

## **State P&T Committee Processes Should be Open to Public Input and Subject to State Administrative Law Requirements**

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### **Overview**

The process for developing a preferred drug list (PDL) under a public prescription drug program - particularly a state Medicaid drug program - should be an open process. All affected stakeholders should be afforded the opportunity to present relevant information and testimony to the pharmacy and therapeutics (P&T) committee developing the PDL. Public P&T committees operate under a delegation of public duties from legislatures and executive branch agencies, and therefore have an obligation to remain responsive to the public trust. Public integrity demands that they operate in a manner that complies with all relevant administrative procedures acts and open meetings requirements. It also demands that internal documents be subject to any relevant public documents laws and regulations.

### **Background**

The Plasma Protein Therapeutics Association (PPTA) is the primary advocate for the world's leading producers of plasma therapies. Plasma therapies treat unique, life-threatening diseases and disorders. Life-saving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, intravenous immunoglobulins (IVIG) to treat complex diseases in persons with immune deficiencies and neurological disorders, and therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy. PPTA's member companies produce 80 percent of the plasma therapies used in the United States. These therapies differ significantly from commonly advertised, compound-based pharmaceutical products:

- Plasma therapies require a series of complex manufacturing steps, validation criteria, and constantly evolving viral inactivation processes, all intended to ensure that plasma therapies be safe and effective.
- The therapies within these classifications are distinct, sole source products that have no generic biological equivalents that could be substituted under a prior authorization program.
- Medicaid spending on all plasma therapies nationwide constituted just 1.5 percent of total Medicaid prescription drug spending in fiscal year 2002.

## **P&T Committee Meetings Must Afford the Opportunity for Stakeholder Input**

The states of Florida and Michigan have led the movement toward controlling Medicaid costs through the implementation of an expanded prior authorization process that utilizes a PDL. More than 20 other states have followed their lead. In each case, the state has created a P&T committee to make recommendations regarding which drugs are to be added to the PDL. In Michigan, the P&T Committee's deliberations were initially kept closed to the public. A January 2003 report released by the Kaiser Commission on Medicaid and the Uninsured' concluded that the Michigan Department of Community Health's (DCH's) approach to implementing its PDL behind closed doors "generally excluded the views of stakeholders, particularly Medicaid beneficiaries." The reported states that:

"...The general exclusion of stakeholders from the policy development process engendered discontentment, isolation, and ultimately opposition ... Future efforts in Michigan and other states to refine or initiate PDLs would benefit from inclusive processes that give beneficiaries and other stakeholders the opportunity to express their positions and to participate more fully in the policymaking process."

The member companies of PPTA believe that PDLs should be developed by P&T committees who have a working knowledge of the wide range of pharmaceutical therapies, including such orphan or highly specialized drugs as plasma-derived and recombinant protein therapies. To ensure that any gaps in a committee's knowledge base are covered, a P&T committee's processes must always be open to public input. If the deliberations of a P&T committee are closed to knowledgeable stakeholders, patients could be inappropriately denied timely access to the therapies they need. The public must be afforded a real opportunity to present input through oral or written testimony. Patients, healthcare providers, and manufacturers should all be given the opportunity to present relevant information about product effectiveness and safety in an open forum, after being given timely and adequate notice of P&T committee deliberations.

## **P&T Committees Operate Under Delegated Authority and a Public Trust**

Unlike the P&T committees utilized by private pharmacy benefit managers (PBMs), public P&T committees -even when working on behalf of a private pharmacy benefits manager contracted by a public entity -do not have the freedom to remain anonymous. They operate under the delegated authority of legislative and/or executive branch public entities. They have the same responsibility for ensuring public input and public responsiveness through compliance with relevant administrative procedures and open meetings laws as do the public entities that have delegated the authority. Materials considered at a P&T committee meeting should be subject to all relevant public disclosure laws and regulations.

## **Conclusion**

P&T committees working on behalf of public entities, exercising duties delegated by those entities, have an obligation to ensure that they remain responsive to the public. Unlike the P&T committees operating on behalf of private insurers or PBMs, P&T committees for public entities do not have the freedom to operate anonymously. They must afford the opportunity for public comment by affected stakeholders in a timely manner, and they must operate in accordance with relevant administrative procedures acts, open meetings laws, and public documents requirements. Their operations must be subject to public scrutiny.