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STAKEHOLDER REPORT

The next stakeholder meeting will take place on Monday, June 13, 2016 from 5:30 - 7:30 p.m. in conjunction with the PPTA Plasma Protein Forum.

On Feb. 2, 2016, PPTA held a stakeholder meeting in Washington, D.C.

Representatives from the following patient groups participated in the meeting, along with PPTA members and staff:

- Alpha-1 Foundation
- Committee of Ten Thousan
- Cavarocchi Ruscio Dennis Associates on behalf of National Hemophilia Foundatio
- Health & Medicine Counsel of Washington on behalf of GBS/CIDP Foundation and Hereditary Angioedema Association
- Hemophilia Federation of America
- Immune Deficiency Foundation
- Jeffrey Modell Foundation
- Patient Services Inc.
- Platelet Disorder Support Association

PPTA's Vice President, Legal Affairs, provided guidance on antitrust compliance.

PPTA's Senior Vice President, North America welcomed participants to the annual Stakeholder Intake meeting which provides the Association with an opportunity to listen to stakeholder advocacy priorities. Access to therapies in all sites of service frames the Association's advocacy priorities and PPTA looks for alignment on issues and opportunities for collaboration. PPTA's Senior Vice President, North America thanked participants for their support of the Patient Notification System in 2015 and noted it will continue to be a priority for PPTA.

Over the course of the day's briefings and discussions, several common objectives and concerns emerged:

- Patient Assistance (HR 3742)
- Specialty Tier (HR 1600)
- Out of pocket costs
- Transparency
- Network adequacy
- Research funding

- Patient discrimination
- Outreach and education
- Evidence-based guidelines
- Step therapy

PPTA STANDARDS PROGRAMS OVERVIEW

PPTA provided an overview of the standards programs it manages for the plasma protein industry. They are voluntary and built on transparency and regular inspections with monthly committee meetings and a regular review process. There are 10 standards and related systems including the International Quality Plasma Program (IQPP), the Quality Standards of Excellence, Assurance & Leadership (QSEAL), the Cross Donation Check System (CDCS), and the National Donor Deferral Registry (NDDR). These standards and systems work to ensure the safety of patients, donors, and plasma protein products from the beginning to the end of the process.

PPTA PATIENT ACCESS ADVOCACY PRIORITIES OVERVIEW

Federal

PPTA continues to work on the 340B program issues. PPTA provided 340B comments in 2015 and will continue to do so as warranted. We will work with coalitions and consumer groups to maintain access to therapies and ensure that non-interchangeable SCIG therapies are not put into DME competitive bidding. PPTA met with all 100 Senate offices to share information on plasma protein therapies and explain how competitive bidding would negatively affect patient access to care. In addition, PPTA will monitor the issues around drug pricing policy to ensure access to lifesaving medications.

PPTA has a sign on letter for DME Competitive Bidding that we will send out via email and hope that stakeholders will join us in supporting this activity.

The date for PPTA's Washington Fly-In is May 12. We welcome everyone to participate.

State

PPTA's goals at the state level are to maintain open access to all plasma protein therapies within Medicaid and other state funded healthcare programs, address threats to the industry, and assist patients with their advocacy goals.

Thank you to Larry LaMotte and APLUS for their help with efforts in Nebraska advocating passage of a bill that would allow 18-year-olds to donate plasma. A focus for this year will be the implementation of the AMP rule. Specifically states will be modifying their Medicaid reimbursement for pharmacies which may lead to patient access issues.

Stakeholder meeting presentations

- GBS/CIDP Foundation International Legislative and Public Policy Priorities
- HAEA: Advocacy Priorities for 2016
- IDF: PPTA Stakeholders Meeting
- PDSA: Voices of ITP presentation
- PPTA Standards: Continual Evolution
- PPTA State Affairs
- DME Sign-on letter

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