TxSCO Update

Dec. 9, 2021
### Overview: Notable Updates

#### Federal
- Looming provider cuts – relief in sight, awaiting Senate vote
- OCM update
- Part B drug reimbursement: BBB Act – the latest
- Appendix
  - 340B implications of Govt Negotiation

#### State
- Bill Implementation
- New Telemedicine Rule
- Vacancies
**Provider Cuts: Relief in Sight**

**Nov 5:** Congress passed **Infrastructure Bill**

**Nov 19:** House passed the **BBB Act** (220-213)

**Dec 2:** Govt Funding: Congress passed CR through Feb 18

**Dec 7:** House passed **S. 610** (222-212):
- **2% Sequester**: 3-month delay, then 3-month at 1%; return 2% July 1st
- **4% PAYGO Sequester** for ARP: waived for 1 year (until 2023)
- **3.75% PFS Payment Cuts**: 1-yr increase of 3%, resulting in 0.75% cut in 2022
- **Radiation Oncology Model**: 1-yr delay
- **PAMA**: 1-yr delay in CLFS cuts and reporting
- **Debt Ceiling**: one-time expedited process through Jan 16 for Senate to consider legislation increasing the debt limit by a specific dollar amount with simple majority vote

**Late Dec/Jan:** Senate hopes to vote on **BBB Act by Christmas**, but Jan 2022 is more likely (by State of the Union)

**Dec 15:** Debt Ceiling breached

**End-of-Year Package?**

**Retroactive End-of-Year Package?** (providers hold claims)

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*Medicare provider cuts:
- 2% sequester: PHE-related moratorium ends Dec. 31, 2021 (unless addressed by Congress)
- 4% PAYGO sequester: from the unfunded American Rescue Plan (unless waived by Congress)
- 3.75% PFS payment cuts: results from expiration of the 3.75% temporary increase in the Medicare physician fee schedule (PFS) conversion factor which was enacted to avoid payment cuts associated with PFS budget neutrality adjustments; cuts begins 2022 (unless addressed by Congress)
OCM Current Status: Still Unclear

CMMI’s First Specialty Model, OCM, Nearing its Sunset with No Details on Replacement

Provides enhanced care coordination payments and performance-based payments (PBP) to practices whose expenditures are below expected benchmarks

Participants
- Originally 175 practices (List) and 10 payers
- Since July 2021, 126 practices (list) and 5 commercial payers

Intended to run July 1, 2016 – June 30, 2021
- Originally a 5-year demo
- Extended to June 30, 2022 to 6 years for voluntary participation due to COVID
  - Last patient enrollment for 6-month episode is Dec. 31, 2021
- CMMI’s RFI process in 2019 for OCM follow-on program (Oncology Care First)
- In 2021, CMMI was expected to re-initiate public feedback from OCM follow-on (“Oncology Care First” or otherwise named)
  - As of Dec. 7, CMMI has remained silent on next steps but continues to meet with oncology stakeholders. At AVBCC, however, Lara Strawbridge from CMMI suggested a replacement to OCM may not be immediately available after OCM’s sunset.
Nov. 15, 2021. COA sent a letter to CMS and CMMI Leadership requesting that the Oncology Care Model (OCM) be extended beyond the June 30, 2022 sunset date

**COA Recommendations to CMS/CMMI**

- Extend the OCM immediately to, at the very least, December 31, 2022. COA notes the OCM should be considered a pilot that should be refined over time.
- Convene a roundtable meeting with select OCM participants to discuss what is working with the program and what should be changed. Innovate by understanding both what is working with the OCM and what should be refined, changed, or eliminated.
- COA will work with CMMI in incorporating very specific elements of the Innovation Strategy Refresh in the OCM, starting with elements of ensuring health equities in cancer care delivered under the OCM.
- Incorporate a concerted effort on biosimilars utilization into the OCM, including considering waiving patient co-payments on biosimilars.
- Incorporate digital ePRO into the OCM.
- Reach out to and involve self-insured employers and involve commercial insurers in OCM 2.0.

“For important reasons summarized in this letter, the OCM should be extended at least through December 31, 2022, while we commit to working with you and the staff at the Center for Medicare and Medicaid Innovation ("CMMI") to refine and expand the OCM, with a particular emphasis on correcting health disparities in cancer care. The millions of dollars of taxpayers’ money invested in the OCM and the dramatic successes of many independent community oncology practices participating in the OCM in enhancing patient cancer care while lowering treatment costs, should be clear reasons why the OCM should not be trashed, but refined and re-envisioned based on what is working.”
OCM Performance Period 6: Net Loss for Medicare

PARTICIPANTS

173 Practices
778,869 Episodes

66% Higher-risk
34% Lower-risk

FINDINGS

Impact on Total Episode Payments (TEP) Waning
- The TEP relative reduction of about $300-$400 per episode (or 1 percent) was significant in PP2-PP5, but not in PP6.
- Change in pattern primarily due to smaller OCM impact for lung cancer episodes, where payments for immunotherapy drugs exceeded that in comparison episodes.

Small OCM impacts on Part A and Part B payments but not Part D
- Among higher-risk episodes, OCM led to a relative reduction in Medicare Part A and B payments but had no impact in Part D payments.
- Conversely, OCM led to a relative increase in Part B spending among lower-risk episodes.

Continued Shift Toward Lower-Cost Non-Chemotherapy Drugs
- OCM led to higher-value (more cost-conscious) use of Part B non-chemotherapy drugs, many of which are supportive care drugs to prevent nausea, neutropenia, and cancer-related bone fractures.
- Still no sign that OCM is driving value-oriented chemotherapy or radiation treatment.

Source: Oncology Care Model - Payment Impacts Evaluation Report: Periods 1-6 (link)
**Issue: OCM Performance 6: Net Loss for Medicare**

**ADVI Insight on Key Findings**
(July 2016-December 2019)

- Overall, episode costs increase in both OCM practices and comparison practices substantially (28K to 34K, or 18%)
- OCM practices increased a little less (i.e., 1% less)
- But savings in Total Episode Payments (TEPs) represent savings against trend not actual savings
- Shift Toward Higher-Value Supportive Care Drugs
  - Part B savings were not due to chemotherapy drug cost savings, but rather supportive care savings (likely driven primarily by use of biosimilars)
- No Part D savings
- No sign that OCM is driving value-oriented chemotherapy or radiation treatment
- Healthcare service utilization remains largely unchanged
  - OCM savings were exclusively in “high risk” disease (lung, breast, colon and NHL receiving chemo) and were Part A and B although not due to decreased hospitalizations
  - No meaningful impact on Emergency Dept visits, hospitalizations overall, chemotherapy-related side effects, office visits, or post-acute care, or on hospice use or timing
- Quality of care maintained under the OCM model
  - OCM patients continue to rate care experience very highly
  - 1% reduction in hospitalizations in last month of life
  - All data from this period (PP1-6) is pre-COVID

**ADVI Takeaways**

- Modest cost savings for Medicare; in fact, net losses to Medicare for all 6 performance periods if the MEOS is included
  - Examination of only high-risk episodes will reflect close to a break-even
  - Performance hasn’t improved over time; little evidence of a “learning curve”
  - Savings generated are 1% of the total cost of care, but if factoring in MEOS and PBP, the extra savings disappears
  - A “subliminal” message that the MEOS ($160/mo) was too much, especially for low-risk cancers where there are no savings to be had
  - “Relative Savings” in OCM practices vs non-OCM were muted during PP6
    - Note: If there were a “learning curve,” savings should increase in later performance periods, which did not occur
  - Essentially no savings by reduced ER and acute care hospital use, arguably the major goal of the OCM
  
  - No savings in drug spend
    - No impact on choice of therapeutics
    - Savings were generated with common “high risk” cancers (e.g., lung, lymphoma, colorectal and breast)
      - Savings were due to reduced use of pegfilgastrim (with substitution of the biosimilar) and denusomab (with substitution of bisphosphonates)
  - End of life care improved (e.g., reduced hospitalizations at end of life and higher referral to palliative care)
  - Physicians in OCM are not making cost cutting decisions that might hurt their patients; use of novel treatments are the same as in the control group
  - Surveys done at 47 participant sites in an effort to define “what works”
  - Conclusion: Every practice tried something different; unclear what worked
BBB Act Govt Negotiation: Part B Drug Implications

Implications for all drugs

Higher launch prices

- New incentive for higher launch prices, across Part B and Part D drugs
- ADVI Advisor: “Manufacturers need to cram 20 years of sales life into 9 or 13 years”
- Slippery slope: the 9 yr/13 yr exclusivity period could one day be dialed down, or eliminated
- Rising launch prices will fuel policymaker arguments that price controls are needed beginning at launch – and fuel bigger-picture arguments for single payer health care

Biologics more attractive than small molecule

- Biologics are not eligible for negotiation until 13 yrs. post-approval; for small molecules, only 9 yrs.

No incentive for new indications or formulations

- Manufacturers no longer have an incentive to invest in new indications or formulations
- Instead, incentive to develop a new product even if only marginally superior to existing product

Lower Part B add-on payments & ASP will decline, reducing commercial and Medicaid reimbursement

- Add-on payments will drop
  - 6% of a high price > 6% of a low price
- Commercial & Medicaid ASP-based reimbursement will drop
  - ASP will drop, possibly dramatically, as the negotiated price is factored in
  - Commercial contracts are based on ASP+X%, and the majority of states reimburse Medicaid providers at ASP+X%
- Lingering questions:
  - Will commercial payers and providers update their contracts (to either a non-ASP benchmark or increased add-on)?
  - Or will ASP spiral downward to the negotiated price (assuming manufacturers respond with additional discounts)?
  - What about diversion?
  - How will manufacturers know the provider is using the MFP purchases for Medicare benes only?
  - How will commercial payers ensure they aren’t reimbursing a provider for drugs purchased at the negotiated rate?

Mixed bag for biosimilars

- Significantly reduced ASP for negotiated products may disincentivize biosimilar development
- Two-quarter lag time for ASP calculation could guarantee biosimilar market share
  - Hypothetical: Drug X’s Maximum Fair Price (i.e., negotiated price) applies beginning 2027, with providers reimbursed at the negotiated price + 6%.
  - Biosimilar launches in 2028: at this point, Drug X is no longer a ‘negotiated drug,’ providers return to ASP +6% reimbursement, and there is no longer a negotiated price included in Drug X’s ASP
  - This will cause Drug X’s ASP to spike, but with the ASP formula’s 2-quarter lag time, it will take 2 quarters for this spike to be realized
  - Therefore, for the first 2 quarters in the calendar year following the biosimilar’s launch*, providers will not be able to afford Drug X
  - This could guarantee market share for the biosimilar, giving the biosimilar no motivation to set its price lower than Drug X

ASP spike following competition launch, inflationary rebates

- After a generic/biosimilar launches, Drug X is no longer a negotiated drug; the Maximum Fair Price is no longer required and no longer pulling down the drug’s ASP
- Drug X’s ASP will increase, following the 2-quarter lag
  - The manufacturer would then be responsible for Inflationary Penalties, because the benchmark ASP would be tied to the Maximum Fair Price (benchmark ASP does not revert back to pre-MFP ASP)

Cell & gene therapies better off with inpatient reimbursement

- Today, the goal for cell and gene therapies is to move from the inpatient to the outpatient setting, and manufacturers make big investments in studies to show the drug is safe for outpatient use
- Now, manufacturers are better off in the inpatient setting with Part A reimbursement, so they are unlikely to invest in additional outpatient studies
- Physicians will be shy to attempt outpatient utilization if there is no data supporting it
- Manufacturers would also be able steer to inpatient utilization by not applying for HCPCS codes/ J Codes (the lack of code would make outpatient reimbursement more burdensome for the provider)
- Increases total cost of care
- An incentive to pursue inpatient utilization will increase overall costs across Medicare and Medicaid, as the outpatient setting is the lower cost site of care

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*If a generic/biosimilar launches midyear, the selected drug stays a negotiated drug throughout that year

COA is advocating for a rebate approach to prevent ASP implications
State Update
Bill Implementation Update

- As of 12/1, the Texas Department of Insurance has not issued proposed rules for comment related to HB 3459 (prior authorization exemption) or HB 1919 (PBM anti-steerage).
- Per HB 1616, the Texas Medical Board is currently working with the Interstate Medical Licensure Compact Commission on implementing the new licensure process and anticipates beginning Compact licensing in early 2022.

- Typically the interim hearing process is a good opportunity to receive status updates on bill implementation from the relevant agencies; we will be working to ensure the committees of jurisdiction press to get these updates at their earliest hearings.
Telemedicine – Issuance of Prescriptions

• The Texas Medical Board adopted a final rule related to the issuance of prescriptions under telemedicine.

• Amendments to §174.5, Issuance of Prescriptions allow physicians to utilize telemedicine to continue issuing previous prescription(s) for scheduled medications to established chronic pain patients, if the physician has, within the past 90 days, seen a patient in-person or via a telemedicine visit using two-way audio and video communication. The amendments will consistently and conveniently provide patients access to schedule drugs needed to ensure on-going treatment of chronic pain and avoid potential adverse consequences associated with the abrupt cessation of pain medication.
Political Update

• Governor’s primary race continues to cause concern for fourth special session
• Beto O’Rourke jumps into Governor’s race for November
• Lieutenant Governor’s race continues to evolve
• Challenges to new legislative maps continue
• Rep. Ryan Guillen switches parties
### Upcoming Vacancies

<table>
<thead>
<tr>
<th>House of Representatives (26 total)</th>
<th>Senate (5 total)</th>
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</thead>
<tbody>
<tr>
<td><strong>Retiring</strong></td>
<td><strong>Seeking Other Office</strong></td>
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<tr>
<td>Kyle Biedermann (R-Fredericksburg)</td>
<td>Michelle Beckley (D-Carrolton)</td>
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<tr>
<td>Garnet Coleman (D-Houston)</td>
<td>Jasmine Crockett (D-Dallas)</td>
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<td>John Cyrier (R-Lockhart)</td>
<td>Alex Dominguez (D-Brownsville)</td>
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<tr>
<td>Joe Deshotel (D-Beaumont)</td>
<td>Jake Ellzey (R-Waxahachie)</td>
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<tr>
<td>John Frullo (R-Lubbock)</td>
<td>Celia Israel (D-Austin)</td>
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<tr>
<td>Dan Huberty (R-Kingwood)</td>
<td>Phil King (R-Weatherford)</td>
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<td>Lyle Larson (R-San Antonio)</td>
<td>Matt Krause (R-Fort Worth)</td>
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<td>Ben Leman (R-Iola)</td>
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<td>Eddie Lucio III (D-Brownsville)</td>
<td>Ina Minjarez (D-San Antonio)</td>
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<td>Jim Murphy (R-Houston)</td>
<td>Bexar Co. Judge</td>
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<td>Leo Pacheco (D-San Antonio)</td>
<td>Tan Parker (R-Flower Mound)</td>
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<td>Chris Paddie (R-Marshall)</td>
<td>Eddie Rodriguez (D-Austin)</td>
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<td>Scott Sanford (D-Dallas)</td>
<td>James White (R-Hillister)</td>
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<td>John Turner (D-Dallas)</td>
<td>Ag Comm.</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.
State Update
### Government Negotiation: 340B Implications

**Definition**
- Government negotiated price is the “Maximum Fair Price” (MFP)

**Assumptions/Calculations**
- AMP as a % of WAC: 91%
- Baseline non-FAMP as a % of AMP: 90%
- Current Law Best Price as a % of WAC: 75%
- Best Price: same as MFP: MFP

<table>
<thead>
<tr>
<th></th>
<th>Current Law</th>
<th>Hypo A MFP: 75% of Baseline non-FAMP (25% cut)</th>
<th>Hypo B MFP: 40% of Baseline non-FAMP (60% cut)</th>
<th>Hypo C MFP: 15% of Baseline non-FAMP (85% cut)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Fair Price (MFP)</td>
<td>$110.0</td>
<td>$67.6</td>
<td>$36.0</td>
<td>$13.5</td>
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<tr>
<td>WAC Price</td>
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<tr>
<td>AMP per unit</td>
<td>$100.1</td>
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<td>Baseline non-FAMP</td>
<td>$90.1</td>
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<td>$87.3</td>
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<td>Best Price per unit</td>
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<td>$67.6</td>
<td>$67.6</td>
<td>$36.0</td>
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<td><strong>Basic Rebate</strong></td>
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<tr>
<td>AMP x 23.1%</td>
<td>$23.1</td>
<td>$21.6</td>
<td>$17.1</td>
<td>$12.8</td>
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<tr>
<td>AMP-Best Price</td>
<td>$17.6</td>
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<td>$6.5</td>
<td>$69.3</td>
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<tr>
<td>Basic rebate: &gt; of minimum rebate or AMP - Best Price</td>
<td>$23.1</td>
<td>$26.0</td>
<td>$17.1</td>
<td>$69.3</td>
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<td><strong>Inflationary Rebate</strong></td>
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<td>Baseline AMP (Jan. 2015)</td>
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<td>$70.0</td>
<td>$70.0</td>
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<tr>
<td>CPI-U increase (Dec. 2014 to Oct. 2021)</td>
<td>17.8%</td>
<td>17.8%</td>
<td>17.8%</td>
<td>17.8%</td>
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<td>Baseline AMP trended to today</td>
<td>$82.5</td>
<td>$82.5</td>
<td>$82.5</td>
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<td>Inflationary rebate</td>
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<td><strong>Total Rebate</strong></td>
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<td>Unit Rebate Amount</td>
<td>$40.8</td>
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<td><strong>340B</strong></td>
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<tr>
<td>340B Ceiling Price</td>
<td>$59.3</td>
<td>$56.4</td>
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<td>340B Discount off WAC (WAC - 340B Ceiling Price)</td>
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<td>340B Discount off AMP (AMP - 340B Ceiling Price)</td>
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Government Negotiation: 340B Implications
Physician-Administered Drugs

<table>
<thead>
<tr>
<th>Definition</th>
<th>Current Law</th>
<th>Hypo A</th>
<th>Hypo B</th>
<th>Hypo C</th>
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<tr>
<td>Government negotiated price is the “Maximum Fair Price” (MFP)</td>
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<td>Sales: Medicare as % of Total</td>
<td>MFP 75% of Baseline non-FAMP (25% cut)</td>
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<td>Assumptions/Calculations</td>
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<td>Low 20%</td>
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<td>Low 20%</td>
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<td>Current Law Best Price as a % of WAC</td>
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<td>ASP: same as non-FAMP</td>
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Future OPPS rulemaking would stipulate the Part B reimbursement formula for 340B Covered Entities for Selected Drugs.

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<tr>
<td>ASP</td>
<td>$90.1</td>
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<td>ASP+6%</td>
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<td>Medicare reimb. today: ASP-22.5%</td>
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<tr>
<td>Medicare reimb: MFN+6%</td>
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<tr>
<td>Medicare reimb: MFN-22.5%</td>
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### Hypo A

<table>
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<th>ASP includes Medicare sales at MFP</th>
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hello@advi.com
202.509.0760

1000 F St NW
Suite 650
Washington, DC 20004