Prescription Drug Access: The Role of State Insurance Regulators

Amy Killelea, NASTAD
### Health Insurance Regulation Post ACA… It’s Complicated

<table>
<thead>
<tr>
<th>Federal Regulation</th>
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<td>• New federal Affordable Care Act (ACA) requirements that apply mostly to individual and small group markets</td>
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<td>• Array of other federal laws that touch other pieces of commercial insurance markets (e.g., ERISA, HIPAA)</td>
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<th>State Regulation</th>
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<td>• Health insurance regulation has typically been the purview of state (and emphatically not federal) laws and regulations</td>
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<td>• 5 states have refused to enforce new ACA protections (TX, MO, OK, AL, WY)</td>
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State Role in ACA Monitoring & Enforcement

- States that are enforcing ACA provisions must first certify QHPs through state department of insurance
  - Essential Health Benefits protections (including discriminatory plan design prohibitions)
  - Network adequacy
  - Rate review
- CMS/CCIIO reviews QHP submissions for FFM states to ensure compliance with federal rules and regulations and is fairly prescriptive in some areas
NAIC represents state insurance commissioners and provides support, advocacy, and a convening body across a range of insurance issues (not just health).

Utilizes a Consumer Representative body made up of experts and consumer advocacy groups to inform NAIC members and activities.

Convenes regulators, Consumer Representatives, and other interested parties to draft model state laws:
  - Including prescription drug coverage – Model Law 22
NAIC Model 22

“Health Carrier Prescription Drug Benefit Management Model Act”

- Sub-committee has formed to update the model law, focusing on:
  - **Transparency**, accuracy, and disclosure of formulary information
  - **Accessibility** of prescription drugs and composition of plan formularies
  - **Non-discrimination protections** and tiering

- Has the potential to impact much broader market than just EHB regulated plans (including large group market in addition to small group and individual market)
State and Federal Priorities for Regulation of Prescription Drug Access

- Non-discrimination requirements
- Pharmacy and Therapeutics (P&T) Committees requirements
- Regulation of Pharmacy Benefit Managers (PBMs)
- Plan transparency requirements
- Models to address emerging and breakthrough therapies
- Continuity of coverage protections
- Consumer friendly and transparent appeals and exceptions processes
Areas to Watch: P&T Committees and Emerging Therapies

- **P&T committee requirements** are a large component of NAIC Model 22 and a new federal ACA requirement for the 2017 plan year
  - Composition - include relevant expertise for formulary decisions
  - Conflict of interest - ensure fair and unbiased decisions
  - Sound basis for decisions - ensure members take into account relevant and timely medical and scientific evidence

- **Emerging and breakthrough therapies** will continue to present access challenges
  - Ensure newly approved drugs are evaluated by P&T committees in a timely fashion
  - Address potential discriminatory plan designs
  - Assess feasibility of value-based pricing models
Resources

- Amy Killelea, NASTAD (akillelea@nastad.org); www.nastad.org


- NAIC Model 22 Sub-Committee (includes call schedules and comments submitted by Consumer Representatives and other interested parties), http://www.naic.org/cmte_b_mod_22_sg.htm