

Health Policy Update

ACBSA Activities

The pathogen reduction practices employed by the plasma protein therapy manufacturers received high praise for their effectiveness at the January 9-10 meeting of the Advisory Committee of Blood Safety and Availability (ACBSA) in Washington, D.C.

In his presentation, "A Reductionist's View of Pathogen Reduction," Harvey Alter, M.D., Chief, Infectious Disease Section, Clinical Center, National Institutes of Health (NIH), described plasma-derived therapies as the model. He added that what once was most risky is now the safest. Alter also discussed his wish to see a commitment to developing a pathogen reduction method for whole blood for donations used in transfusion medicine from all involved parties-government, industry, blood bankers and so on. Harvey Klein, M.D., Transfusion Medicine, Clinical Center, NIH, also complimented the results the plasma protein therapeutics industry has achieved in pathogen reduction. The ACBSA passed a resolution on pathogen safety that currently is being vetted, after which it will be posted for public review on (<http://www.hhs.gov/oph/bloodsafety/>)

John Chapman, Ph.D., VP of Research and Development, ThermoGenesis Corp., in his presentation on, "Toxicology Related Issues in Pathogen Reduction," underscored Alter's position by pointing out that In the U.S. there are roughly 12 million source plasma units that are used to treat 1 million patients. All of these units are subject to pathogen reduction. By contrast, there are about 14 million donations of whole blood each year

that are used to treat 4 million patients in transfusion medicine. None of these units is pathogen reduced.

Federal Action

Medicare Patient Access

Given recent changes in federal reimbursement policies across sites of service, we wanted to provide you with a recent update of our "Reimbursement Primer" (attached). This primer aims to assist PPTA Stakeholders in navigating the numerous and complex reimbursement policies currently in effect that pertain to plasma protein therapies.

Congressional Outlook For 2008

As the Second Session of the 110th Congress begins, many lawmakers are positioning themselves for successful reelection campaigns. Because 2008 is a Presidential election year, the likelihood of passing any meaningful legislation becomes even more challenging on Capitol Hill.

As the campaign trails begin to heat up, presidential and congressional candidates will debate health care issues, but not much legislation will move this year. According to key staff from both the House and the Senate, the congressional committees that oversee the Medicare and Medicaid programs will focus their attention on conducting hearings on the Medicare program for the purpose of examining its successes and how they can be improved.

In addition to this oversight, exploring comprehensive Medicare reform strategies is a top priority for Senate Committee on Finance Chairman Max Baucus (D-MT). In this environment, it is crucial for all Stakeholders to support H.R. 2914, the IVIG Medicare Access Act of 2007. H.R. 2914, which is sponsored by Representative Kevin Brady (R-TX), is an important piece of bipartisan legislation that will ensure Medicare beneficiary access to intravenous immune globulin. Representative Brady currently has 35 co-sponsors on this bill.

Prescription drug safety will be a likely issue that is considered during this election year. In addition, since physicians are scheduled to take a 10.6% pay cut from the Medicare program beginning on July 1, 2008 and an additional 6% cut beginning on January 1, 2009, Congress will likely be committed to moving at least one piece of healthcare legislation during this election year. The vehicle for the physician fix is, however, uncertain.

State Action

Market Access (State Medicaid)

Focus on the Uninsured and Budgetary Concerns in the States

The Kaiser Family Foundation estimates that there are 46.5 million uninsured Americans. Of this total, 9.4 million are children. As a result of the growing ranks of the uninsured, universal health care is one of the top domestic policy issues for the 2008 Presidential elections. In fact, a recent survey found that 68% of U.S. adults support a requirement that all residents obtain health insurance, with government subsidies for those who cannot afford coverage. Of course, the devil lies in the details. States have often played the role of “laboratory” to develop solutions to major public policy issues. In fact, in 2007 close to 2/3 of the states considered some plan to

address the uninsured. Among those, at least 20 were comprehensive approaches to ensuring universal access to health care coverage. Three states, Massachusetts, Maine, and Vermont currently have programs in place. Many other states have looked to the Massachusetts plan as a model.

Universal Health Care in California: Framing the Issue

As the most populous state, California faces significant challenges in ensuring universal access to health care coverage. This is compounded by the fact that California also has the seventh highest uninsured rate in the country. Recent estimates show that 6.6 million Californians lack health insurance—(approximately 15% of the population). For comparison, this is more than the entire population of Massachusetts (6.3 million). Of those lacking insurance in California, 1.3 million are children. The California proposal passed the Assembly late in 2007 but stalled in the Senate and faces major obstacles in the coming months. Specifically, here are some of the key concerns: 1) Should residents be required to buy insurance, and if so what can be done about people who cannot afford the coverage; 2) whether tax breaks are preferable to direct subsidies for lower income workers; 3) how much to fine companies that refuse to offer insurance to their employees; 4) how much to tax doctors and hospitals to raise money for subsidies; 5) whether to require insurance companies to issue coverage to individuals, regardless of their age or pre-existing medical conditions; and finally 6) funding.

One broader issue that impacts the chances of health care reforms passing is the recent development of budget deficits in a number of states across the country. For example, California projects that it has a \$14 billion budget deficit for 2009. These budget concerns may also result in states taking a renewed interest in cost-containment strategies such as preferred drug lists and

sole-source provider contracts. PPTA is monitoring developments in the states closely and plans to work cooperatively with the patient community and other entities within the distribution channel to help ensure that access to plasma protein therapies is maintained.

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.**

Attachment: Reimbursement Primer

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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Health Policy Update

Federal Action

Medicare Patient Access

In its advocacy efforts, PPTA communicates to Congress and agencies within the Department of Health and Human Services (HHS) the importance of unfettered consumer access to all plasma derived and recombinant analog therapies (collectively known as plasma protein therapies) while at the same time educating policymakers on this unique biological industry that produce these lifesaving medicines.

H.R. 2914, the IVIG Medicare Access Act

On June 29, 2007, Representative Kevin Brady (R-TX) and 17 original co-sponsors introduced H.R. 2914, the IVIG Medicare Access Act. Since the bill's introduction, the Immune Deficiency Foundation (IDF) has led all advocacy efforts by working tirelessly with other stakeholders including PPTA to increase awareness of this legislation in both the House and the Senate. Currently, 36 Members in the House of Representatives are co-sponsoring this bipartisan legislation.

The IVIG community led by IDF received additional support on the existing access crisis when Senator John Kerry (D-MA) announced on Sunday, March 16, 2007 his intent to introduce companion legislation upon Congress' return from the March recess (see attached article). Senator Kerry is expected to push for the inclusion of this bill in the Senate Finance Committee's Medicare package. Many in Congress as well as the American Medical Association

are pushing for that Medicare package to include language to prevent the reduction in reimbursement for physician services that is scheduled to go into effect on July 1, 2008.

H.R. 2914 directs the Secretary of HHS to review the 2007 reports from its Office of Inspector General and its Assistant Secretary of Planning and Evaluation as well as other surveys to update the Medicare payment to provide appropriate reimbursement to cover the acquisition costs associated with furnishing IVIG in both the physician office and the hospital outpatient department. In addition, the bill provides for an IVIG home infusion benefit that will help Medicare beneficiaries with primary immune deficiency diseases access IVIG in their homes. Lastly, the bill requires CMS to conduct two beneficiary surveys over three years to measure changes in patient access to IVIG and providers, as well as changes in health outcomes.

Legislative opportunities for H.R. 2914 are extremely fluid, especially in this 2008 presidential election cycle. For example, a budget reconciliation bill is looking increasingly unlikely because of the election year politics. Although there is great interest in attaching the aforementioned Medicare package to a broader piece of legislation, it is unclear what if any vehicle there will be. Moreover, the House of Representatives have implemented a self-imposed 'pay-go' rule that require budgetary offsets for all new expenditures. Despite these practical difficulties, PPTA will continue to work with its members and others in the IVIG community to garner support for H.R. 2914 in Congress so that at least some of these crucial patient access provisions found in the legislation will be considered.

PPTA would like to make you aware that IDF will be holding a Capitol Hill Day on April 17, 2008 where they will fly patients, physicians, family members and volunteers from all over the country to meet with their Senators' and Representative's offices to discuss the current Medicare IVIG reimbursement issue, including H.R. 2914. Lastly, readers are also encouraged to log onto the IDF website at: www.primaryimmune.org and click on the 'Action Alert' banner on the right hand side to find your local U.S. Representative and urge them to support this important piece of legislation.

H.R. 1282, the Medigap Access Improvement Act

A coalition of stakeholders in the plasma protein therapies community, led by consumers, are engaging Congress to support equal treatment for all Medicare beneficiaries in efforts to obtain Medigap supplemental insurance programs that would help consumers on Medicare due to disability better afford their medicines. Presently, H.R. 1282 has 44 co-sponsors including Bobby Rush (D-IL) as the lead Democrat and Phil English (R-PA) as the lead Republican. The bipartisan bill introduced in March 2007, attempts to close the gap for Medicare beneficiaries who lack access to Medigap supplemental insurance programs. Currently, only 24 states mandate that Medigap be offered to those eligible for Medicare due to disability. In many states, Medigap open enrollment protections provided to aged beneficiaries are not extended to those who qualify for Medicare because they are disabled. Those most affected by this policy are typically chronically ill individuals with high cost medications such as hemophilia, HIV/AIDS, motor neuron disease, end stage renal and many other similar patient groups. Because of the current barrier for disabled Medicare beneficiaries to acquire the Medigap supplemental insurance in 26 states, H.R. 1282 would allow all Medicare beneficiaries,

regardless of age, to be eligible for critical Medigap coverage. The bill provides that the disabled and ESRD patients would still need to comply with existing enrollment rules, including a 6 month open enrollment period regardless of pre-existing condition and a 6 month open enrollment period if previous coverage is lost or the beneficiary moves. Traditionally, if a beneficiary decides to enroll after a 6 month open enrollment period, they must endure the same penalties as Medicare beneficiaries.

PPTA supports H.R. 1282 because it would provide parity among the 50 states for chronically ill patients who have trouble paying for their high priced medications. PPTA believes that regardless of where a Medicare beneficiary may reside, all Medicare beneficiaries, including those enrolled because of a disability should be afforded the same options to access their lifesaving treatments.

S. 2706, the Health Insurance Coverage Protection Act

On March 5, 2008, Senator Byron Dorgan (D-ND) introduced S. 2706, the Health Insurance Coverage Protection Act. This critical legislation would amend the Employee Retirement Income Security Act of 1974 and the Public Health Service Act to limit the ability of insurance providers to impose caps in an aggregate dollar amount of less than \$5,000,000 over the first two years of the plan and \$10,000,000 with respect to the third and fourth years of the plan. For each subsequent year after the fourth year, the cap must adjust according to inflation. This legislation does not require health plans offered or maintained for employees of a small business.

State Action

Market Access

California

The Hemophilia Council of California has introduced a Quality of Care bill (SB 1594). The legislation, if enacted would establish standards of service for entities delivering clotting factor therapies for use in the home for individuals with bleeding disorders. PPTA will be formally supporting this bill and has offered assistance to the hemophilia community and the Hemophilia Council of California in the effort to help achieve enactment.

Florida

PPTA is hosting a special mini-legislative day in Tallahassee, Florida on March 19, 2008. Representatives from the Alpha-One Foundation, Immune Deficiency Foundation and the National Hemophilia Foundation are planning to participate. The purpose of this event is to help enable consumers to interact with their state legislators and discuss their own concerns about access to health care.

An editorial entitled "**They're fighting for a voice and their lives**" was published in the *Tallahassee Democrat* on March 8, 2008 (editorial attached). The editorial was written by a patient advocate with the IDF who is participating in the Legislative Day. This type of media coverage helps to raise awareness about the unique nature of plasma protein therapies and the importance of maintaining access to these life-saving treatments.

Minnesota

House File 3013 (Senate Bill 2290 companion) was introduced on February 14 and referred to Health and Human Services Committee. This legislation

would ensure that consumers receive the therapy as prescribed by their physician and that no substitutions are made without the consent of the treating physician and the patient. This provision safeguards the sanctity of the physician-patient relationship. Following are some other key provisions of the bills: 1) protect the consumer's ability to receive services in the setting most appropriate to meet their unique medical needs, whether through a home care provider or at an appropriate infusion center; 2) stipulate minimum requirements for home care providers/specialty pharmacies for treating users of plasma protein therapies. This provision would help ensure that only providers with the requisite expertise and experience can contract with health plans to provide services to this fragile population; 3) require that health plans provide specific information to consumers about portions of services associated with the delivery of plasma protein therapies not covered by their insurance policies or by their Medical Assistance program; 4) ensure that persons with bleeding disorders would have in-network access to laboratories with specific expertise in the diagnosis of and management of bleeding disorders; 5) ensure that prior to receiving a hysterectomy that women be screened for Von Willebrand's Disease which would help prevent medically unnecessary hysterectomy procedures. Due to procedural obstacles, the bills will not be heard in committee this session. PPTA will continue to work with the consumer community to help ensure passage of these bills in the next session of the Minnesota legislature.

Texas

PPTA and industry staff attended the meeting of the state Hemophilia Advisory Board February 20 in Austin, Texas. One significant development is that the Board requested additional treatment data from Texas Medicaid. PPTA staff has reached

out to hemophilia chapter members who were in attendance. The next meeting of the Hemophilia Advisory Board will be held in May.

Announcement

Subject: A Message from the Secretary

Message from Mike Leavitt, Secretary of Health and Human Services, On Senate Confirmation of Joxel Garcia, M.D., MBA

I am happy to announce that Dr. Joxel Garcia was recently confirmed as Assistant Secretary for Health and Medical Director for the U.S. Public Health Service (USPHS). I am pleased he will be joining our team and providing important leadership on public health matters.

Throughout his career, Dr. Garcia has distinguished himself as a public servant through his devotion to patients, community and country. His previous public health experience includes service as Deputy Director of the Pan American Health Organization/World Health Organization and Public Health Commissioner for the State of Connecticut. His expertise will be invaluable as this Department pursues an aggressive public health agenda.

I look forward to working closely with him, the Office of Public Health and Science and the USPHS as we strive for a healthier nation, improve healthcare for all Americans and protect our nation against public health threats.

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Attachments:

1. Senator Kerry Announcement
2. Tallahassee Democrat Editorial

Save the Date

**PPTA is hosting the
Plasma Protein Forum**



**June 17 and 18, 2008
Washington, DC**

**Program and Registration
information can be found at:
www.plasmaproteinforum.com**

***Consumer Organizations –
Mention Code-HPU and receive
50% off of the consumer
registration rate!!***

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Health Policy Update

Federal Action

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.

PPTA Congressional 'Fly-In'

On May 14, 2008, PPTA held its annual Congressional 'Fly-In' on Capitol Hill. This significant event allowed plasma protein therapies' consumer organization representatives and PPTA member companies to gather together and meet with over *sixty-five* members of both the United States House of Representatives and Senate to advocate for legislation that improves access to plasma derived and recombinant analog therapies. In addition to the concerted advocacy messages, the 'Fly-In' was used as an important forum for participants to educate policymakers and their key staff on the unique differences between plasma protein therapies and the traditional pharmaceutical industry.

The event was highlighted by the appearance of several congressional leaders including Representative(s) Kevin Brady (R-TX), sponsor of H.R. 2914, the Medicare IVIG Access Act of 2007; Steve Buyer (R-IN) sponsor of H.R. 5839, the Safeguarding America's Pharmaceutical Act of 2008; and Jay Inslee (D-WA) sponsor of

H.R. 1956, the Patient Protection and Innovative Biologics Medicines Act of 2007. The Congressmen engaged the audience by taking questions and briefing 'Fly-In' participants on relevant health care legislation. Moreover, PPTA was honored to issue 'Legislative Leadership Awards' to the lawmakers in recognition of their commitment to patient access and their dedication to prescription drug and biological quality and safety measures.

110th Congress Legislative Update and Legislative Priorities

President Bush signs GINA into Law

In a Congress where there have been many highly publicized vetoes by the White House, PPTA is thrilled to report a significant legislative victory for the consumer organizations. On May 21, 2008, President George W. Bush signed into law The Genetic Information Non-Discrimination Act of 2008 (Pub. L. 110-233).

After many years of persistent advocacy work by consumers, physicians, researchers, and manufacturers, these increased protections for consumers are now a reality. Specifically, this new law will extend the current HIPAA protections against discrimination by group health plans and issuers of health insurance in both the group and individual markets, and restrict their acquisition, use and disclosure of genetic information. Additionally, GINA will prohibit an employer from discriminating against an employee on the basis of genetic information. Employers are also now prohibited from acquiring genetic information, except under certain specified

circumstances. A person will no longer have to worry that admitting a condition such as hemophilia to his employer will limit advancement within his workplace or lead to his termination. Individuals will also no longer have to worry that their children or grandchildren that are carriers of alpha-1 antitrypsin disease will be denied health insurance coverage.

S. 2990 and H.R. 2914, 'The Medicare IVIG Access Act'

On May 7, 2008, Senators John Kerry (D-MA) Lamar Alexander (R-TN) and Debbie Stabenow (D-MI) introduced the Medicare IVIG Access of 2008. The introduction of S. 2990 is a significant step in the efforts to restore access to lifesaving immune globulin therapies for Medicare beneficiaries. Garnering support for the Senate legislation has been a priority for many consumers in the IVIG user community including PPTA since last June's introduction of H.R. 2914, the Medicare IVIG Access Act, by Representative Kevin Brady (R-TX). H.R. 2914 currently has 49 co-sponsors from both the Democrat and Republican sides of the aisle. Similar to its House companion bill, S. 2990, the bipartisan Senate legislation directs the Secretary of Health and Human Services (HHS) to review the 2007 OIG and ASPE reports and other surveys to update the Medicare payment to provide appropriate reimbursement for providers related to the furnishing of IVIG in both the physician office and the hospital outpatient setting. In contrast to the House bill, because of practical budgetary constraints, the payment adjustment for acquisition of IVIG in the Senate bill is capped at two years, whereas the House bill allows the Secretary to continue payment adjustments until deemed adequate. Both versions of the bill direct the Secretary to continue the vital pre-administration-related services payment for IVIG in both physician and hospital outpatient department until the Secretary deems that reimbursement is adequate. In addition, both the House and

Senate bills provide for an IVIG home infusion benefit that will help Medicare beneficiaries with primary immune deficiency diseases access IVIG therapies in their own homes. Lastly, in contrast to its House counterpart, S. 2990 is budget neutral with the statutory inclusion of a budgetary offset. A budgetary offset is vital this year in helping the bill move forward because of 'pay-go' rules instituted by the House of Representatives Democrat leadership at the beginning of the 110th Congress. Simply put, 'pay-go' rules compel new spending or tax changes to not add to the federal deficit. Thus, new proposals must either be "budget neutral" or offset with savings derived from existing funds.

The best opportunity to achieve success for S. 2990 is to have the bill included in a final Senate Finance Committee Medicare legislative package. Currently the Senate Finance Committee is negotiating this legislation in order to stave-off the statutory scheduled 10 percent cut to Medicare physician reimbursement. The proposed Medicare package is scheduled to hit the Senate floor in June. As you may recall, last December, Congress avoided the unpopular physician cuts by providing for a six month extension of payments with a sunset date of June 30, 2008.

"What can you do?"

Contact your Member of Congress and ask for their Co-Sponsorship of S. 2990 and H.R. 2914.

S. 2706, 'The Health Insurance Protection Act'

S. 2706 was introduced in February 2008 by Senator Byron Dorgan (D-ND). The bill phases in an increase in lifetime caps to \$10 million with an annual inflationary index. The bill exempts health plans offered at businesses with fewer than 20 employees, but would require that health plans meeting the parameters of the bill be offered to a small business at the employer's request.

The bill is important to many plasma protein therapy consumers because of the high value medicines used to treat chronic conditions such as hemophilia and other bleeding disorders, genetic emphysema and primary and secondary immune deficiencies. Many patients with the aforementioned conditions may reach their lifetime cap within a few years or sooner if they have complications. Even if patients are able to find a way to maintain coverage, in the process they are often forced to make drastic choices that affect their employment, place of residence or even family life.

Currently, there is no companion bill to S. 2706 in the House of Representatives. However, leaders in the hemophilia community who are spearheading support for this important bill are encouraged that a member of the House of Representatives will introduce a bill in the near future. Although, it is unlikely that S. 2706 will be considered by the full Senate or the Committee on Health, Education, Labor and Pensions in 2008, advocating for this bill and bringing the unacceptable realities of the current insurance lifetime caps issue to the forefront is of major importance to PPTA and numerous stakeholders in the plasma protein therapy users community. This crucial access issue will be sure to arise again in the next Congress beginning in January 2009, so please keep it on your radar screen.

“What can you do?”

Contact your Member of Congress and ask for their Co-Sponsorship of S. 2706.

H.R. 1282, ‘The Medigap Access Improvement Act’

Presently, H.R. 1282 has 53 co-sponsors including Bobby Rush (D-IL) as the lead Democrat and Phil English (R-PA) as the lead Republican. The bipartisan bill introduced in March 2007, attempts to close the gap for Medicare beneficiaries who lack access to Medigap supplemental insurance

programs. Currently, only 24 states mandate that Medigap be offered to those eligible for Medicare due to disability. In many states, Medigap open enrollment protections provided to aged beneficiaries are not extended to those who qualify for Medicare because they are disabled. Those most affected by this policy are typically chronically ill individuals with high cost medications such as hemophilia, HIV/AIDS, motor neuron disease, end stage renal and many others. Because of the current barrier for disabled Medicare beneficiaries to acquire Medigap supplemental insurance in 26 states, H.R. 1282 would allow all Medicare beneficiaries, regardless of age, to be eligible for critical Medigap coverage. The bill provides that the disabled and ESRD patients would still need to comply with existing enrollment rules, including a 6 month open enrollment period regardless of pre-existing condition and a 6 month open enrollment period if previous coverage is lost or the beneficiary moves. Traditionally, if a beneficiary decides to enroll after a 6 month open enrollment period, they must endure the same penalties as Medicare beneficiaries.

PPTA supports H.R. 1282 because it would provide parity among the 50 states for chronically ill patients that must pay for the high deductibles under Medicare Part B. PPTA believes that regardless of where a Medicare beneficiary may reside, all Medicare beneficiaries, including those enrolled because of a disability should be afforded the same options to access their lifesaving treatments. Similar to S. 2706, the Medigap Access Act is unlikely to be enacted this year because there is no companion bill in the Senate and there are only a limited number of Medicare expansion measures being considered in the ‘skinny’ Medicare legislative package currently being negotiated in the Senate. Advocacy efforts led by numerous stakeholder organizations on Capitol Hill have, however, increased the awareness of this bill and continued support will be

imperative for re-introduction in the 111th Congress.

“What Can You Do?”

Contact your Member of Congress and ask for their Co-Sponsorship of H.R. 1282.

State Action

Market Access

California

On April 2, the Hemophilia Council of California-sponsored bill on Standards of Service for people with hemophilia passed unanimously out of the California Senate Health Committee. PPTA offered public support for the legislation through letters to the bill's authors. The legislation was then referred to the Senate Appropriations Committee for Review. The bill was then placed in the suspense file based on anticipated costs of implementation. While these costs are relatively low, the California budget deficit has had a substantial impact on proposals that require any new funding. The bill did not advance from the Appropriations Committee and would have to be reintroduced in 2009.

Florida

On March 21, PPTA Staff assisted in organizing a Patients' Day at the Florida Legislature in Tallahassee. This is the first time that PPTA, in coordination with local consumer group representatives, has held such an event at the state level. Patients representing individuals with bleeding disorders and primary immunodeficiency diseases visited with Members of the Florida House of Representatives and Florida Senate. Patients were empowered to share their personal stories with legislators and, in their own words, convey

the importance of access to plasma protein therapies. The meetings were held with some of the most prominent Members of the Florida Legislature including Representative Aaron Bean, Chairman of the House Health Council.

The Florida Legislature needed to reduce the budget by \$4 billion during Session. The Senate Budget Chairman recommended eliminating two Medicaid eligibility categories that PPTA staff discovered included 33 individuals with hemophilia. The House Budget Chairman recommended eliminating a state sponsored Alpha-1 Screening and Detection Program that was previously funded at \$364,000. PPTA staff worked closely with the Alpha-1 Foundation, the Hemophilia Foundation of Greater Florida, the Florida Hemophilia Association, and the National Hemophilia Foundation to assist them in their efforts to persuade the Florida Legislature to amend their budget proposals to restore these reductions. The Florida Legislature passed the budget on May 2, 2008. It included the funds necessary to continue the Alpha-1 Screening and Detection Program and Medicaid coverage for the 33 individuals with hemophilia.

These initiatives reflect PPTA's commitment to ensuring patients' access to therapies that are appropriate to their unique medical needs. PPTA staff works to foster these relationships with the patient groups so that the coordination is seamless when the need arises.

Minnesota

PPTA co-hosted a legislative event for consumers in St. Paul, Minnesota at the state capitol on April 23. More than 20 representatives from the Immune Deficiency Foundation, the Alpha-1 community, the bleeding disorders community, and industry took part in this important effort to raise awareness. Participants had the opportunity to meet with their own elected

representatives and the authors of the Minnesota Quality of Care legislation (SF 2290 and HF 3013). There were also several meetings with members from key legislative committees. The day was part of the efforts to continue the momentum on the legislation with an eye toward passage in 2009.

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Save the Date

**PPTA is hosting the
Plasma Protein Forum**



**June 17 and 18, 2008
Washington, DC**

**Program and Registration
information can be found at:
www.plasmaproteininform.com**

***Consumer Organizations –
Mention Code-HPU and receive
50% off of the consumer
registration rate!!***

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Health Policy Update

The next Advisory Committee on Blood Safety and Availability (ACBSA) meeting will be held on December 16-17, 2008 at the Hilton Rockville Hotel (1750 Rockville Pike, Rockville MD 20852).

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.

110th Congress Legislative Update and Legislative Priorities

On July 15, 2008 Congress overwhelmingly overrode President Bush's veto of H.R. 6331, The Medicare Improvements for Patients and Providers Act. By doing so, Congress passed legislation that prevented an immediate 10.6 reduction in the physician fee schedule's conversion factor, and an additional payment reduction of 5.4 percent beginning January 1, 2009. If Congress had not intervened, doctors would have had their services payment drastically cut for treating Medicare beneficiaries, even for administering drugs to them. The bill replaced the scheduled reimbursement cut with a payment freeze for the rest of 2008 and a 1.1 percent pay increase for physicians for 2009.

The House overrode the veto by a 383-41 vote, with 153 Republicans joining 230 Democrats and a mere 41 Republicans voted to sustain the veto. The Senate followed shortly after voting 70-26 to override the veto, as 21 Republicans joined 47 Democrats and two independents. To note, a presidential veto is overridden by a two-thirds vote in each the upper and lower bodies of Congress.

Prior to President Bush's veto, this bill passed by a colossal margin in the House by a vote of 355-59. The Senate subjected this legislation and a similar bill to weeks of political gamesmanship. Eventually, the realities of the difficult races facing a number of Republicans in the Senate made a third filibuster for a physician fix impossible.

In addition to the Medicare physician reimbursement payment update, a plethora of other policy provisions were also included in the bill, including a mandatory accreditation for those physicians providing diagnostic medical imaging services and a delay in a durable medical equipment (DME) competitive bidding program being launched by the Centers for Medicare & Medicaid Services. To pay for the physician fee update, Congress is in part reducing Medicare Advantage indirect medical education program payments and through new requirements for private fee-for-service plans, also known as Medicare Advantage plans. President Bush was against cutting the funds for Medicare Advantage plans because the coverage is deemed to be favorable by many beneficiaries, especially in rural areas.

S. 2990 and H.R. 2914, 'The Medicare IVIG Access Act of 2008'

As many of you may be aware, in the weeks and many months leading up to the vote, Presidential veto and subsequent override of H.R. 6331, many in the IVIG community, led by the Immune Deficiency Foundation (IDF) have advocated for the inclusion of the Medicare IVIG Access Act, S. 2990 and H.R. 2914 into this Congress' last major Medicare related legislation. Unfortunately, despite the victories of getting the bill introduced by plasma protein therapy user legislative champions Representative Kevin Brady (R-TX) and Senator John Kerry (D-MA), H.R. 6331 was narrowly tailored, limited in its scope with only a few Medicare related priorities addressed. Thus, important provisions of the Medicare IVIG Access Act were left out of the final bill passed by the House and the Senate. It is, however, important to note that H.R. 2914 has large bipartisan support with 51 co-sponsors while S. 2990 has also garnered support from influential Senators from both parties evidenced by 8 cosponsors, including, in addition to Senator Kerry, lead sponsors Senators Debbie Stabenow (D-MI) and Lamar Alexander (R-TN).

Although it is highly unlikely that there will be any other legislative opportunities for the Medicare IVIG Access Act to be considered this Congress, the extraordinary efforts by IDF and many others in the IVIG community including PPTA to increase awareness of the patient access issues surrounding IVIG in the last few years should not be understated. For example, the issue has gained attention from the highest levels of Congress by leaders in both parties in the most influential positions. To this end, PPTA will continue to work with other stakeholders and with Members of Congress to work towards a solution to the ongoing IVIG patient access dilemma.

CMS Proposed Rules Limit Reimbursement for Providers of Plasma Protein Therapies and Their Recombinant Analogs

The Centers for Medicare and Medicaid Services (CMS) announced on July 1, 2008 that they will discontinue the IVIG Preadministration-Related Services Payment Code, G0332, in the Physician Fee Schedule (PFS) Proposed Rule. Three days later on July 3, 2008, the agency announced that they will 'package' the IVIG Preadministration-Related Services Payment Code, G0332, in the Hospital Outpatient Prospective Payment Systems (OPPS) Proposed Rule. By packaging the G0332 payment code into the administration payment for IVIG, CMS is proposing to eliminate entirely the vital additional payment for IVIG providers in the outpatient setting. In addition, the agency proposes to reduce reimbursement to providers for most drugs and biologicals, including which includes IVIG, blood clotting factors, and alpha-1 antitrypsin, from the current average sales price (ASP) plus 5 percent methodology to ASP plus 4 percent in the hospital outpatient department. It is important to note that in last year's Calendar Year 2008 OPPS Final Rule the agency stated that they believed ASP plus 3 percent accurately reflects hospital costs for non-pass through drugs and biologicals in the hospital outpatient department and intimated that ASP plus 3 percent would be targeted for CY 2009. Although the agency does not propose to reduce the payments to ASP plus 3 percent, the reduction from CY 2007 levels of ASP plus 6 percent to CY 2008 ASP plus 5 percent, to their current proposal of ASP plus 4 percent illustrates the agencies determination to erode provider reimbursement for all drugs and biologicals including plasma derived protein therapies and their recombinant analogs in the hospital outpatient setting.

In order to be considered by the agency, any public comments to the proposed rules must be received by CMS by August 29,

2008 for the physician fee schedule and by September 2, 2008 for the OPFS. Thus, PPTA will be working with stakeholders in the coming weeks to garner support from the plasma protein therapy user's community to oppose CMS proposals to reduce provider payments. Ultimately, the nexus between provider reimbursement and patient care have never been more apparent and it is crucial that the plasma protein therapies community join together with a concerted voice to advocate for unfettered access to the lifesaving therapies that PPTA member companies produce.

State Action

Market Access

PPTA staff attended the third annual National Medicaid Congress in Washington, D.C. This meeting brings together leading policymakers and private sector representatives in Medicaid. Policymakers stressed the fact that with limited resources, they are looking for novel ways to achieve efficiencies. This underscores the need to advocate effectively on behalf of the plasma protein therapies community.

California

On June 27, the California Budget Conference Committee adopted trailer bill language pertaining to blood factor products. The language was adopted via a unanimous 6-0 vote. The first amended section § 14105.3 provides new authority to for the Department of Health Care Services ("the Department") to enter into contracts for the distribution of specialty drugs. The language does not include exclusive (or sole source) type contracts that were contained in the original trailer bill language from May 16, 2008. The avoidance of sole source arrangements is a clear victory for the community.

The second section amends § 14105.86 of the Welfare and Institutions Code. Most

notably, pursuant to subsection (e) (1), the language establishes a mechanism for the collection of additional rebates for the sales of blood clotting factor. These rebates will be determined through negotiations between the Department and individual manufacturers. This is typical of supplemental rebate approaches in other states. In reviewing the final language as compared to the May 16 version, many potential access concerns raised following the release of the original trailer bill language have been addressed.

First, the final language includes the following statement, "**All blood factors that meet the definition of a covered outpatient drug pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8) shall remain a benefit subject to the utilization controls provided for in this section.**" This language appears to address the concern raised by both industry and the patient community that the Department could unilaterally decide to not cover a specific factor product regardless of the patient's medical need. More significant, § (e) (1) (2) provides that "**The review of medical need (in a treatment authorization request scenario) shall take into account a beneficiary's clinical history and/or use of the blood factor pursuant to payment by another third party.**" On its face, this language addresses concerns raised by the industry and the patient community that cost would be the overriding and determining factor in making coverage decisions on factor products. While we continue to have concerns about the use of "and/or" in this language, it is PPTA's understanding that assurances were given to the National Hemophilia Foundation by the Department that this would not result in the reliance on recent restrictive mechanisms adopted by some health plans in California. Procedurally, this language does not become law until final adoption of California's fiscal year 2009 budget. While this was supposed to be final by June 30, it is very likely that the negotiations and

deliberations will continue well into July and perhaps beyond.

North Carolina

The North Carolina Legislature agreed in Conference to modify the state's spending plan. The Conference Report for House Bill 2436 is available on-line to the public at: <http://www.ncleg.net/sessions/2007/budget/2008/conferencecommitteereport.pdf>.

Section 10.10(e) provides that the state's contractor shall place specialty pharmacy products on the State Maximum Allowable Cost (SMAC) List if reimbursement for the product exceeds \$1,500. The bill does not define what the \$1,500 is being measured by to determine the threshold. PPTA staff spoke with North Carolina budget staff about the threshold and was told it would be \$1,500 per month. The Legislature is expecting North Carolina Medicaid to save \$5 million in state funds as a result of this change.

PPTA is concerned with the impact of this legislation on patient access to hemophilia therapies. The reduction actually means reimbursement for specialty pharmacies will be reduced by \$13.9 million because of the loss of the federal matching funds for Medicaid. It is projected that reimbursement for hemophilia therapies will account for \$6.9 million of the \$13.9 million reduction. This would be a reduction of roughly 23% for hemophilia therapies. PPTA is not sure specialty pharmacies will be able to provide patients their current therapies at the reduced prices.

PPTA staff has been working with Hemophilia of North Carolina (HNC) on the issue. North Carolina Medicaid has assured HNC that the reimbursement will not be that drastic. PPTA will continue to monitor the issue and work with interested parties to protect patient access to medically appropriate therapies.

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Health Policy Update

New Website

PPTA launched its new educational website (www.DonatingPlasma.org). The site provides information and boosts awareness for source plasma donation. The site shares information about donor eligibility and health, links to consumer groups, stories from patients and donors, video testimonials, and details on how plasma is used to produce life-saving therapies.

Calendar

The next Advisory Committee on Blood Safety and Availability (ACBSA) meeting will be held on December 16-17, 2008 at the Hilton Rockville Hotel (1750 Rockville Pike, Rockville MD 20852). The ACBSA meetings tentatively scheduled for 2009 are April 30 – May 1 and October 1-2.

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.

110th Congress Legislative and Regulatory Update

Stakeholder's Submit Joint Comments to CMS in Opposing Provider Reimbursement Reductions

Several plasma protein therapy advocacy organizations, including the Alpha-One Foundation, GBS-CIDP International Foundation, Immune Deficiency Foundation and the Jeffrey Modell Foundation and ASD Healthcare submitted joint comments to CMS opposing the agency's plan to significantly reduce provider reimbursement for plasma protein therapies in the 2009 Physician Fee Schedule (PFS) and Hospital Outpatient Prospective Payment System (OPPS) proposed rules. Thanks to each organization for their active role in the comment process.

In its proposed rules published in July 2008, CMS announced that they will discontinue the IVIG Preadministration-Related Services Payment Code, G0332, in the physician office setting and that they will 'package' the IVIG Preadministration-Related Services Payment Code, G0332, in the hospital outpatient department. By packaging the G0332 payment code into the administration payment for IVIG, CMS is proposing to eliminate entirely the vital additional payment for IVIG providers in the outpatient setting. In the OPPS proposal, the agency also plans to reduce reimbursement to providers for most drugs and biologicals in the hospital outpatient department, including IVIG, blood clotting factors, and alpha-1 antitrypsin, from the current average sales price (ASP) plus 5 percent methodology to ASP plus 4 percent. It is important to note that in last year's 2008 OPPS Final Rule the

agency stated that they believed ASP plus 3 percent accurately reflects hospital costs for non-pass through drugs and biologicals in the hospital outpatient department and intimated that ASP plus 3 percent would be targeted for CY 2009. Although the agency does not propose to reduce the payments to ASP plus 3 percent, the reduction from CY 2007 levels of ASP plus 6 percent to CY 2008 ASP plus 5 percent, to their current proposal of ASP plus 4 percent illustrates the agencies determination to erode provider reimbursement for all drugs and biologicals in the hospital outpatient setting, including plasma derived protein therapies and their recombinant analogs.

In its joint comments opposing the aforementioned reductions in the PFS and OPSS proposed rules, stakeholders stressed the need to continue the vital IVIG preadministration-related services payment code. Stakeholders argued that CMS' reasoning behind the elimination of the code is flawed and could exacerbate the already fragile patient access problem to this lifesaving therapy.

For example, in their comments, the stakeholders illustrate that CMS used certain figures from the April 2007 Office of Inspector General Report (OIG) as proof that marketplace has stabilized by citing that in the third quarter of 2006, 56 percent of IVIG sales to hospitals and over 59 percent of IVIG sales to physicians occurred at prices below the Medicare payment amounts. Using this same data, stakeholders argued that the same data showing that 44% of hospitals and 41% of physicians unable to purchase product at or below the Medicare payment rate, does not demonstrate market stability and the drastic measures such as eliminating the entire preadministration-related services code is unwarranted.

Even more troubling, when making its decision to continue the payment code in the 2008 OPSS and PFS rules, CMS cited the very same statistics cited above to

rationalize continuing payment for the IVIG preadministration related-services code. Furthermore, in proposing to discontinue the code for 2009, CMS stated that it requested that the OIG further study the IVIG marketplace. However, to date, no new report of study has been initiated, thus, with no new information; stakeholders within the plasma protein therapies community argue that there is no basis for CMS to now rely on the April 2007 OIG report in support of a claim that there is improved market stability.

In addition to the elimination of the preadministration-related services payment code, the stakeholders' comments to CMS' OPSS proposed rule, contested the agency's preliminary decision to implement the ASP plus 4 percent in the hospital outpatient prospective payment system. Stakeholders focused its comments towards the agency's use of hospital claims data in setting the payment level because hospital claims data is subject to charge compression and includes drugs sold at or below the 340B ceiling price – both of which drastically skews the data set. Stakeholders urged CMS to restore OPSS reimbursement to a level that is not less than ASP +6% in order to preserve patient access.

By joining together for a concerted message, stakeholders in the plasma protein therapies community have the ability to better achieve the goal of unfettered patient access. PPTA appreciates the combined efforts of Alpha One Foundation, GBS/CIDP Foundation International, Immune Deficiency Foundation, Jeffrey Modell Foundation and ASD Healthcare for all its efforts in providing comments to CMS for this year's PFS and OPSS proposed rules.

Lastly, to see the stakeholder's complete comments to CMS regarding the CMS' 2009 PFS and OPSS proposed rules, please contact the Association.

PPTA Presents to CMS' Ambulatory Payment Classification Advisory Panel

On August 27-28, PPTA staff participated in the CMS Ambulatory Payment Classification (APC) Panel's semi-annual meeting in Baltimore, Maryland. At this meeting, PPTA staff presented arguments to continue the crucial IVIG preadministration-related services payment code in the hospital outpatient department. PPTA also joined with the Association of Community Cancer Centers (ACCC) American Society of Health-System Pharmacists (ASHP), Direct Research LLC, Biotechnology Industry Organization (BIO) and the Alliance of Dedicated Cancer Centers, in presenting to the APC panel new data illustrating that payments for non-pass through separately paid drugs and biologicals, including plasma protein therapies, are severely underpaid in the hospital outpatient setting and should be reimbursed at a minimum of ASP plus 6 percent. As a result of this combined effort, the APC panel recommended that CMS continue payment for non-pass through separately paid drugs and biological, which include plasma protein therapies and their recombinant analogs, at ASP plus 5 percent in calendar year 2009. This recommendation is an important first step in maintaining provider reimbursement levels in the hospital outpatient department for the upcoming year.

IVIG Community Supports Representative Kevin Brady (R-TX) in Urging CMS to Halt Proposed Reductions in 2009 Proposed Rule

On September 16, 2008, Congressman Kevin Brady and twenty-two other members of the House of Representatives sent a bipartisan letter to CMS urging the agency to reconsider its proposal to drastically reduce provider reimbursement in its 2009 PFS and OPFS Proposed Rules. The Congressional letter to CMS states in part, "we are concerned that the agency's proposed payment rules for 2009 suggest an elimination of the pre-administration

codes in both the physician office and hospital outpatient settings in addition to a reduction in the hospital outpatient reimbursement formula. These two measures will exacerbate instability in the marketplace and will lead to adverse consequences for patients reliant on this life-saving therapy." This letter was a nice addition to a July 28 letter sent by Senator John Ensign (R-NV) on this issue as well as Senators Lamar Alexander (R-TN) and Sam Brownback (R-KS) who weighed-in with CMS on September 18, regarding the elimination of the preadministration service-related payment. In that letter, Senators Alexander and Brownback stated, "we are worried that eliminating these payments could adversely affect Medicare patients who rely upon IVIG products." To see these congressional letters go to:

http://pptaglobal.org/en/issues_us_federal.cfm.

The Immune Deficiency Foundation along with others in the IVIG community, including PPTA, have been working with policy makers to find a solution to the IVIG access dilemma since the implementation of the ASP reimbursement methodology for Medicare Part B drugs pursuant to the Medicare Modernization Act in 2005. This year, Congressman Brady and Senator Kerry have been legislative champions for introducing the Medicare IVIG Access Act in both the House and Senate (H.R. 2914, S. 2990). Members of the IVIG community are grateful to them for the steadfast support of patient access issues surrounding IVIG. The stakeholders who have been working with these vigilant policymakers will continue to do so in the next Congress. Moreover, stakeholders will continue to reach out to CMS in efforts to establish adequate provider reimbursement that ensure patient access to this vital therapy.

State Action

Market Access

Supplemental Rebates

On June 27 Language was adopted in California by the joint Senate-Assembly Budget Conference Committee containing a supplemental rebate mechanism. However, the adopted language also included additional patient protections as compared to the original language that first prompted these discussions. Notwithstanding these protections, concerns still remain regarding the potential that the overarching motivation for the Department of Health Care Services in California may be to limit open access to all therapies. It should be noted that this language does not become law until after the California Budget is adopted by 2/3 of each chamber of the legislature and signed by the Governor.

California Budget Update

As of this publication, there is still no California budget for the 2008-09 fiscal year. The budget was due by June 30th making this the longest budget impasse in California history. Accordingly, the proposal discussed above and numerous other pieces of legislation in California are in a state of limbo. The latest news is that the Governor has issued a veto threat on the budget deal approved by the legislature. Initially, the legislature indicated that the votes were there to override the veto but they moved away from that stance under increased pressure from the Governor. As of September 19, it appears that the Governor has gotten sufficient concessions from the legislature and that an approved budget is imminent.

Kentucky

PPTA recently submitted comments on the "Hemophilia Treatment and Reimbursement Via the 340B Drug Pricing Program"

proposed rule; 907 KAR 3:205 in Kentucky (letter available at: http://pptaglobal.org/en/issues_us_state.cfm).

The primary goal of the proposed rule is that the 37 individuals that are currently treated by the Lexington Hemophilia Treatment Center would also get their clotting factor therapies on a routine basis from the HTC instead of through a specialty pharmacy/home care company. The Lexington HTC is a participating 340B covered entity which would enable it to obtain therapies at the 340B ceiling price level under applicable federal law. The state has indicated it expects to save \$200,000 (\$61,000 in state funds, \$139,000 in federal matching funds) through this proposal.

The Medicaid program stated its intention is not a sole source provider approach. Rather, they have indicated that patients would still be able to choose to obtain therapies from their current provider. PPTA is working with the hemophilia community on the proposed rule to ensure that access is maintained and that the language in the proposed rule is further clarified.

Texas Bleeding Disorders Advisory Counsel meeting update

PPTA Staff attend a meeting of the Texas Bleeding Disorders Advisory Council (TBDAC) in Austin on August 13, 2008. The purpose of the meeting was to discuss the draft recommendations for the TBDAC to submit on December 1st to the Legislature and the Governor.

Texas Medicaid Staff were present at the meeting to answer questions the TBDAC had on the current Texas Medicaid program. The questions focused on how someone would qualify for the Medicaid Buy-In Program, a program that allows individuals who may not otherwise meet the various eligibility criteria to buy-in to the Medicaid program for a specified premium amount. The next meeting will be held on October 8th when the TBDAC is to release their report for public comment.

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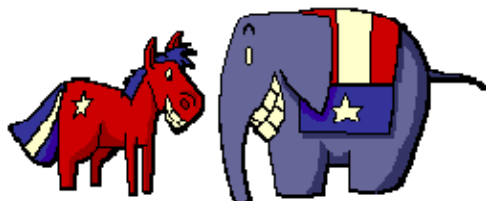
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Health Policy Update

****** Special Edition ******



Federal Action

Special Election Update: Presidential Candidates Health Care Agendas Aim to Break Tradition

With less than a week before the nation's electorate chooses the next President of the United States, both candidates have been spending considerable time in what the mainstream media has dubbed "battleground states." In their travels not only in recent weeks, but also throughout the campaign, the candidates have found that the American people are incredibly concerned about obtaining affordable, quality health care.

Many citizens work for small businesses that cannot afford to provide their employees with health insurance coverage, leaving them to fend for themselves in the individual insurance market to purchase at retail price, rather than the wholesale price. A large number of individuals are unable to afford the individual policies and are also unable to qualify for public programs like Medicaid. Rather than spend down to obtain

Medicaid coverage, most citizens in this situation go bare. Additionally, the Medicare program, which covers the elderly and some citizens that qualify because of disability, is nearing financial insolvency. These issues driving the crisis of the uninsured and underinsured are a priority for both Presidential candidates.

Although Senators John McCain (R-AZ) and Barack Obama (D-IL) share the goal of ensuring every citizen has affordable, quality health care coverage, they differ in the overall policy strategies that would effect such a sweeping change. McCain and Obama both support the expansion of embryonic stem cell research and favor cost containment measures such as mandatory adoption of interoperable health information technology, an abbreviated Food and Drug Administration approval process for follow-on biologics, manufacturer transparency in drug pricing, medical liability reform, utilization of comparative effectiveness research, investment in preventative care and treatment of chronic conditions, and adoption of pay for performance measures. Again, McCain and Obama do differ on how to implement such policies, but recognize

the importance of doing so. Both candidates have been proponents for reimportation of prescription drugs, but have softened that stance considerably in the last six months because of some public health issues and now committed to ensuring the safety of not only the importation of drugs, but also the importation of the ingredients used in the manufacturing process. Senator McCain also diverges from the Republican Party platform by supporting direct price negotiation by the federal government with drug manufacturers for products covered under Medicare Part D.

Obama and McCain offer contrasting views on ways to achieve health care availability and access for Americans

Although the two candidates share the aforementioned views on some specific areas in health care policy and they both envision meaningful changes from the current health care insurance coverage models, the means to that end are as diverse as the two candidates themselves. Barack Obama favors increased federal control in building a “universal” system in incremental stages while John McCain prefers to maximize the incentives for individuals and families to buy private health insurance on their own. McCain seeks to use the tax code to promote fairness and greater access, while Obama seeks to cover the growing number of uninsured by providing a meaningful government-run program that would compete with the private sector. Policymakers on both sides of the aisle see merits in both proposals and believe dangers can be averted – nobody envisions the Obama plan moving toward a single payer system, and nobody envisions the McCain plan driving people from the employer-based system. Under either administration, the current system of public and private payers will remain intact and serve as the basis for an improved system.

The Obama Plan

Senator Obama’s health care agenda emphasizes universal health care coverage by 2012, but the plan would only mandate health insurance for children and require, all but some of the smallest employers, to offer employee health benefits or contribute to the cost of the new public program. Senator Obama’s plan will expand Medicaid and the State Children’s Health Insurance Program (SCHIP) and create the National Health Insurance Exchange in which small businesses and individuals without access to other public programs or employer-based coverage could enroll. Under the Obama proposal, health insurance coverage would be portable, thus allowing workers to keep their insurance when moving between jobs.

Other key elements to Obama’s proposals include changes to private insurance, such as prohibiting insurers from denying coverage based on pre-existing conditions and allowing children up to the age of 25 to continue to be covered through their parents’ plan. Senator Obama also wants to go after insurance companies by repealing McCarran-Ferguson, requiring health plans to disclose the percentage of their premiums that actually goes to paying for patient care as opposed to administrative costs, and in market areas where there is not enough competition, require insurers to pay out a “reasonable share” of premiums on patient care benefits.

Lastly, the Obama campaign purports to finance the nearly \$50-65 billion a year health care agenda through savings within the health care system and additional revenue coming from the discontinuing tax cuts for those with incomes of over \$250,000.

The McCain Plan

Senator McCain's health care agenda is premised on a free-market, consumer based system that utilizes a \$5000 tax credit for families and \$2500 tax credit for individuals to buy their own insurance. The McCain plan eliminates the often criticized tax deductibility of employee sponsored health insurance that has traditionally benefited workers with the highest incomes. Although McCain's tax credit proposal can co-exist with employer-based insurance, in order for it to be effective, it would need to attract young, single, and healthy workers to opt out of employer-provided insurance. The premise would be these individuals could save money by purchasing high-deductible plans that cost less on the open market. This could be dangerous to employer-based plans because their pool of older, less-healthy workers would increase. Experts believe enough young, healthy families could balance the risk by remaining in these plans and offset any need to increase costs, which would make both the employer-based model and individual model attractive options under the McCain plan.

Senator McCain's health care plan also calls for states to work with the federal government in creating a federally supported 'Guaranteed Access Plan' for people who are denied coverage due to pre-existing conditions. Premiums in the plan would be limited and financial assistance would be given to those below a certain income level. By doing so, McCain's plan would promote competition and individual choice of insurance programs by allowing insurance to be sold across state lines in hopes to encourage innovative multi-year insurance products.

Although financing for Senator McCain's health care plan is not yet specified, the plan envisions cost containment measures that would make insurance more affordable.

Whose Plan is Better?

The old adages, 'beauty is in the eye of the beholder' and 'the devil is in the details' holds true when analyzing both plans in the back drop of a highly partisan, politicized atmosphere where media sound bites and awkward political debates create confusion at best and animosity at worst. Both candidates' health care plans, however, offer dramatic changes to some aspects of the current health care system in the United States that most Americans believe is broken. Unfortunately, both candidates' plans have been criticized for lack of specificity and high costs to an already bankrupt health care system. Thus, when all the ballots are counted and the president-elect is given the opportunity to deliver his health care vision for the future, one would hope that the nation can come together and find solutions to increase health care coverage through access and availability while making sure the system is solvent for future generations.

State Action

PPTA's State Handbook

The PPTA State Handbook has been updated and is available on our website (<http://pptaglobal.org>).

Visit WWW.DonatingPlasma.org

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