentations, and assist in developing advocacy strategies and messages, as appropriate, with consumers. Please contact PPTA Staff at any time to discuss these activities.

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