State Prescription Drug Upper Payment Limits Explained

March 22, 2021

Jane Horvath

What Is an Upper Payment Limit?

What a PDAB UPL Can Be

- It is a payment limit that applies to all purchases and payments for some high-cost drugs
- It is applicable to only drugs intended for sale in the UPL state
- UPL is a payment limit that can create greater access to costly drugs and improved ability to finance treatment with costly drugs
- UPL is not a price control
  - UPL does not affect a manufacturer list prices or ability to offer price concessions per standard business practice.

Why Use a UPL?

State Rx Policy Options are Limited

- State options to protect residents from high costs of drug treatments are limited owing to federal statute and case law.
- Drug industry has raised a host of perceived legal issues with different state activity
  - Dormant Commerce Clause
  - Potential Patent law violations/Supremacy Clause
  - Trade Secrets laws
  - Free Speech
- The UPL will likely be challenged but should be found to be legal
  - US Supreme Court issued a unanimous decision that states have full authority to establish payment rate regulation in an ERISA case (PCMA v Rutledge).

UPL is Ubiquitous in Healthcare

- No one pays list prices, everyone sets their payment limits
  - Think about your insurance EOB – rate setting
- State ability to set payment rates is solid –
  - Supreme Court in Rutledge just confirmed state authority to regulate payment rates
- UPL uses the standard operating procedures of manufacturers and suppliers ….. Negotiated discounts for different drugs for different payers and purchasers supplied by wholesalers

UPL Gets the Job Done

- UPL carries a lower cost through the supply chain, to the patient, at the point of service
  - No other mechanism does this
    - Pharma industry wants their insurer rebates to be provided to the patient to point of service (while somehow keeping rebate amount secret.....) is not workable
- Reducing costs in the supply chain is what will turn the market around.
    - transparency
    - cost certainty
    - better competition
    - can de-link supply chain profit from drug price to supply chain compensation from fees
    - can help independent pharmacies – front line providers in underserved communities
- UPL designed to protect all consumers without "opt in" of Medicare Part D or ERISA plans (although SCOTUS Rutledge decision means ERISA can be subject to state rate regulation)

How to Create a UPL?

Establishing a UPL

- Avoid creating a UPL that would be the deepest discount in the US market
  - Impact on Medicaid will need to be determined
  - Might be considered a Medicaid 'best price'
    - If so, manufacturer would have to provide that discount to all state Medicaid programs
    - Violation of the Dormant Commerce Clause?

Establishing UPL

- In-State Estimate UPL
  - estimate in-state existing discounts to establish the UPL
  - May not reduce net cost for all payers/health plans but would reduce claims payment spend and will get lower cost into the supply chain to the point of service
- Commercial Market UPL
  - evaluate/estimate US commercial market discounts, FFS and VA discounts
  - work with advisory council to determine a UPL that would expand access and by how much.
- Budget-Based UPL
  - Determine how much is currently spent on therapeutic alternate or other treatment for the disease – all payors and state purchasers
  - Assess unmet need
  - Perhaps increase the budget by some factor depending on unmet need, characteristics of the drug or other factor
  - Establish a UPL based on current spend and includes unmet needs
  - Similar in concept to Louisiana Hep C contracting budget development

Implementing a UPL

- UPL is optimized when applied statewide –
  - UPL product has one maximum cost/charge in state market
    - Eliminates claims payment headaches
    - Avoids burden on pharmacies and stocking providers
- If UPL applies less than statewide (to government payers and purchasers)
    - May need to be mail order for health plan enrollees or
    - May need to be rebated to payers (but this does not automatically lower costs to the patient)
- Each UPL should have a delayed effective date
  - Allow time to move stock and be reimbursed for stock acquired before the UPL decision
  - Will likely need some additional segue time to account for a variety of stock situations
  - Advisory council and others can be very helpful in designing the transition framework

Thank You

Jane Horvath
Horvath Health Policy, *Innovations in Healthcare Financing*
Linkedin.com/in/horvathhealthpolicy
www.horvathhealthpolicy.com
HorvathHealthPolicy@gmail.com
202/465-5836