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Polsinelli's 6th Annual Health Care Reimbursement Virtual Summit – Part 1

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Reimbursement Year-in-Review

Speakers:

Bragg Hemme
Shareholder
Denver
BHemme@Polsinelli.com
303-583-8232

Kyle Vasquez
Shareholder
Chicago
KVasquez@Polsinelli.com
312-463-6338

Inpatient Prospective Payment System

Graduate Medical Education

- Hospitals' GME (weighted and unweighted) and IME FTE counts in IRIS must match cost report counts
- 1,000 New Medicare-Funded Residency Positions for Qualifying Hospitals Serving Rural and Underserved Communities
  - 200 slots per year over five years (2023-27)
  - Prioritized based on HPSA scores + 4 prioritization categories
- Incentivizes Creation of Rural Training Track ("RTT") by Allowing an Increase in FTE Cap for Participating Hospitals
- Restores Ability of Hospitals with Low or $0 Per Resident Amounts ("PRA") to Reset or Establish New PRAs (or new FTE caps, if low cap) if Hospital Trains Residents in New Residency Program

Other IPPS Updates

COVID-19:

- New COVID-19 Treatment Add-On Payment ("NCTAP") extended through end of the fiscal year in which PHE ends
- Enhanced payment for eligible inpatients that involve use of certain new therapeutics
- Hospitals can receive HCTAP ***plus*** traditional new technology add-on payments, if qualifications are met

Inpatient Quality Reporting:

- New measure added related to percentage of health care personnel who are vaccinated against COVID-19

-**Bad Debt:**

- Requires state Medicaid agencies to enroll providers so that Medicare patient cost-sharing amounts can be determined

Outpatient PPS/ASC

OPPS Highlights

- **Site Neutrality (G0463)**
  - CMS continues off-campus clinic (E/M) visit payment at 40% of OPPS rate
  - Policy is here to stay, despite significant industry pushback
    - 2019: AHA successfully challenged policy in US District Court
    - 2020: CMS successfully appealed in US Court of Appeals
    - 2021: US Supreme Court declined to hear AHA appeal

- **Hospital Price Transparency**
  - Effective 1/1/2021, the Final Rule increased the penalties for hospitals who fail to publish a list of all standard charges for all items and services.
    - 300 per day for hospitals with ≤ 30 beds
    - $10 per bed, per day for hospitals with > 30 beds
    - Annual min.: $109,500 per hospital | Annual max.: $2,007,500 per hospital

OPPS Highlights

- **Reinstatement of Inpatient Only List (IPO)**
  - Reinstated for 2022
  - Responds to stakeholder pushback after removal of IPO in 2021, including concerns re: patient safety and OPPS rate setting accuracy

- **ASC Covered Procedures List (CPL)**
  - Reinstates the ASC Covered Procedures List criteria from CY 2020.
  - Criteria excludes from reimbursement surgical procedures that may pose a safety risk to beneficiaries when performed in an ASC.
  - The 2022 Final Rule removed 255 procedures from the CPL and installed nomination process for adding services to CPL.

OPPS Highlights

- **OPPS and ASC Rate Updates**
  - For CY 2022, CMS increased OPPS and ASC payment rates by 2% for hospitals and ASCs that meet applicable quality reporting requirements.
  - Failure to meet requirements will result in a 2% rate reduction.
- **Temporary COVID-19 Measures**
  - CMS sought comment on whether to permanently adopt certain COVID-19 flexibilities
    - (e.g., remote mental health services and use of audio-virtual technology to supervise rehabilitation).
  - Not adopted by CMS will continue to evaluate comments
- **Quality Reporting Programs**
  - CMS finalized updates to quality reporting measures under the Hospital Outpatient Quality Reporting Program and the ASC Quality Reporting Program, including the addition of COVID-19 Vaccination of Health Care Personnel Among Healthcare Personnel as a reporting measure.

Medicare Cuts for 340B Drugs Continue

- **1/1/2018 - CMS Implements ASP Minus 22.5% 340B Drug Formula**
  - Separately payable, non-pass-through Part B drugs (SI K)
  - Applies only to DSH/RRC/urban SCHs/non-excepted HOPDs (CEs)
  - JG modifier created to indicate payment reduction

- **Several Pending Cases**
  - Supreme Court review: *American Hospital Association (AHA) v. Becerra*
  - AHA lawsuits challenge the payment cuts for 2018 – 2019
  - Additional lawsuit challenging 2021 payment cuts

Medicare Cuts for 340B Drugs Continue

- **Question of CMS's Authority to Discriminate**
  - **HHS win:** CMS could potentially implement even more 340B reimbursement cuts (*potential purpose of TB modifier*)
  - **AHA win:** Impacted 340B CEs are entitled to reimbursement that was withheld by CMS

- **Litigation Status**
  - Oral arguments took place on November 30, 2021
  - CEs can expect the opinion to be released by June 2022

Medicare Physician Fee Schedule

MPFS Highlights

- **Conversion Factor**
  - Conversion Factor = the amount that is multiplied by the service's RVU to determine baseline price
  - With Budget Neutrality Requirements and Expiration of 3.75% CY 2021 Payment Increase (under CAA of 2021) → Decrease in CF of $1.30
  - Congress Subsequently Minimized Impact to a Decrease of only $0.29

MPFS Updates

- **Evaluation and Management**
  - Changes made to reflect changes in E/M visit codes in CPT Book and to clarify policies in withdrawn Manual provisions
- **Split/Shared E/M Visits**
  - New methodology for billing visits in which physician and NPP both provide portions of same service in facility; Practitioner who furnishes “Substantive Portion” of visit bills for service

E/M Visit Code Family	Substantive Portion - 2022	Substantive Portion - 2023
Other Outpatient (not office visit)	History, or exam, or MDM, or more than half of total time	More than half of total time
Inpatient/Obs./Hospital/NF	History, or exam, or MDM, or more than half of total time	More than half of total time
Emergency Department	History, or exam, or MDM, or more than half of total time	More than half of total time
Critical Care	More than half of total time	More than half of total time

Split/Shared Visits (Cont.)

- Split/Shared Visits can be reported for ***new*** or established patients
- Split/Shared Visits can be used for initial, subsequent and prolonged services
- Modifier required - “FS”
- Both practitioners must document in the medical record; individual who performs “substantive portion” must sign and date

Critical Care Services

- Critical care services can be:
  - Furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty
  - Furnished as split/shared visit
  - Paid on the same day as other E/M visits by the same practitioner or another practitioner ***in the same group*** of the ***same specialty***, if E/M provided prior to need for critical care and was separate and distinct
  - Paid separately in addition to a procedure with a global surgical period if the critical care is unrelated to the surgical procedure.

Other MPFS Updates

- Teaching Physician Services
  - If time-based code, only time spent by the teaching physician can be included for code selection
  - Primary Care Exception:
    - Time cannot be used to select visit level
    - Only Medical Decision Making (“MDM”) may be used to select visit level
- Physician Assistant Services
  - Implements CAA provision authorizing direct payment to PA

340B Contract Pharmacy Update

Manufacturer Pricing Restrictions

- **Brand Drug Companies Unilaterally Restricting Access in Several Ways**
  - Outright denial of 340B pricing for items shipped to contract pharmacy
  - Restrictions tied to contract pharmacy dispense data
  - Restrictions but with certain exceptions (e.g., single contract pharmacy)

- **Impact to Covered Entities**
  - CEs face declining contract pharmacy reimbursement
  - CEs are making difficult decisions around data sharing
  - CEs are expending funds pursing advocacy, 340B ADR, etc.

Manufacturer Pricing Restrictions

- **Current Landscape**
  - Conflicting court decisions across multiple jurisdictions
  - Appeals filed and pending
  - No final / consistent opinion expected for 2-3 years

- **Covered Entity Options**
  - Identify other resources (e.g., centralize outpatient pharmacy operations)
  - File ADR complaints with HRSA
  - Advocacy
  - Litigation
  - Direct manufacturer negotiations / 340B ESP

Manufacturers Restrict Access – Part 1

7/1/2020: **Eli Lilly** limits distribution of Cialis directly to CEs and child sites. CEs without an in-house pharmacy may designate one contract pharmacy.

July 2020: **Merck** and **Sanofi** sent a letter to CEs to begin using 340B ESP to track their drugs dispensed by a contract pharmacy

9/1/2020: **Eli Lilly** expands previous limitation to all drugs.

10/1/2020: **Sanofi** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. **AstraZeneca** limits dispensing 340B drugs at one contract pharmacy location.

November 2020: **Novartis** limits dispensing 340B drugs to contract pharmacies within a 40-mile radius of CE. **United Therapeutics** will deny 340B drugs at contract pharmacies unless contract pharmacy was utilized by CE during the first 3 quarters of 2020.

1/1/2021: **Novo Nordisk** stops shipping 340B drugs to contract pharmacies. CEs without an in-house pharmacy may designate one contract pharmacy.

May 2021: **United Therapeutics** requires use of 340B ESP, or it will stop shipping 340B drugs to contract pharmacies.

8/1/2021: **Boehringer Ingelheim** will stop shipping drugs to contract pharmacies. CEs without an in-house pharmacy may designate one contract pharmacy using 340B ESP. CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

CE = covered entity

Manufacturers Restrict Access – Part 2

9/1/2021: **Merck** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. CEs without an in-house pharmacy may designate one contract pharmacy. CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

10/29/2021: **Eli Lilly** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. CEs without an in-house pharmacy may designate one contract pharmacy.

December 2021: **United Therapeutics** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. (Applies to specific drugs). **UCB** stops shipping 340B drugs to contract pharmacies if the CE has not registered. CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

2/1/2022: **AbbVie** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. (Applies to specific drugs). CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

1/3/2022: **Amgen** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. (Applies to specific drugs). CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

1/1/2022: **J&J** stops offering voluntary 340B pricing on orphan drugs to CEs subject to the orphan drug exclusion

3/1/2022: **Bristol Meyers Squibb** stops shipping 340B drugs to contract pharmacies if the CE has not registered. CEs without an in-house pharmacy may designate two contract pharmacies (one for IMiD products and one for non-IMiD products). CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

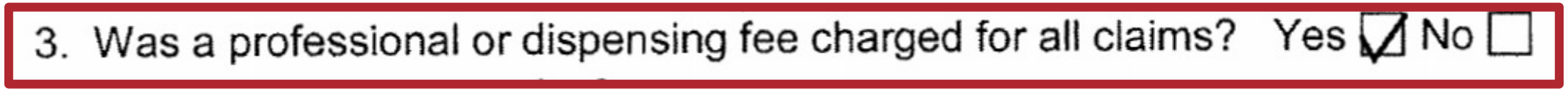
3/1/2022: **Pfizer** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. (Applies to specific drugs). CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

2/14/2022: **GSK** stops shipping 340B drugs to contract pharmacies if the CE has not registered and submitted data to 340B ESP. (Applies to specific drugs). CEs can apply for a wholly owned contract pharmacy exception on 340B ESP.

Medicaid Drug Reimbursement Issues

Medicaid Drug Reimbursement Issues

- **California Medi-Cal 340B self-audits (2021)**
  - Statewide confusion over scope of professional dispensing fee
  - Retail only, physician administered drugs, or both?



- **Interplay between Medicaid Drug Rebate Program (MDRP) and 340B**
  - 340B ESP
  - Kalderos
  - Build Back Better Act proposed to extend MDRP to CHIP programs

Payor / PBM Drug Reimbursement Issues

Commercial Reimbursement Drug Developments

- **Continued PBM Discriminatory Conduct**
  - Whitebagging
  - Attempted reimbursement cuts (e.g., MA, Medicaid MCO)
  - Require unique modifiers
  - N1 transactions

- **States Push Back**
  - MI just passed 3 bills (HB4348; HB4351; HB4352)
  - Pending IL bill (HB4595)
  - 20+ states have passed bills or have bills pending

Commercial Reimbursement Drug Developments

- **Preemption and Validity of State PBM Laws**
  - *Rutledge v. Pharmaceutical Care Management Ass'n*
    - Unanimous U.S. Supreme Court decision re: Arkansas PBM law
    - ERISA does not preempt state law that regulates PBM reimbursement rates
  - *Pharmaceutical Care Management Association v. Wehbi, et al.*
    - 8th Circuit revisited a North Dakota PBM law in light of *Rutledge*
    - ERISA does not preempt state law that regulates PBM practices
    - Certain elements are preempted by Medicare Part D
    - Likely supports 340B discrimination laws with Part D carve out
    - Impacts laws in Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota

Thank You

Bragg Hemme
Shareholder
Denver
BHemme@Polsinelli.com
303-583-8232

Kyle Vasquez
Shareholder
Chicago
KVasquez@Polsinelli.com
312-463-6338

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