

# *Stakeholder Report*

On Wednesday, November 18, PPTA hosted a Stakeholder Dinner in connection with the Advisory Committee on Blood Safety and Availability in Rockville, Maryland. Representatives from the consumer community and PPTA member companies attended as did guests from the Patient Services Incorporated.

After brief introductory remarks and a statement from antitrust counsel, PPTA welcomed Corey Dubin, president of the Board of Directors of the Committee of Ten Thousand (COTT) via teleconference, who informed the group about the most recent meeting of the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) with respect to the presentation by UnitedHealthcare. It was noted that the purpose of the dialogue was to use what was learned at NHF as a case study, and certainly not to have a negative discussion regarding any health insurance provider. It was also pointed out that the goal of the presentation was to lead to a discussion about guideline development and to create awareness among attendees of the unfolding dynamics of how insurers are approaching coverage decisions. The discussion did not focus on MASAC in any way. The construct of MASAC is solely within the realm of the NHF and this was not discussed. PPTA also clarified that the Association cannot conduct direct outreach with individual private insurers; however advocacy to public payers is appropriate.

Mr. Dubin's opening remarks set the tone for a vibrant discussion that was engaging

and motivating. He commented that during the MASAC meeting it came to light that the insurance company refers to guidelines from the American Society of Hematology (ASH) with respect to treatment of hemophilia, rather than consulting the NHF-affiliated MASAC, citing as one reason its connection with an advocacy organization. Mr. Dubin discussed the meeting and the exchange with the assembled stakeholders as a way to provide insight into how insurance companies in general may view the treatment of hemophilia; their potential lack of awareness of the scientific and clinical expertise of the MASAC; and as a catalyst for the need for additional outreach and education about the optimal care of individuals with hemophilia. He also encouraged other stakeholders to engage in similar outreach with respect to how their diseases and the therapies that are used to manage them are looked at by large private insurers. Mr. Dubin's comments stimulated discussion at the meeting and positive ideas about ways in which consumer groups, their medical advisory councils and medical societies may work together to the benefit of patients by providing the most relevant clinical information to insurers in order to avoid formularies and other restrictions to access. Mr. Dubin cited with some concern a growing trend among insurers to move blood clotting factors from the prescription drug coverage side to the major medical benefit. Discussion on this issue ensued, and it was noted that shifting into medical is a tool to curtail reimbursement, and a move towards formularies and the use of tiers that could ultimately lead to a shift into Part D.

He also expressed from COTT's point of view a concern for comparative effectiveness research (CER) and shared his opinion that it is really designed to look at cost effectiveness. Mr. Dubin did not have a lot of confidence that the Rare Disease Panel created in health reform legislation would be sufficient to withstand pressures to make decisions based on cost.

**OUTCOME:** *The outcome from this discussion was that there is a "chasm" or lack of understanding among state Medicaid directors, particularly with regard to individuals with severe bleeding disorders and the benefits of prophylaxis, as well as a general knowledge gap about plasma protein therapies and their lifesaving nature. The Stakeholders agreed that it would be beneficial to revisit this issue in more detail at the February 17, 2010 meeting. In preparation for that meeting, Stakeholders were requested to give some thought to the states that should be prioritized for visits and the issues that should be addressed. PPTA will similarly come prepared for such a discussion. The goal is to launch a synchronized state-based advocacy campaign in furtherance of patient access to plasma protein therapies.*

Jim Romano with Patient Services Incorporated (PSI) presented an overview of the major differences between the House and Senate health care legislation being considered and the affect on private market health insurance reforms. While the timing of the meeting (the Senate bill and score was released just an hour before the dinner commenced), was fortuitous, Mr. Romano outlined significant provisions and highlighted some major differences in the bills including a discussion of mandates, Medicaid expansion and other coverage vehicles; insurance exchanges; the public option; consumer protections; and what PSI

is doing on behalf of their patients' concerns. Many Stakeholders have been focused on several key provisions in health care reform legislation that specifically affect their patients, such as CER and lifetime insurance caps, and expressed that they appreciated the chance to learn more about the major differences in the bills and some context on the existing challenges and barriers.

Mr. Romano made the point that cost sharing requirements differ among the plans proposed in the bills. On the issue of affordability, it was interesting to clarify that the federal poverty level (FPL) for an individual is \$10,800 and for a family of four (4) the FPL is approximately \$19,000. This really put things in perspective and discussion continued to focus on high risk pools. Mr. Romano noted that 21 of 35 states with high risk pools ban PSI from paying premiums for patients to access coverage. There are 15 states with no high risk pools. Health reform legislation provides for the creation of a "national pool" that would be at the discretion of the Secretary of Health and Human Services. Another concern highlighted and shared by all is access to specialists and the important role specialists play in treating plasma protein therapeutics users.

**OUTCOME:** *Mr. Romano's presentation stimulated considerable discussion, prompting an invitation for him to attend the next meeting, tentatively scheduled for February 17, 2010 to provide an update on where legislation stands.*

Members of the Plasma Users Coalition (PUC) provided an update to the group on the advocacy work they are doing surrounding their key principles and where things currently stand in the proposed Senate and House legislation. Further, PPTA's

Federal Affairs Director discussed a number of top issues the Association is tracking, including CER and biosimilars, next steps in terms of procedure and some insight into the timetable and the political backdrop for the debate. It was noted that if health reform legislation passes, the regulatory or implementation phase will be extremely important and that Stakeholders will have to remain engaged.

**OUTCOME:** *Given the fact that health reform legislation is pending, it was agreed that an update or a wrap-up would be given by PPTA and PUC representative(s) at the February meeting.*

The next Stakeholder Meeting is scheduled for **February 17, 2010**. As always if you have any specific agenda items that you would like to see on the agenda, please contact Julie Birkofer at PPTA ([jbirkofer@pptaglobal.org](mailto:jbirkofer@pptaglobal.org)). In addition to the items noted above (specific insurance provisions in health reform legislation, state Medicaid Director discussion and federal update) another agenda item that may be of interest is to have a “refresher” presentation on PPTA’s voluntary standards program.

Attachments:

1. Powerpoint Presentation, PSI
2. Nplate set-back as NICE leans towards a rejection for NHS use:  
*PharmaTimes*
3. Excerpt from Pew Report: State Fiscal Health