TxSCO Board Meeting: Policy Update

Oct. 1, 2021
Federal Policy
Congressional consideration of the Build Back Better (BBB) Act is underway. The $3.5T House draft includes drug pricing cuts totaling $700B, serving as the bill’s second largest pay-for behind $2T tax increases. Following demands from House and Senate moderates, the overall size of the package and drug pricing provisions specifically will likely be scaled down, but the compromise package may still include significant cuts to Part B drug reimbursement. If Congress fails to enact legislative reforms, reimbursement threats remain as the Biden administration is expected to leverage the Center for Medicare and Medicaid Innovation’s (CMMI) vast authority to implement Medicare drug pricing reforms through a demonstration.

Oncology Care Model (OCM) in limbo

- Model could sunset June 30, 2022 without a replacement as CMMI focuses on larger scale drug pricing demos.

Radiation Oncology Model (RO) looms

- Begin Jan. 1, 2022, despite provider pushback.

Medicare 2% sequestration extension

- Infrastructure bill would extend sequester one year through 2031.
State Issues
Special Session Update

• The Texas Legislature has been in session for all but 6 weeks this year
• Currently on third special session with a possible fourth on the horizon
• Most special session policy issues have been addressed at this point
• Redistricting is still on the table with a contentious debate set to begin soon with the release of House, Senate and Congressional draft maps
• $16B in ARPA funds still need to be appropriated but there is no rush
• Depending on how redistricting finishes up and additional retirements there is likely to be a large freshman contingent in the next legislative session
  – So far 13 House members and 2 Senators will not be returning to their chamber
Statewide Campaign Update

• Governor
  – With $55 million cash on hand, Abbott is easily the most well funded Texas Gubernatorial candidate of all time; most prominently, he faces former Senator Don Huffines and former state party chair/former Florida Congressman Allen West

• Lt. Gov.
  – Dan Patrick ($23M) faces several lesser-known opponents from both his left and right; this week political pundit Matthew Dowd announced a run for the Democratic primary

• Attorney General
  – Ken Paxton faces opposition from recently retired Supreme Court Justice Eva Guzman, current Land Commissioner George P. Bush, and current State Rep. Matt Krause (Fort Worth) in the Republican Primary; Paxton could outspend them all combined two to one

• Ag Commission
  – Sid Miller faces primary opposition from State Rep. James White; basically a tie in funding

• Others
  – Comptroller Glenn Hegar, GLO Candidate Sen. Dawn Buckingham, and Railroad Commissioner Wayne Christian will all walk into the seats they’re competing for
APPENDIX
Drug Pricing Reforms: State of Play

2 Pathways to Watch

“Build Back Better Act” is underway
- The $3.5T “Build Back Better Act,” also known as the reconciliation bill, is currently under debate by congressional committees
- Timing: unclear. Speaker Pelosi previously planned to pass the House bill by the end of September, but vote delayed following moderates’ opposition

Administrative action looms
- If Congress is unable to enact legislative reforms, the Biden administration may leverage its executive authority
  - Notably, the Center for Medicare and Medicaid Innovation (CMMI) can waive the entire Medicare statute when implementing a demonstration
  - CMMI could attempt significant Medicare drug pricing reforms, like government negotiation

Build Back Better Act
- Government negotiation of drug prices
  - House draft bills (E&C, W&M) include international reference pricing (IRP), but the Senate is considering “domestic reference pricing” potentially tied to the Federal Ceiling Price or a “least costly alternative” approach
  - Inflationary penalties
  - Medicare rebates if prices rise faster than inflation
  - Democrats may attempt to reach commercial market as well, but likely prohibited under Senate rules
  - Part D benefit redesign
  - Out-of-pocket cap
  - Higher manufacturer and plan liability throughout benefit
  - OIG Rebate Rule Repeal
  - Permanently repeal the Trump administration’s rule that would have prohibited rebating in Part D unless provided at point-of-sale

Biden’s Drug Pricing Plan
- The “Comprehensive Plan for Addressing High Drug Prices” provides insight into policies the administration may attempt to pursue under its executive authority
  - Government negotiation of drug prices
  - Inflationary penalties
  - Part D benefit redesign
  - Promote biosimilars

Likelihood?

Moderate likelihood that Congress enacts significant reforms like govt. negotiation. Key moderate Democrats oppose the $3.5T size of the package, and the House and Senate still lack consensus on the mechanics for government negotiation.

High likelihood that CMMI will pursue significant Medicare reforms like govt. negotiation if Congress fails to enact legislatively.

TxSCO takeaway: Policymakers’ attempts to address drug pricing could significantly reduce physician reimbursement for Part B drugs and may have indirect impacts on commercial reimbursement as well.
**Drug Pricing Reforms: BBB Act Negotiations Get Messy**

### House

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<th>Sept. 15, 2021: <strong>Energy and Commerce Committee</strong> completed its markup and voted 29-29 on the <em>drug pricing section</em>, which is estimated to generate $700B in federal savings over 10 years.</th>
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<td>The tied vote means the drug pricing section is not approved by the committee (majority vote required).</td>
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<td>Democrat Reps. Peters (CA), Schrader (OR) and Rice (NY) joined Republicans to vote against the drug pricing subtitle, citing concerns with the scale of the government negotiation policy, the use of international reference pricing specifically, and concerns for innovation and jobs.</td>
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<td>Sept. 15, 2021: <strong>Ways and Means Committee</strong> also completed its markup and approved the <em>drug pricing section</em> (same language as E&amp;C) 24-19</td>
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<td>Notably, Rep. Murphy (D-FL) voted against all components of the Build Back Better Act, including drug pricing, arguing the process has been unnecessarily rushed and members have not had enough time to review the bill.</td>
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<td><strong>This is a notable win.</strong></td>
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<td>Procedurally, the drug pricing policies could still be included in the larger package that would be voted on by the full House, but the dissent of 4 key committee Democrats means leadership does not yet have the votes to pass the drug pricing policies on the House floor.</td>
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<td>Another member to watch: Rep. Correa (CA)</td>
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<td>Rep. Correa, along with Reps. Rice and Murphy, supports Reps. Peters and Schrader’s <em>alternative drug pricing proposal</em> that would limit government negotiation to a subset of Part B drugs.</td>
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### Senate

| Senate Democrats continue to work on their version of the Build Back Better Act and have yet to release policy details and legislative text. |
| The government negotiation provisions are expected to generate less savings than the House version. |
| In lieu of international reference pricing (IRP), the Senate is rumored to be considering a “domestic reference pricing” policy tied to the Federal Ceiling Price or a “least costly alternative” approach. |
| Finance Chairman Wyden (D-OR) claimed smaller biotech companies would be exempt from government negotiation policies. |
| The tension between House moderates and progressives is playing out in the Senate as well. |
| Big picture: |
| Sens. Sinema (AZ) and Manchin (WV) have repeatedly emphasized opposition to the $3.5T size of the package, while Budget Chairman Sanders (VT) claims $3.5T is “the minimum of what we should be spending.” |
| Drug pricing: |
| Sen. Sinema (AZ) is opposed to the current drug pricing proposals in the House and the Senate, as well as the House alternative pitched by moderate Reps. Peters and Schrader that would limit negotiation to Part B drugs lacking exclusivity and competition. |
| Sen. Carper (DE) is opposition to cutting $600B+ from the pharma industry. |
| Sen. Menendez (NJ) voted against government negotiation in the past and has more recently expressed skepticism with government negotiation proposals that do little to improve out-of-pocket costs. |

### Next steps?

- House previously expected to vote on the bill on Sept. 30, but will instead wait and hold a vote on a package that can actually pass the Senate.
- House Ways & Means Chairman Neal (D-MA) said his staff and Senate Finance staff “are deep in negotiations over the eventual package,” and he is open to domestic pricing in lieu of IRP, stating “I just want to get an agreement.”

**TxSCO takeaway:** Policymakers’ attempts to address drug pricing could significantly reduce physician reimbursement for Part B drugs and may have indirect impacts on commercial reimbursement as well.
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