TxSCO Update

Nov. 9, 2023

Overview: Notable Updates

Federal

- E&C MACRA hearing + Dr. Patt's testimony
- Final Rules: PFS, OPPS, 340B
- EOM Updates
- Speaker update

State

- Special sessions update
- COVID Vax mandate prohibition
- Retirements
- State Budget Update

Dr. Patt Testifies at House E&C Health Subc. Hearing

The House E&C Committee held a hearing titled, "What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors" on October 19. Other witnesses included Dr. Meena Seshamani (CMS), Dr. Steven Furr (AAFP), and Dr. Matthew Fiedler (Brookings)

Medicare Reimbursement

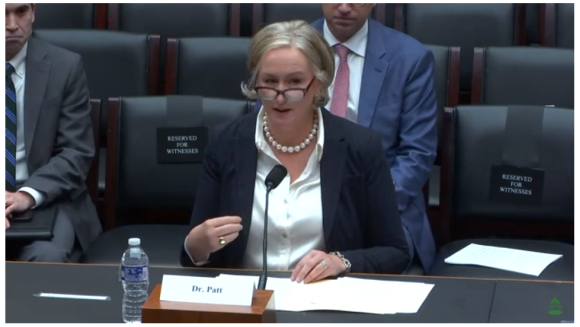
- "Decreasing reimbursement causes a chain reaction that results in provider network inadequacy, decreased access to care, inability to manage staffing shortages, and decreased quality of care for American seniors and other Medicare beneficiaries."
- Since 2014, medical inflation has increased by 28.4% while the conversion factor has decreased by 5.4%.
- MACRA caused "a new SGR in Medicare payment cuts."

Network Adequacy, Quality of Care, and Physician Burnout

- 145,000 healthcare practitioners left the healthcare industry from 2021-2022; half were physicians.
- "I frequently have breast cancer patients who cannot find primary care physicians who accept new Medicare patients and I have to try to scramble to find physicians to take care of them."
- Other consequences of staffing shortages include closing treatment facilities or limiting hours of operation.

340B

- Some 340B hospitals mark up cancer drugs five times – meaning a cancer drug that cost $5,000 is marked up to $25,000.
- CMS is "overpaying 340B hospitals by close to 50 percent."



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Source: Testimony (10/19/23, link)

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Value-Based Payment Models

- "Reliable, sufficient reimbursement is the foundation for advancing innovative payment models. Without payment certainty and predictability, independent physician practices will be reluctant to take on additional risk."
- The number of providers participating in APMs is not aligned with the goals of the statute, for several reasons:
  - COVID-19
  - Practice transformation is a slow process
  - High inflation rates
  - Staffing shortages
  - Rising practice expenses
- Achieving QP status (to qualify for the additional financial incentive and be exempt from MIPS) is challenging.
  - For OCM, the average payment threshold score was 53% (50% threshold for QP status) and the average patient threshold score was 21% (35% threshold for QP status.)
- EOM contains additional challenges not found in OCM, including having a smaller population of payments and patients and requiring practices to accept two-sided risk from the beginning.
- Recommendations to improve APM participation: Voluntary models, stakeholder engagement and physician buy-in, allowing time for practice transformation to take place.

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Source: Testimony (10/19/23, link)

PFS Final Rule for CY 2024: Oncology Impact

November 2, 2023: CMS released the CY 2024 PFS Final Rule (link) with an accompanying fact sheet (link). CMS finalized the following proposals:

- Overall: 3.45% decrease
- Interventional Radiology: -4%
- Nuclear Medicine: -3%
- Radiology: -3%
- Radiation Oncology and Radiation Therapy Centers: -2%
- Hematology/Oncology: +2%

- Begin payment for G2211 (add-on code for complex E/M visits) in CY 2024
  - CMS finalized changing the status of HCPCS code G2211 to make it separately payable by assigning it an "active" status indicator, effective January 1, 2024.
  - Due to stakeholder concerns that a physician or practitioner would not perform a preventive service on the same day as an O/O E/M visit merely to avoid the policy to not pay G2211 when the O/O E/M visit is reported with modifier - 25, CMS noted that it intends to monitor the utilization of this code and continue engagement with interested parties as this policy is implemented.

- Reimbursement for specific care navigation as part of a treatment plan for a serious, high-risk disease
- Covered services include
  - Person-centered assessment
  - Identifying or referring patient to appropriate supportive services
  - Practitioner, home, and community-based care coordination
  - Health education
  - Building patient self-advocacy skills
  - Healthcare access/health system navigation
  - Facilitating behavioral change as necessary
  - Facilitating and providing social and emotional support

- Dental services will be covered prior to
  - Chemotherapy when used in the treatment of cancer
  - CAR T-Cell therapy, when used in the treatment of cancer
  - Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer

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ADVI Instant (link)

OPPS Final Rule for CY 2024: Oncology Impact

November 2, 2023: CMS released the OPPS final rule (link) with an accompanying fact sheet (link). CMS finalized the following proposals:

- Continue to pay the statutory default rate of ASP+6% for 340B acquired drugs and biologicals (consistent with CMS policy for drugs and biologicals not acquired through 340B program)
  - CMS refers stakeholders to the recent 340B Remedy final rule (link)
    - While the final rule does not include changes to the CY 2024 OPPS drug payment policy or conversion factor, CMS notes that it does include changes to the calculation of the conversion factor beginning in CY 2026
- Effective Jan. 2025 all 340B covered entity hospitals paid under OPPS must report the "TB" modifier, even if hospital previously reported the "JG" modifier
  - The "JG" modifier will remain in use through 12/31/24 but hospitals may choose to transition to the "TB" modifier anytime in 2024

- CMS sought comments on proposed APC and status indicator assignments for new HCPCS codes established and made effective on April 1, 2023.
  - This includes "M0010: Enhancing oncology model (EOM) monthly enhanced oncology services (MEOS) payment for EOM enhanced services".
  - The full list of status indicators and definitions can be found in Addendum D1 of the final rule.

- In the proposed rule, CMS sought comment on a proposal to establish separate payment for hospitals under the IPPS for establishing and maintaining access to a buffer stock of one or more of 86 essential medicines.
- CMS states that while commenters broadly agreed on the need to address domestic drug shortages and medical supply chain issues, there was a lack of consensus on a potential payment policy.
- CMS is not finalizing any changes but notes that it intends to propose a future policy "addressing aspects of hospital practices with respect to pharmaceutical supply", through future payment rules and/or Conditions of Participation.

CMS Releases 340B Remedy Final Rule

On November 2, 2023, CMS released the Remedy for the 340B-Acquired Drug Payment Policy for CY 2018-2022 Final Rule (link). CMS finalized the following proposals:

Lump Sum Payments to Affected Providers for 340B-Acquired Drugs

- CMS estimates that providers received $10.6 billion less in reimbursement with the ASP -22.5% policy in place
  - Some CY2022 340B drug claims have already been reprocessed at ASP +6%, those providers have already received $1.6 billion
- **CMS finalized its proposal to make a one-time lump sum payment for the remaining ~$9 billion to affected providers, to be issued by MACs within 60 calendar days of receipt of instructions.**
- CMS will establish a technical correction process to all 340B covered entities to alert CMS to potential errors in the calculation of their lump sum payment amount

Beneficiary Copayments

- The ~$9 billion payment includes $1.8 billion attributable to what the affected covered entities would have collected from beneficiaries.
- CMS emphasizes that 340B covered entity hospitals may not bill beneficiaries for coinsurance on remedy payments, regardless of the adjustment.

Prospective Offset for Higher Payments for Non-Drug Items and Services from CY 2018-2022

- CMS estimates that hospitals were paid $7.8 billion more for these non-drug items and services between CY 2018-2022
- **In an effort to maintain budget neutrality, CMS finalized a reduction to future payments by decreasing the OPPS conversion factor to all OPPS providers except new providers by 0.5%**
- CMS will start the conversion factor reduction in CY 2026 (originally 2025 in proposed rule).
- This decrease in the OPPS conversion factor will remain in effect until the full $7.8 billion is offset, which CMS estimates will take 16 years.

New Providers

- CMS will exclude providers that did not enroll in Medicare until after January 1, 2018, from the proposed prospective rate reduction
- CMS will designate these hospitals as “new providers” and pay these hospitals the rate for non-drug items and services that would apply in the absence of the 0.5% conversion factor adjustment for the duration of its application.
- CMS is adding “biologicals” to the regulation text that references separately payable drugs to align with the exclusion of separately payable drugs and biologicals from the prospective payment rate for hospitals.

ADVI Source: ADVI Instant (link)

EOM: Perspectives from AVBCC

Practice Participation

- Most practices noted they did not participate due to the math, and the ones who are participating have large enough patient volumes or are in high cost regions where it's easier to succeed
- EOM risk is too much for practices to be reinsured - one practice was told $1M reinsurance would cost $900k.
- Doctors' goals aren't to make huge profits off of EOM – goal is for their practice to survive, and EOM risks that

Disagreement about patient benefit

- CMMI noted they are most excited about the patient benefit in EOM
- Doctors noted that EOM is set up so that patients are at risk of not receiving the best treatment for them - if they do what's right for the patient, it will harm the practice; if they do what's right for the practice, it will harm the patient

Disagreement about Health Equity

- CMMI noted the importance of capturing data to improve health equity
- Doctors do not want to ask questions "to check a box" without being able to do something or help
- Doctors noted that disadvantaged groups are extremely distrustful of the government collecting invasive information that could have ramifications (e.g., questions about how many people live with them in an apartment that may have an occupancy limit they are exceeding)

Why EOM?

- Support expressed for Oncology Care First and models that deal with drugs separately
- CMMI noted that EOM is an iteration of OCF, and that it was designed for sustainability going forward to last in a post-FFS environment

Federal Updates: Speaker Mike Johnson

Speaker Johnson's Previous Healthcare Policies

Led the Republican Study Committee from 2019-2021, releasing a healthcare plan containing the following recommendations:

- Creating "federally-funded, state-administered Guaranteed Coverage Pools" for patients with high-cost illnesses
- Turning ACA subsidies and Medicaid expansion funding into block grants
- Expanding HSA usage for certain medical expenses
- Promoting telehealth, association health plans, direct primary care, and health sharing ministries

State Update

88th Legislature – Special Sessions

- The 88th Legislature has been called into 4 special sessions since the adjournment of the regular session on May 29th, 2023.
- The first special session, which began on May 30th, 2023, was focused on two items:
  - property tax relief delivered by compression of rates, and
  - Increasing penalties for those involved in human smuggling or the operation of a stash house
- The second special session, called on June 28, 2023, was called for the purpose of considering the following items:
  - Property tax relief delivered by compression of rates, and
  - Legislation to put Texas on a pathway to eliminate school district maintenance & operations property taxes

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88th Legislature – Special Sessions

- The third special session began on October 9 and ended November 7. Issues on the call included:
  - Private school vouchers;
  - Reducing illegal immigration by creating a criminal offense for illegal entry;
  - Impeding illegal immigration by providing funding for border barriers;
  - Public safety, security, environmental quality and property ownership in areas like Colony Ridge;
  - Impede illegal entry into Texas by increasing the penalties for certain criminal conduct involving the smuggling of persons or the operation of a stash house; and
  - Prohibition of COVID-19 vaccine mandates by private employers.

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88th Legislature – Special Sessions

- The fourth, and hopefully final, special session began on November 7th, the same day the last special session ended and has two issues on the call:
  - Private school vouchers;
  - School safety measures and related state funding;
  - Reducing illegal immigration by creating a criminal offense for illegal entry; and
  - Funding for construction, operation and maintenance of border barrier infrastructure and funding for DPS due to an increased law enforcement presence in Colony Ridge.
- The chambers have come to an agreement on border security and funding but the House has yet to find a pathway to passage for vouchers.

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Prohibition of COVID-19 Vaccine Mandates by Private Employers

- Senate Bill 7 (Sen. Middleton/Rep. Leach) would prohibit an employer, other than a governmental entity, from adopting or enforcing certain COVID-19 vaccine mandates.
- The bill would prohibit such an employer from taking an adverse action against an employee, contractor, applicant for employment, or applicant for a contract position for a refusal to be vaccinated against COVID-19, but would create an adverse action exception for certain health care facilities, health care providers, and physicians.
  - A health care facility, health care provider, or physician may establish and enforce a reasonable policy that includes requiring the use of protective medical equipment by an individual who is an employee or contractor of the facility, provider, or physician and who is not vaccinated against COVID-19 based on the level of risk the individual presents to patients from the individual's routine and direct exposure to patients.
  - Establishing or enforcing a policy is not considered an adverse action under this chapter.
- The bill would require TWC to impose on an employer who violates the bill an administrative penalty of $50,000 for each violation unless the employer takes certain corrective action.
- The Senate concurred in House amendments on 10/31 and has been sent to the Governor.
- The bill will become effective on February 6, pending the signature by the Governor which is planned for Friday.

Retirements

News of retirements has slowly come out since the end of the 2nd special session in July; these include:

- Rep. Abel Herrero (D), Corpus Christi
- Rep. Julie Johnson (D), Dallas – she is running for U.S. Congress
- Rep. Tracy King (D), Uvalde
- Rep. Lina Ortega (D), El Paso
- Rep. Four Price (R), Amarillo
- Rep. John Raney (R), College Station
- Rep. Matt Schaefer (R), Tyler – current chair of the House Freedom Caucus
- Rep. Carl Sherman (D), Dallas – running in D primary for an opportunity to run against Sen. Cruz
- Rep. Ed Thompson (R), Pearland
- Sen. Drew Springer (R), Muenster
- Sen. Roland Gutierrez (D), San Antonio –running in D primary for an opportunity to run against Sen. Cruz

State Budget Update

- On October 5, 2023, Texas Comptroller Glenn Hegar released a new Certification Revenue Estimate (CRE) for the 2024-25 biennium.
- The new CRE provides the Legislature a new basis with which to work related to how much general revenue can be spent during this current special session.
- As a result of legislative actions and an updated economic forecast, the Comptroller's office now expects revenue available for general spending in 2024-25 to total about $194.57 billion, up 24.8 percent from the 2022-23 biennium.
- This revenue will support the $176.28 billion in general-purpose spending called for by the 88th Legislature and will result in a projected fiscal 2025 balance available for certification of **$18.29 billion**.
- The CRE also projects a fiscal 2025 ending Rainy Day Fund balance of **$23.77 billion**.

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APPENDIX

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PhRMA: IRA and Biden Administration Drug Policies Harm Cancer Moonshot Efforts

October 17, 2023: PHRMA sent a letter Dr. Carnival regarding the impact of the IRA and other prescription drug policies on Cancer Moonshot efforts.

The letter was signed by several drug manufacturers, including Merck, J&J, Bayer, Eli Lilly, Gilead, Sanofi, Incyte, Pfizer, BioMarin, BMS, Boehringer Ingelheim, Eisai, and Otsuka.

Key Points

cancer

medicines

Source: PHRMA (10/17/23, link)

Proposed Rule Includes Changes to No Surprises Act's IDR Process

On October 27, 2023, the Departments of HHS, Treasury, and Labor released a proposed rule including changes to the IDR process. Comments are accepted until January 2, 2024.

Communication Between Payers and Providers

- Payers must provide additional information at the time of initial payment/notice of denial of payment, including the legal business name of the plan, issuer, or plan sponsor, and its IDR registration number
- Payers must provide applicable claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) to communicate whether a claim is eligible for the IDR process

Open Negotiation Process

- Require one party provide an open negotiation notice to the other party and Departments through the Federal IDR portal
- Specify the date the 30 business day open negotiation period begins
- Require new content elements to help parties identify the item or service, the reasons for the denial of payment or initial payment amount, and whether the Federal IDR process applies
- Require an open negotiation response notice be furnished by the party receiving the open negotiation notice by the 15th business day of the open negotiation period

Batching

- Allow the following qualified IDR items and services to be batched
  - Items and services furnished to a single patient on one or more consecutive dates of service and billed on the same claim form
  - Items and services billed under the same service code or a comparable code under a different procedural code system
  - Anesthesiology, radiology, pathology, and laboratory items and services billed under service codes belonging to the same Category I CPT code section
- Limit batched determinations to 25 qualified IDR items and services in one dispute

IDR Eligibility

- Require certified IDR entities to determine eligibility within five business days of final certified IDR entity selection
- Require parties to submit additional information within five business days of the request for additional information
- Establish a Departmental eligibility review process to support eligibility determinations during a period of systemic delay
  - Departments would provide advance public notice for when the Departmental eligibility review would begin and the reasons for ending a Departmental eligibility review
  - Departmental eligibility review would only determine eligibility and would not make payment determinations

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Source: Proposed Rule (10/27/23, link)

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Administrative Fee

- Departments would collect the administrative fee directly from the disputing parties
- Payment would be due within two business days of the date of preliminary certified IDR entity selection (for initiating parties) and receiving notice of eligibility determination (for non-initiating parties)
- If parties fail to pay the administrative fee within two business days, the dispute would be closed
- Departments would establish debt collection procedures if a non-initiating party fails to pay the administrative fee
- A reduced administrative fee would be charged when:
  - The highest offer made during open negotiation by either disputing party was less than a predetermined threshold
  - The dispute is determined ineligible by either the certified IDR entity or the Departments (non-initiating party only)

Extenuating Circumstances

- Amend the extenuating circumstances in which the time periods may be extended to include events that contribute to systematic delays in processing disputes, such as a high volume of disputes or Federal IDR portal system failures
- Departments would provide advance public notice in the event of an extenuating circumstance

IDR Registry

- Require payers subject to the Federal IDR process to register with the Departments and provide general information on the applicability of the Federal IDR process to items or services covered by the plan
- Plan or issuer would receive an IDR registration number, which can be used by initiating parties to acquire the necessary information to ensure disputes are eligible for the Federal IDR process

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Source: Proposed Rule (10/27/23, link)