TxSCO Update

September 9, 2021
Overview: Notable Updates

Federal

- Drug Pricing Reforms: latest developments, intel
- Physician-administered Drugs: Employer Payments to HOPDs are 3x Physician Office Rate
- Hospitals Spend $310M/Year on White & Brown Bagging Requirements
- Prior Authorization Update: Anthem’s “Dose Reduction Program”

State

- Special Session Update
- TDI Updates
- COVID Update
## Drug Pricing Reforms: State of Play

### Reconciliation Bill
- **$3.5T health care plan** to include drug pricing reforms, like government negotiation, inflationary rebates and Part D redesign
- **Policy details TBD:** Committees have until **Sept. 15** to assemble the reconciliation bill, which leadership hopes to pass into law by **Oct. 1** (these deadlines are self-imposed and may shift)

### CMMI Demonstration
- **CMMI can waive** the entire Medicare statute when implementing a demo; there are no statutory restrictions on a demo’s duration, and no requirement for notice and comment rulemaking
- **Once it becomes clear** that Congress is unable to enact legislative reforms, expect CMMI to act
- **CMMI likely to attempt** significant Medicare reforms, like government negotiation

### Ways this could fall apart:
- **Democrats’ slim margins:** Senates can lose 0 votes, House can lose 3 votes
- **May 3:** 10 moderates threatened to oppose government negotiation
- **Aug. 10:** 96 progressives threatened to block infrastructure bill unless they vote on infrastructure bill at same time as reconciliation bill
- **Aug. 13:** 9 moderates threatened to block reconciliation bill unless they first vote on the infrastructure bill
- **Aug. 23:** Sen. Kyrsten Sinema (D-AZ) “will not support a budget reconciliation bill that costs $3.5 trillion”
- **Aug. 25:** Regarding reduction of the $3.5T topline target, Senate Budget Chairman Sanders (D-VT) said “I already negotiated. The truth is we need more. The needs are there. This is, in my view, the minimum of what we should be spending.”
- **Sept. 2:** Sen. Manchin (D-WV), in a WSJ op-ed, said “I, for one, won’t support a $3.5 trillion bill, or anywhere near that level of additional spending, without greater clarity about why Congress chooses to ignore the serious effects inflation and debt have on existing government programs.”

### Ways this could fall apart (continued)
- **A court may find** the demonstration exceeds CMMI’s authority (CMMI’s authority to enact wide scale demonstrations has yet to be litigated)
September 8, 2021

The Honorable Charles E. Schumer  
Majority Leader  
United States Senate  
322 Hart Senate Office Building  
Washington, D.C. 20510

The Honorable Mitch McConnell  
Minority Leader  
United States Senate  
317 Russell Senate Office Building  
Washington, D.C. 20510

The Honorable Nancy Pelosi  
Speaker  
United States House of Representatives  
1236 Longworth House Office Building  
Washington, D.C. 20515

The Honorable Kevin McCarthy  
Minority Leader  
United States House of Representatives  
2468 Rayburn House Office Building  
Washington, D.C. 20515

Dear Majority Leader Schumer, Minority Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), we are writing to ask that you please help address the unfolding cancer care “infrastructure” crisis in this country and not make it worse with destructive policy and regulations that threaten America’s patients. While Congress is working to address physical and “human” infrastructure, it is overlooking the very real threats to the nation’s cancer care infrastructure and the strain it is under.

As the politics swirl over competing infrastructure packages and how to pay for them, please help protect the nation’s cancer care infrastructure. Very specifically, we implore you to do the following:

- Stop the Medicare sequester cuts – don’t extend the sequester further.
- Stop the CMS proposed Medicare payment cuts to cancer care.
- Stop the implementation of the mandatory radiation oncology experiment.
- Rein in PBM abuses and rebates, as well as hospital 340B discounts – discounts that should be going to patients, not institutions – that are fueling drug prices.
- Help us access biosimilars and remove barriers to their use.
- Do not advance any provisions, such as in H.R. 3, that would limit oncologists’ access to and use of cutting-edge, life-saving cancer therapies.
- Remove barriers to value-based drug arrangements to push pharmaceutical manufacturers to compete in lowering drug prices.

We welcome the opportunity to discuss any of this in greater detail.

Sincerely,

Kashyap Patel, MD  
President

CC: The Honorable Ron Wyden  
The Honorable Mike Crapo  
The Honorable Frank Pallone  
The Honorable Cathy McMorris Rodgers  
The Honorable Richard Neal  
The Honorable Kevin Brady  
The Honorable Xavier Becerra  
The Honorable Chiquita Brooks-LaSure

Ted Okon  
Executive Director

COA letter, Sept. 8, 2021
Physician-administered Drugs: Employer Payments to HOPDs are 3x Physician Office Rate

Allowed payments were higher in HOPDs than in POs for all but two of the 72 PAODs examined in this study. The annual median price differential was $5,099 but reached $78,674 for one specific oncology injection. The average unit price differential was 201 percent (Figure 3). In other words, on average, plan payments to HOPDs were triple what plan payments were to POs for the same unit of medication. The median unit price differential was 98 percent. We did not examine the price differential between HOPD and other sites of treatment, because for most of the PAODs studied, very few were administered outside an HOPD or PO.

Figure 3
Average and Median Percentage Price Differential per Unit Based on 72 Physician-Administered Outpatient Drugs

Physician-administered Drugs

Employer plan payments to HOPDs = 3x physician office payments

If the price differential were eliminated, employers would save $14B a year
Overall, the survey stressed that the growing trend of payer-imposed white/brown bagging complicates delivery and dispensing, creates coverage and access barriers, and harms patient care.
U.S. Hospitals Spend $310M/Year on White & Brown Bagging Requirements

Percentage of respondents who reported experiencing the following pharmacy operations and product management issues that could impact patient safety:

- 65%
- 63%
- 60%
- 43%
- 42%
- 42%
- 35%

- Separate inventory management system
- Delivery location/security disruptions
- Lack of space to hold medication (e.g., refrigeration)
- Product not built into computer order entry system
- Product was non-formulary
- Bar code scanning (i.e., administration)
- Product not built in IV infusion pump library

The percent of survey respondents who indicated operational issues associated with white/brown bagging practices:

- 95%

- 23%

- N=143

Have established policy in place in attempt to prohibit white/brown bagging:

- 29% Yes and follow consistently
- 19% Yes and partially enforced
- 1% Yes and enforced
- 52% No policy

N=155

Having a policy does not ensure an organization can prevent all payer mandated actions, but having a standard approach can help providers approach this challenge in a consistent fashion.

Developed educational materials on the impact of alternate channels and their effect on the hospital:

- 28% Yes for the C-suite
- 28% Yes for prior authorization verification positions
- 36% Yes for finance/payor management team
- 56% No educational materials

N=145
Prior Authorization Update: Anthem’s "Dose Reduction Program"

Background

• For Medicare Advantage and Commercial patients, providers are asked to voluntarily reduce doses to the nearest whole vial for 43 oncology drugs and unspecified non-oncology drugs.
• Reviews will continue to be administered by the reviewing company: either AIM Specialty Health or IngenioRx.
• Medicare Advantage: Oncology Drugs.
• July 1, 2021: effective date across CA, CO, CT, GA, IN, KY, ME, MO, NV, NH, NY, OH, VA, and WI (CA example).
• Commercial: Oncology and Non-Oncology Drugs.
• Aug. 1, 2021: oncology drugs in CT, and non-oncology drugs in CT, GA, ME and NH (CT example); targeted non-oncology drugs not specified.

At initial review point in PA request, providers asked to accept dose reduction via pop-up.

• If the patient is considered unable to have their dose reduced, then a second question will appear asking for the provider’s clinical reasoning.
• “Since this program is voluntary, the decision made regarding dose reduction will not affect the final decision on the prior authorization.”

Communications regarding oncology drugs cite HOPA recommendation.

• “The dose reduction questions will appear only if the originally requested dose is within 10% of the nearest whole vial. This threshold is based on current medical literature and recommendations from the Hematology and Oncology Pharmacists Association (HOPA) that it is appropriate to consider dose rounding within 10%. HOPA recommendations can be found here.”

Oncology Drugs Targeted

<table>
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<tr>
<th>Drug Name</th>
<th>Manuf.</th>
<th>HCPCS</th>
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<tbody>
<tr>
<td>Abraxane (paclitaxel-protein-bound)</td>
<td>Celgene</td>
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<tr>
<td>Actimmune (interferon gamma-1B)</td>
<td>Horizon</td>
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<td>Adeccetrix (brentuximab vedotin)</td>
<td>Seagen Inc.</td>
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<td>Alimta (pemetrexed)</td>
<td>Eli Lilly</td>
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<td>Asparlas (calaspargase pegol-mknl)</td>
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<td>Bendeka (bendamustine)</td>
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<td>Besponsa (inotuzumab ozogamicin)</td>
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<td>Binlycto (blinatumomab)</td>
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<td>Cyramza (ramucirumab)</td>
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<td>Doxorubicin liposomal</td>
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<td>Elzonris (tagraxofusp-erz)</td>
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<td>Empliciti (elotuzumab)</td>
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<td>Enhertu (fam-trastuzumab deruxtecan-nxki)</td>
<td>Daiichi Sankyo</td>
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<td>Ethylol (aminofosfate)</td>
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<td>Herceptin (trastuzumab)</td>
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<td>Imfinzi (durvalumab)</td>
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<td>Lumoxit (moxetumomab pasudotox-tdfk)</td>
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<td>Padcev (enfortumab vedotin-epv)</td>
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<tr>
<td>Zaltrap (ziv-aflibercept)</td>
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State Update
Special Session Update

• The Legislature wrapped up its 2nd called special legislative session on September 3rd
• The controversial election reform bill finally passed, as did the mandatory funding bill needed following the Governor’s veto of legislative branch appropriations
• Governor Abbott announced that a 3rd called special legislative session will begin on September 20th.
• Items on the initial call include redistricting, appropriations of federal dollars from the American Rescue Plan Act, and whether any state or local governmental entities in Texas can mandate that an individual receive a COVID-19 vaccine and, if so, what exemptions should apply to such mandate
TDI Seeks Input on HB 3459

• Texas Department of Insurance has requested input on implementation of HB 3459 the prior authorization gold carding bill from the regular legislative session
• Comments should be submitted by September 20
• Additionally, TDI will host an online stakeholder meeting September 23 to discuss comments received
• You may visit the following link to view the RFI and to register for the meeting https://www.tdi.texas.gov/health/hb3459.html
**HB 1919 and HB 1763 Implementation**

- These PBM regulatory bills related to PBM steerage to affiliated pharmacies, reduction of claims payment amounts by PBMS (DIR fees), and other PBM/pharmacy-related issues were passed in the regular session and became effective September 1.
- Discussions with TDI have revealed they do not plan to pass rules or even agency guidance related to the new laws.
- This means the process for ensuring PBMS comply with the new laws will be largely complaint based and up to providers to monitor.
- Discussions with the agency continue in hopes they will take an active role in ensuring PBMs are complying with the law.
New Commissioner Appointed to TDI

- Cassie Brown, formerly the Commissioner of Workers’ Compensation was named TDI Commissioner earlier this week
- Brown has worked at TDI for more than a decade and also formerly served on the staffs of Governors George W. Bush and Rick Perry
COVID-19 Stabilizing?

• The Delta variant of COVID-19 is still resulting in high positivity rates, hospitalizations, and deaths
• Although high, statewide numbers are leveling out
• Impacts of children going back to school and gatherings over Labor Day Weekend still remain to be seen
• In order to maintain and increase staffed hospital capacity, Governor Abbott has directed approximately 8,100 state-funded supplemental staff to be allocated across the state
COVID-19 Stabilizing?

13,499
COVID-19 Inpatients

9,429 in General Beds
3,766 in ICU Beds
304 in Hospitals

1,486 Confirmed COVID-19 Admissions Previous 24 Hours
2,863 Confirmed COVID-19 Patients on Ventilators

63,192 Total Staffed Hospital Beds
58,950 Total Staffed Inpatient Beds
6,388 Available Ventilators

7,731 Available Staffed Hospital Beds
334 Available Staffed Adult ICU Beds
80 Available Staffed Pediatric ICU Beds

Disclaimer: All data are provisional and subject to change. This dashboard will be updated daily by 4:00 PM CT.

COVID-19 Case Data
9/7/2021 1:30 PM CT