TxSCO Update

Nov. 11, 2021
## Overview: Notable Updates

### Federal
- Sequester cuts loom
- Build Back Better (BBB) Act
  - The latest
- Recent Rules
  - RO APM moves forward
  - PFS
  - OPPS

### State
- Special session
- Budget outlook
- COVID-19 trends
- Redistricting fallout
- Legislative vacancies
Federal Update
The 2% sequester moratorium ends Dec. 31, 2021

A new 4% sequester looms for 2022 unless Congress waives before end of year

- This is a 4% “PAYGO” sequester resulting from the American Rescue Plan’s increase in the deficit
- Historically, Congress has always waived the PAYGO sequester rules when enacting a law that increases the deficit
- Congress has yet to waive the PAYGO rules for the American Rescue Plan
- There is hope that Congress will address this in an end of year package, but fate is unclear as all attention is focused on the Build Back Better Act
BBB Act: Drug Pricing Policies

Misinformation and confusion abounds

• The Drug Pricing “Framework” circulated on the Hill and released by the White House on Nov. 2nd omitted numerous key policy details, appeared deliberately vague (e.g., # negotiated drugs is cumulative, 100 negotiated by 2030)
• Many articles in the press are misleading and downplay the implications to industry
• Nov. 4: Moderates seek a few changes to text
  • Exclusivity period from FDA approval date:
    • Biologics 13 years
    • Small molecule stays at 9 years

Next steps

• Awaiting official projection from CBO
• 5 House moderates told Speaker Pelosi they would not vote for the BBB Act until seeing an official score from CBO → this demand has slowed the process for the House vote
• Initial attempts Nov. 4 and 5
• House vote planned for the week of Nov. 15th
• Sen. Manchin (D-WV) similarly declared he could not voice support for the BBB Act until seeing official projections from CBO/JCT

<table>
<thead>
<tr>
<th>Offsets</th>
<th>$2,150</th>
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<tbody>
<tr>
<td>15% Corporate Minimum Tax on Large Corporations</td>
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<tr>
<td>1% Stock Buybacks Tax on Corporations</td>
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<tr>
<td>Corporate International Reform to Stop Rewarding Companies That Ship Jobs and Profits Overseas and Other Corporate Reforms</td>
<td>365</td>
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<td>AGI Surcharge on Millionaires and Billionaires: 5% Tax on Income Above $10 Million and Additional 3% on Income Above $25 Million</td>
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<td>Close Medicare Tax Loophole for the Wealthy</td>
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<td>Limit Business Losses for the Wealthy</td>
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<td>IRS Investment to Close the Tax Gap</td>
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<tr>
<td>Reduce Cost of Prescription Drugs</td>
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<td>Other Loophole Closers</td>
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Treasury “Preliminary Estimates” (based on Nov. 4 text)

Senator Joe Manchin @Sen_JoeManchin · 3h
By all accounts, the threat posed by record inflation to the American people is not “transitory” and is instead getting worse. From the grocery store to the gas pump, Americans know the inflation tax is real and DC can no longer ignore the economic pain Americans feel every day.

3.3K 2.7K 8.3K Nov. 10, 2021
Govt. Negotiation

- Includes Part B and Part D, and negotiated price included in Medicaid Best Price
- Targeted drugs: highest gross spending in Parts B and D
  - Single source drugs on the market for:
    - 9+ years for small molecule drugs
    - 13+ years for biologics (per Nov. 5 revision)
    - All insulin products
- Number of drugs
  - Negotiate up to 10 drugs in 2023, price applies 2025
  - Part B drugs: exempt first 2 years; negotiated price applies 2027 at earliest
  - Targeted number increases each year until negotiated prices apply for up to 20 new drugs in 2028+
  - These numbers are cumulative
  - 100 drugs negotiated in 2030
- Negotiated price cannot exceed:
  - 75% of non-federal average manufacturer price (non-FAMP) for a small molecule drug 9 to 12 years passed initial exclusivity
  - 65% of non-FAMP for a drug 12 to 16 years passed initial exclusivity
  - 40% of non-FAMP for a drug 16 years+ passed initial exclusivity
  - Exempt drugs
    - <$200M Medicare spend and price increases limited to CPI-U
    - Orphan: If designated as a drug for only 1 rare disease or condition under FDCA 526, and that drug’s only indication(s) are for that 1 disease or condition
- Small biotech exemption:
  - 3-year exemption; negotiated price applies 2028 at the earliest
  - Phase-in reductions from negotiation for the first 2 years the price applies

Inflationary Penalties

- Benchmark year: 2021
- Rebate calculated based on “all units sold” (includes commercial)

Part D Benefit Redesign

- $2,000 OOP cap
- Initial Coverage Limit (ICL): beneficiary liability 23%
- Manufacturer discounts: 10% in ICL, 20% in catastrophic
- Small Biotech: phase-in liability
- Exemption: drugs subject to negotiation are exempt from manufacturer liability
- Insulin: $35 max copay

Orphan Drug Tax Credit

- Credit for clinical testing of orphan drugs limited to first use or indication ($2.72B over 10 years)

PBM Transparency

- PBM’s required to report their rebates to employers and plan sponsors
<table>
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<tr>
<th><strong>Government Negotiation: Snapshot</strong></th>
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<tr>
<td><strong>Effective Dates</strong></td>
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<tr>
<td><strong>H.R. 5376</strong></td>
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<td>BBB Act, Rules Committee Print</td>
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<td><strong>BBB Act House E&amp;C, W&amp;M</strong></td>
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<td>Sept. 2021 &amp; H.R. 3 April 2021</td>
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<td><strong>Reps. Peters (D-CA) &amp; Schrader (D-OR)</strong></td>
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<td>Sept. 2021</td>
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November 2, 2021. CMS Released the 2022 Medicare Physician Fee Schedule Final Rule and other revisions to payment policies under Medicare Part B with an accompanying fact sheet (link). The following was finalized:

### Telehealth
- CMS did not add any of the requested services (i.e., biofeedback, PT, personal care) to the permanent Medicare telehealth list for CY 2022.
- Services temporarily added to the Medicare telehealth list during the COVID-19 PHE will remain on the list under end of CY 2023.
- CMS will require regular in-person, non-telehealth visits for beneficiaries receiving mental health telehealth services.
- CMS will limit the use of audio-only telecommunications to only beneficiaries not capable of using two-way audio/video technology.

### Clinical Laboratory Fee Schedule (CLFS)
- CLFS provides a nominal fee for specimen collection and a fee for transportation and personnel (i.e., a travel allowance).
- At the end of the COVID-19 PHE, CMS will terminate increased payments for specimen collection from homebound beneficiaries.

### Notable Prescription Drug Issues
- CMS will require manufacturers without a Medicaid Drug Rebate Agreement to report average sales price (ASP) data on their Medicare Part B drugs and biologicals beginning January 1, 2022.
- CMS finalized the proposal to use the “lesser of” methodology when calculating ASP for drugs and biologicals with Medicare Part B-covered and self-administered versions. This calculation methodology was already applied to Cimzia and Orencia as of July 1, 2021.

### Quality Payment Program (QPP)
- CMS will begin the transition to MIPS Value Pathways (MVPs) in the 2023 MIPS performance year.
- CMS identified 7 MVPs for reporting in 2023.
- Each MVP includes measures to address performance categories found in the traditional MIPS program as well as population health measures, including measures of quality, cost, and improvement.
- In the meantime, CMS updated the performance threshold and category weights for the traditional MIPS program.

### Others
- Conversion factor: Final conversion factor for CY 2022 is 4% less than in CY 2021.
- Physician Assistant (PA) services: PAs now allowed to bill Medicare directly.
- Opioid treatment programs (OTPs): CMS created a new code, G1028, for higher dose naloxone and will continue to allow OTPs to furnish therapy and counseling using audio-only telephone calls.
- Colorectal cancer screening: CMS will reduce the co-insurance requirement (down to 0% in CY 2030) for procedures planned as colonoscopies but become diagnostic tests.
- Removal of NCDs 180.2 (enteral and parenteral nutritional therapy) and 220.6 (positron emission tomography scans) to allow local coverage discretion.
### 340B
- CMS is keeping the payment rate for separately payable drugs and biologicals acquired through the 340B program at the current rate of ASP - 22.5%.
- CMS is continuing the payment rate for 340B acquired biosimilars at ASP –22.5% of the biosimilar's ASP (rather than the reference product).
- CMS will continue to exempt rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from the 340B payment adjustment.

### Hospital Transparency
- CMS is finalizing several methods to more strictly enforce the Hospital Transparency mandate.
- Larger fines for non-compliance using a scaling factor based on hospital bed size.
- Requiring machine-readable files be accessible to automated searches and direct downloads.
- Deeming state forensic hospitals compliant if they meet certain criteria.

### Radiation Oncology (RO) Model
- CMS finalized a January 1, 2022 start date for the RO model.
- The RO model will run for 5 years, ending December 31, 2026.
- The baseline period will be calculated from 2017-2019.
- CMS will remove liver cancer from the RO model and exclude any hospitals participating in the CHART Model.
- CMS will adopt an extreme and uncontrollable circumstance policy that will allow CMS to make additional changes.

### Health Equity
- CMS received comments on several of their efforts to address health equity gaps.
- Improve data collection to better measure and analyze disparities across programs and policies.
- Future efforts to address health equity in the hospital Outpatient Quality Reporting (OQR) program.
- Future efforts to address health equity in the Ambulatory Surgical Center Quality Reporting (ASCQR Program).
- Addressing disparities in rural emergency hospitals (REH).

### Others
- CMS will use CY 2019 claims data to set devise pass-through rates for CY 2022 and is continuing the policy of making all biosimilars eligible for pass-through payment.
- CMS finalized its payment policies for drugs, biologicals, and radiopharmaceuticals if ASP is not available and for those without pass-through status.
- CMS will halt the elimination of the Inpatient Only (IPO) List.
- CMS will reinstate the ASC covered procedures list (CPL) criteria and removal of 258 procedures from CPL.
- CMS finalized payment policies for the Partial Hospitalization Program and non-opioid pain management products.
- CMS is finalizing the proposal to keep the drug packaging threshold at $130 per day.
1 in 3 Medicare Beneficiaries without Subsidies Do Not Fill Their Oral Anticancer Prescriptions

Dusetzina also found dual-eligibles were twice as likely to fill their anticancer prescriptions than non-duals.

Policy Opportunities to Increase Access to Care and Reduce Health Inequities: Cap Out-of-Pocket Costs on Part D

Non-Initiation of Part D Anticancer Drug by Medicare Beneficiaries, by Receipt of Low-Income Subsidy

Presenter: Stacie B. Dusetzina, PhD Associate Professor of Health Policy Ingram Associate Professor of Cancer Research Vanderbilt University School of Medicine
State Update
Special Sessions Over, for Now

• The Texas Legislature concluded its 3rd special session in October, completing most of the items on the Governor’s call, except for prohibiting vaccine mandates
• Redistricting maps for the Texas House and Senate, Texas Congressional districts, and the State Board of Education also passed, and as expected these are already in litigation
• Senate Bill 8 appropriates $13.3 billion of available federal dollars from the American Rescue Plan Act:
  – $7.2 billion to shore up the depleted Unemployment Insurance Fund
  – $2 billion for hospital surge staffing reimbursement, purchasing COVID-19 therapeutic drugs, and operation infusion centers
  – $380m for critical staffing for nursing facilities, assisted living, etc.
Texas Budget Outlook

• The federal government allocated billions of dollars to the state over the course of the pandemic, which allowed the state to spend federal money in places where it would traditionally spend state general revenue.

• Last week, the Comptroller estimated an available balance of almost $12 billion dollars, which will be available at the start of the next regular session in January 2023. This additional available revenue could be used to pay down existing shortfalls in Medicaid, border security, and the buydown of property taxes.

• The Texas economy rebounded strongly from the deep but short recession caused by the onset of the COVID-19 pandemic. Since April of this year, the Texas economy and state tax collections, particularly from sales taxes, have continued to outperform expectations.

• Continued risks include continued global supply chain disruptions and bottlenecks affecting a range of products. Labor shortages and inflationary pressures could impact both business and consumer demand. Volatile energy prices and the potential spread of coronavirus variants also remain uncertainties for Texas’ economic outlook.
COVID-19 Update

- COVID cases, hospitalizations, reported deaths, and positivity rates continue to decline statewide
- New availability of vaccine for children 5-12; the FDA gave emergency use authorization to the Pfizer vaccine and the CDC has approved its use
Impacts of Redistricting

• New maps for House, Senate, SBOE and Congress have been passed and are currently being challenged in court by several groups suggesting they violate the federal Voting Rights Act

• Overall, the legislature bolstered incumbents’ prospects by strengthening districts instead of drawing many new majority party-leanining districts meaning fewer districts will be competitive in November 2022 general election races
  – State Senate – 1 district (SD 27) expected to be competitive in November
  – State House – 8 districts
  – US House – 3 districts

• Last election cycle more than 40 districts were rated as competitive in November, now 12. meaning policy will continue to push toward the left and right extremes
# Upcoming Vacancies

## House of Representatives

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<tr>
<th>Retiring</th>
<th>Higher Office</th>
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<tbody>
<tr>
<td>Ben Leman (R-Iola)</td>
<td>James White (R-Hillister)</td>
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<tr>
<td>Jim Murphy (R-Houston)</td>
<td>Ag Comm.</td>
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<tr>
<td>Chris Paddie (R-Marshall)</td>
<td>Celia Israel (D-Austin)</td>
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<tr>
<td>Scott Sanford (D-Dallas)</td>
<td>Mayor</td>
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<tr>
<td>John Turner (D-Dallas)</td>
<td>Phil King (R-Weatherford)</td>
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<tr>
<td>Jake Ellzey (R-Waxahachie)</td>
<td>Senate</td>
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<tr>
<td>Leo Pacheco (D-San Antonio)</td>
<td>Tan Parker (R-Flower Mound)</td>
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<tr>
<td>Eddie Lucio III (D-Brownsville)</td>
<td>Senate</td>
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<tr>
<td>Michelle Beckley (D-Carrolton)</td>
<td>Matt Krause (R-Fort Worth)</td>
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<tr>
<td>Kyle Biedermann (R-Fredericksburg)</td>
<td>AG</td>
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<tr>
<td>Lyle Larson (R-San Antonio)</td>
<td>Alex Dominguez (D-Brownsville)</td>
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<tr>
<td>Dan Huberty (R-Kingwood)</td>
<td>Senate</td>
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<tr>
<td>John Frullo (R-Lubbock)</td>
<td>Eddie Rodriguez (D-Austin)</td>
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## Senate

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<tr>
<td>Tan Parker (R-Flower Mound)</td>
<td>Jane Nelson (R-Flower Mound)</td>
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<tr>
<td>Matt Krause (R-Fort Worth)</td>
<td>Kel Seliger (R-Amarillo)</td>
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<td>Alex Dominguez (D-Brownsville)</td>
<td>Eddie Lucio, Jr (D-Brownsville)</td>
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<td>Dawn Buckingham (R-Lakeway)</td>
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While the list above represents those voluntarily retiring, there will of course be some who are retired by voters or by the nature of their newly drawn districts.

We expect another 10-15 House members will not be returning in addition to those above and at least one more Senator.
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