KEEPING IT STRAIGHT WITH THE FEDS AND THE STATE:
ASC PAYMENT, COMPLIANCE, RISK MANAGEMENT, AND INSURANCE

PANELISTS:
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SKIP PLENINGER • MIKE ROMANSKY, JD

MONDAY, MARCH 22ND, 2021 @ 7 PM ET
KEEPING IT STRAIGHT WITH THE FEDS AND THE STATE

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OOSS.ORG
TOPICS FOR TODAY

• The Sprint to Coordinated Care
  – a.k.a. 550 pages of new rulemaking from CMS and the OIG creating new and revising existing Stark Law exceptions and Anti-Kickback Safe Harbors
  – AKS focus since ASC services not covered by Stark

• Government Investigations Update
Since the passage of the Affordable Care Act (ACA), there has been a priority to transition away from traditional fee-for-service payment systems and move toward value-based models that tie provider reimbursement to increased quality, reduced costs, enhanced care coordination, and improved patient outcomes.

HHS has had to furnish various waivers of the AKS, the Stark Law, and civil monetary penalty (CMP) laws in connection with CMS-driven innovation models because there was a recognition that many traditional fraud and abuse concerns, such as provider overutilization, are mitigated when payments are tied to value instead of volume.
PURPOSE OF THE NEW AND REVISED REGULATIONS

• Intended to cover a broad array of arrangements, offering flexibility for payors and providers to “design their own model”
  – Patient populations, value-based purposes and activities, quality measures, payment methodologies, referral requirements, and other components that fit the “value-based purpose”
• Arrangements that fit within the parameters of the new safe harbors will be able to take advantage of operating outside traditional fraud and abuse safeguards.
  – Arrangement may not need to be set at fair market value
  – Compensation may not need to be set in advance
  – May permit directed referrals of patients to specific providers
  – May permit remuneration under an arrangement to take into account the volume or value or referrals
STRUCTURE OF THE NEW SAFE HARBORS

- The safe harbors set up a sliding scale of regulatory flexibility based on degree of risk sharing that is incorporated into the arrangement.

- Full Financial Risk
- Meaningful Downside Risk
- Other Arrangements (e.g., coordinated care)
PURPOSE OF A “VALUE BASED ARRANGEMENT”

- Safe harbors intended to protect a “value-based arrangement” that is part of a “value-based enterprise.” Every protected arrangement must have, at its core, one or more value-based purposes, which are defined as:
  - Coordinating and managing the care of a target patient population;
  - Improving the quality of care for a target patient population;
  - Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
  - Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.
NOTABLE SAFE
HARBOR REGULATIONS
PATIENT ENGAGEMENT AND SUPPORT SAFE HARBOR

- Protects the provision of in-kind patient engagement tools furnished directly by a VBE participant to a patient in a target population.
- Must advance one or more of several specified goals:
  - adherence to a treatment regimen, drug regimen, or follow-up care plan as determined by the patient’s HCP.
  - prevention or management of a disease or condition, as directed by the patient’s HCP.
  - ensuring patient safety.
- Participant exclusions.
CYBERSECURITY TECHNOLOGY AND RELATED SERVICES

• Allows non-monetary donations of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity if the required conditions are met
  – The donor does not:
    • Directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated
    • Condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals
  – Neither the recipient nor the recipient’s practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor
• Key Terms
  – To be eligible for safe harbor protection, the donated technology (both software and hardware) must be "necessary and used predominantly" for cybersecurity purposes.
  – No restriction on protected parties, which significantly broader than in the EHR Safe Harbor.
    • Patients may be recipients.
REVISIONS TO EXISTING SAFE HARBORS:
PERSONAL SERVICES SAFE HARBOR

• More flexibility for part-time/per-diem arrangements
  – The current requirement that the aggregate compensation payable under the services arrangement is set in advance is replaced with a requirement that the methodology for determining the compensation paid to the agent over the term of the agreement is set in advance.

  • Compensation must still reflect fair market value, be commercially reasonable, and not take into account the volume or value of referrals of business otherwise generated between the parties.
  – The current requirement that, if an agreement provides for services on a periodic, sporadic or part-time basis, the contract must specify the schedule, length and the exact charge for such intervals is eliminated.
REVISIONS TO EXISTING SAFE HARBORS: LOCAL TRANSPORTATION

• Increases the distance patients residing in rural areas may be transported, from 50 miles to 75 miles.
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GOVERNMENT REGULATIONS
Co-management

• Large multi-office ophthalmology practice received civil investigative demand seeking documents related to:
  – Co-management
  – List of referral sources
  – Tracking of referrals
  – Remuneration provided to referral sources, including CME, dinners, entertainment
  – Information provided to patients regarding co-management, including information regarding patient choice
  – Fee-splitting involving both premium and conventional IOLs
  – Allegations of patient harm related to cataract surgery
• Early stage; suspect a whistleblower, same DOJ counsel as TN case
RETINA DRUGS

• Subpoenas issued to several large retina practices seeking documents related to:
  
  – Price paid for drugs, inclusive of all rebates, discounts and other benefits received
  – Samples and replacement drug
  – Credit card purchasing
  – Profit margins
  – Distributor relationship
EQUITY INCENTIVES AND UNNECESSARY SERVICES

- Advanced Pain Management Holdings: Hold Co./MSO/physician practices/ASC
- Hold Co. gifted stock to non-employee physicians who performed services at the ASCs that could redeemed upon the sale of Hold Co. Value of stock dependent on the profitability of Hold Co., which would largely depend on referrals to the ASCs.
- Hold Co. paid non-employee physicians to serve as ASC medical directors in a manner that was tied to volume of procedures at ASCs. No written agreements outlining duties and no records of services provided.
- Settled $886,000
• Trevose Ambulatory Surgery Care (Trevose ASC), OIG alleged that Trevose ASC paid remuneration to a professional corporation in the form of leased space that was free or below fair market value.
• ASC self-disclosed, agreed to pay $88,328.58
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2021 ASC UPDATES

Presented by:
Kirk Mack, COMT, COE, CPC, CPMA
Senior Consultant
Today’s Agenda

1. ASC fee schedule changes
2. Medicare costs
3. Quality reporting
4. Code updates/revisions
5. Medical necessity challenges
6. Questions
ASC Fee Schedule Changes
Final ASC 2021 Fee Schedule

Mostly good news…other challenges remain.

+2.4% increase to ASC conversion factor ($48.952)
Tied to hospital market basket update
Multi-factor productivity adjustment 0.0%

Sequestration suspended through March 31, 2021

2% reduction if failed quality reporting
No change to ASC Quality Reporting list
Removal of inpatient-only list by 2024

www.ascassociation.org
https://qualitynet.cms.gov/asc/ascqr
## 2021 ASC Rates

<table>
<thead>
<tr>
<th>CPT/Description</th>
<th>2020 Rates</th>
<th>2021 Rates</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>15823 - Blepharoplasty</td>
<td>$ 819.95</td>
<td>$ 871.28</td>
<td>6.26%</td>
</tr>
<tr>
<td>66180 – Tube shunt</td>
<td>$ 2462.24</td>
<td>$ 2530.67</td>
<td>2.78%</td>
</tr>
<tr>
<td>66821 - YAG</td>
<td>$ 256.14</td>
<td>$ 255.93</td>
<td>--</td>
</tr>
<tr>
<td>66982/4 – Cat ext w/IOL</td>
<td>$ 1012.72</td>
<td>$ 1044.65</td>
<td>3.15%</td>
</tr>
<tr>
<td>67108/13 – RD repair</td>
<td>$ 1835.84</td>
<td>$ 1881.96</td>
<td>2.51%</td>
</tr>
<tr>
<td>67904 – Ptosis repair</td>
<td>$ 836.94</td>
<td>$ 857.97</td>
<td>2.51%</td>
</tr>
<tr>
<td>67961 – Lid excision/repair</td>
<td>$ 836.94</td>
<td>$ 857.97</td>
<td>2.51%</td>
</tr>
<tr>
<td>66711 – ECP Laser</td>
<td>$ 1,012.72</td>
<td>$ 1,044.65</td>
<td>3.15%</td>
</tr>
<tr>
<td>66987/8 – Cat ext w/IOL +ECP</td>
<td>$ 2,393.04</td>
<td>$ 2,447.16</td>
<td>2.26%</td>
</tr>
<tr>
<td>0191T – MIGS (e.g. iStent)</td>
<td>$ 2,717.65</td>
<td>$ 2,830.59</td>
<td>4.15%</td>
</tr>
<tr>
<td>66761 – Iridotomy</td>
<td>$ 189.83</td>
<td>$ 181.16</td>
<td>-4.57%</td>
</tr>
<tr>
<td>65756 – Endothelial transplant</td>
<td>$ 1,835.84</td>
<td>$ 1,881.96</td>
<td>2.51%</td>
</tr>
<tr>
<td>67036-67042 – Vit/Mem peel</td>
<td>$ 1,835.84</td>
<td>$ 1,881.96</td>
<td>2.51%</td>
</tr>
<tr>
<td>67028 – Intravitreal injection</td>
<td>$ 47.28</td>
<td>$ 56.71</td>
<td>19.94%</td>
</tr>
</tbody>
</table>

Source: [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates)
Medicare Costs
2021 Medicare Costs

**Part B Monthly Premiums**

$148.50 for 2021
An increase of $3.90 from $144.60 in 2020. Varies by income.

**Part B Annual Deductible**

$203 in 2021
An increase of $5 from $198 in 2020.

**Part D (drug benefit) Monthly Premiums**

$33.06 in 2021
An increase of $3.06 from $30 in 2020. Varies by income.

Source: https://www.medicare.gov/Pubs/pdf/11579-Medicare-Costs.pdf
Quality Reporting
ASC Quality Reporting

- ASC Center Quality Reporting Program (ASCQR)
  - ASCs must meet quality reporting requirements or receive a reduction of 2.0% in annual facility reimbursements if requirements not met
- Suspended Measures:
  - ASC-1: Patient Burn
  - ASC-2: Patient Fall
  - ASC-3: Wrong Site, Wrong Side, etc.
  - ASC-4: All-Cause Hospital Transfer/Admission

Source: Ambulatory Surgical Center Quality Reporting Specifications Manual Release Notes Version: 10.0
ASC Measures

- ASC-11 Cataracts, Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery
  - Retained in 2021
  - Voluntary
  - Submission via web-based tool
  - Need pre and post surgery visual function survey
  - Codes: 66840, 66850, 66852, 66920, 66930, 66940, 66982, 66983, 66984, 66987, 66988
ASC Measures

- ASC-14 Unplanned Anterior Vitrectomy
  - Retained in 2021
  - Submission via web-based tool
  - Codes: 66982, 66983, 66984
  - Data sources: ASC medical records, incident/occurrence reports and variance reports are potential data sources.
    - Anterior vitrectomy codes (67005, 67010) bundled with cataract codes. Not likely listed in PM system.

Source: Ambulatory Surgical Center Quality Reporting Specifications Manual Release Notes Version: 10.0
- Updated ASC Quality Reporting Specifications Manual
- Version 10.0 is available on the QualityNet website describing ASC 2020 data collection and reporting

Code Updates/revisions
### 2020 ICD-10 Changes (eff 10/1/2020) – Laterality

**6th Character**
- 1 – right
- 2 – left
- 3 – bilateral
- 9 – unspecified

#### ICD-10 Description Table

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H18.50 _</td>
<td>Unspecified hereditary corneal dystrophies</td>
</tr>
<tr>
<td>H18.51 _</td>
<td>Endothelial corneal dystrophy</td>
</tr>
<tr>
<td>H18.52 _</td>
<td>Epithelial (juvenile) corneal dystrophy</td>
</tr>
<tr>
<td>H18.53 _</td>
<td>Granular corneal dystrophy</td>
</tr>
<tr>
<td>H18.54 _</td>
<td>Lattice corneal dystrophy</td>
</tr>
<tr>
<td>H18.55 _</td>
<td>Macular corneal dystrophy</td>
</tr>
<tr>
<td>H18.59 _</td>
<td>Other corneal dystrophies</td>
</tr>
</tbody>
</table>

### 2020 ICD-10 Changes (eff 10/1/2020)

#### 7th Character
- 1 – right
- 2 – left
- 3 – bilateral
- 9 – unspecified

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T86.840_</td>
<td>Corneal transplant rejection</td>
</tr>
<tr>
<td>T86.841_</td>
<td>Corneal transplant failure</td>
</tr>
<tr>
<td>T86.842_</td>
<td>Corneal transplant infection</td>
</tr>
<tr>
<td>T86.848_</td>
<td>Other complications of corneal transplant</td>
</tr>
<tr>
<td>T86.849_</td>
<td>Unspecified complication of corneal transplant</td>
</tr>
</tbody>
</table>

2021 New CPT Category III Codes

**Insertion of Iris Prosthesis**

**0616T** - Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens

- 2021 Rate - $1,354

**0617T** - ; with removal of crystalline lens and insertion of intraocular lens

- 2021 Rate - $2,440

**0618T** - ; with secondary intraocular lens placement or intraocular lens exchange

- 2021 Rate - $2,440

Source: [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates)
2021 New CPT Category III Codes

**Trabeculostomy**

0621T - Trabeculostomy ab interno by laser;

0622T - Trabeculostomy ab interno by laser; with use of ophthalmic endoscope

(Do not report with gonioscopy 92020)

No published ASC rates
XenGel Stent – CPT 0449T

- Refractory glaucoma patients that failed previous surgery
- OAG, Pseudoexfoliative, Pigmentary, that are unresponsive to maximum medications
- ab interno approach aqueous from AC to subconjunctival space
- With or without cataract surgery
- 2021 national rate MPFS: MAC discretion
- ASC national rate: $2,909
- HOPD national rate: $3,917
- Multiple surgery rules may apply
- +0450T – each additional device, no separate ASC payment

Source: CPT 2021. CMS 2021 MPFS, OPPS, ASC
XEN EX – CPT 66183*

- Off-label
- Same indications
- *ab_externo* (external approach)
- AAO Guidance
- ABN/waiver/preauth/precert
- 2021 national rate MPFS: $1,038
- 2021 ASC national rate: $2,725
- 2021 HOPD national rate: $3,917

Sources: CPT 2021. CMS 2021 MPFS, OPPS
DURYSTA™

An ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant. **DURYSTA should not be readministered** to an eye that received a prior DURYSTA.

- intracameral administration (placement)
- (bimatoprost implant)
DURYSTA™ Implant

**J7351 - Injection, bimatoprost, intracameral implant, 1 microgram**

**Indications:** Prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

**Pricing** - Jan 1. 2021 - $206.375/1mcg

**Claim** – 10 units

**ASC Payment Indicator K2**

“Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list…”

**66030 – Injection, anterior chamber of eye (sep procedure); medication**

Sources: January 2021 ASC Addenda BB (https://edit.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates)
Pass-Through Status Update

J1097 - Phenylephrine 10.16mg/ml and ketorolac 2.88mg/ml ophthalmic irrigation solution, 1 ml.

Effective Oct. 1. 2020 - new pass-through payment is $101.71.

Per CMS - “Omidria does qualify as a non-opioid pain management drug”

Payment Indicator K2

“Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list…”

January 2021 ASC Addenda BB (https://edit.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates)
Medical Necessity Challenges
Medicare Necessity Challenges

- ASC obligated to have documentation supporting medical necessity
  - Same requirements as the surgeon
- Procedures where ASC medical necessity is often weak
  - Cataract surgery
  - YAG capsulotomy
  - Blepharoplasty
  - Ptosis repair
  - iStent
- Set a standard for those procedures requiring added medical necessity
IN DEPTH LOOK INTO REGULATORY INSURANCE COVERAGES FOR AMBULATORY SURGERY CENTERS

Presented By:
Skip Pleninger
President, Medical Insurance Division Paris Kirwan Associates, Inc.
Rochester, New York, Long Island
WHERE TO LOOK FOR COVERAGE

• Commercial Package Policy/BOP Extension/Sublimit
  – Very Limited if any coverage at all
  – Cyber more common and usually Sublimit of $25,000 to $100,000
• Medical Malpractice Policy Extension/Sublimit
  – Typically $25,000 Defense Only and restricted to OPMC related issues.
WHERE TO LOOK FOR COVERAGE (CONTINUED)

- Directors & Officers Liability Extension/Sublimit
  - Coverage anywhere from $50,000 to $1,000,000 with very high deductibles matching Sublimit
  - Defense Only, No Fines and Penalties
  - Reimbursement vs. Duty to Defend
  - Coinsurance Clause as high as 50%
  - Settlement Payments vs. Penalties sometimes restricted
  - Forced to use Panel Counsel – If not 25% coinsurance
  - In essence very Limited Coverage
WHERE TO LOOK FOR COVERAGE (CONTINUED)

• Stand Alone Regulatory Compliance Insurance Coverage
• Stand Alone Cyber & Security Breach Insurance Coverage

Let’s go more in Depth Here!
UNDERSTANDING YOUR INSURANCE OPTIONS

What Stand Alone Regulatory Compliance Insurance Covers

• If an OIG or U.S. Attorney Audit or DOJ Audit
  – Fines $10,957-$21,961 per False Claim
  – Penalties: Treble Damages
  – Whistleblower Claims
  – Self Disclosure
  – Settlement on restitution is not covered
UNDERSTANDING YOUR INSURANCE OPTIONS (CONTINUED)

- In all cases legal, consulting and “shadow audit” costs
- RAC & Commercial Payor Audit
- Stark, Law, Anti-Kickback Law, HIPAA, EMTALA BOMER, ACO
- Full Prior Acts Coverage
- Limits Ranging from $1,000,000-$5,000,000
- Per Claim, Per Provider limits available depending on Company
- $2,500 Retention (Other Options Available)
- Be sure to compare coverage forms between Companies
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BILLING AUDIT CASE STUDY
• Alleged overpayment. The CMS Medicare Program Safeguard Contractor conducted an audit of 120 medical records from the insured that resulted in the allegations that the insureds billings had resulted in overpayments totaling $2,420,584.26.
• Defense counsel was successful in reversing all but five claims, totaling $857, which was paid by the insured. Underwriters have paid approximately $35,000 in defense and consulting fees on behalf of the insured.
• This matter is now closed.
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EVEN MORE TO WORRY ABOUT…

Federal and State Compliance rules governing protection and use of patient information to create a new liability exposure for healthcare providers:

Privacy and Security Breach Coverage
PRIVACY & SECURITY BREACH RESPONSE INSURANCE & WHAT IT COVERS

– Notification costs to patients
– Credit monitoring program
– IT forensics expense
– Business income lost
– 3rd Party Liability

– Ransomware coverage
– Attorney fees and expert expenses
– Protection on 3rd party liability claims
– $1,000,000 to $5,000,000 Coverage Limits
CASE STUDY – CYBER ATTACK

- Physician office experienced a cyber attack on April 22, 2017. As a result, the insured could not access HER system and practice management system.
- Insured advised that it was investigating the attack and had notified the FBI.
- EHR was not restored until April 28 (seven days after the attack), and the insured’s imaging and Practice Analytics remained down until May 4 (thirteen days after the attack).
- During the downtime, the insured reported its phone system could not complete automated appointment reminders for patients, which resulted in no-shows.
CASE STUDY – CYBER ATTACK

• Losses Incurred
  – Insured expended $13,402.50 for employee overtime it reportedly incurred responding to this incident
  – Insured had a Business Income Loss of $10,500
  – Insured incurred expenses transcription services incurred as result of this incident for $770.60
  – $11,430 in legal fees charged by law firm
  – Following application of the retention leaving a total claim paid by insurance was $35,102

Had there been a requirement for patient notification/credit monitoring, the claim would have tripled
QUESTIONS?
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