Federal Update: Current Regulatory Issues Impacting ASCs

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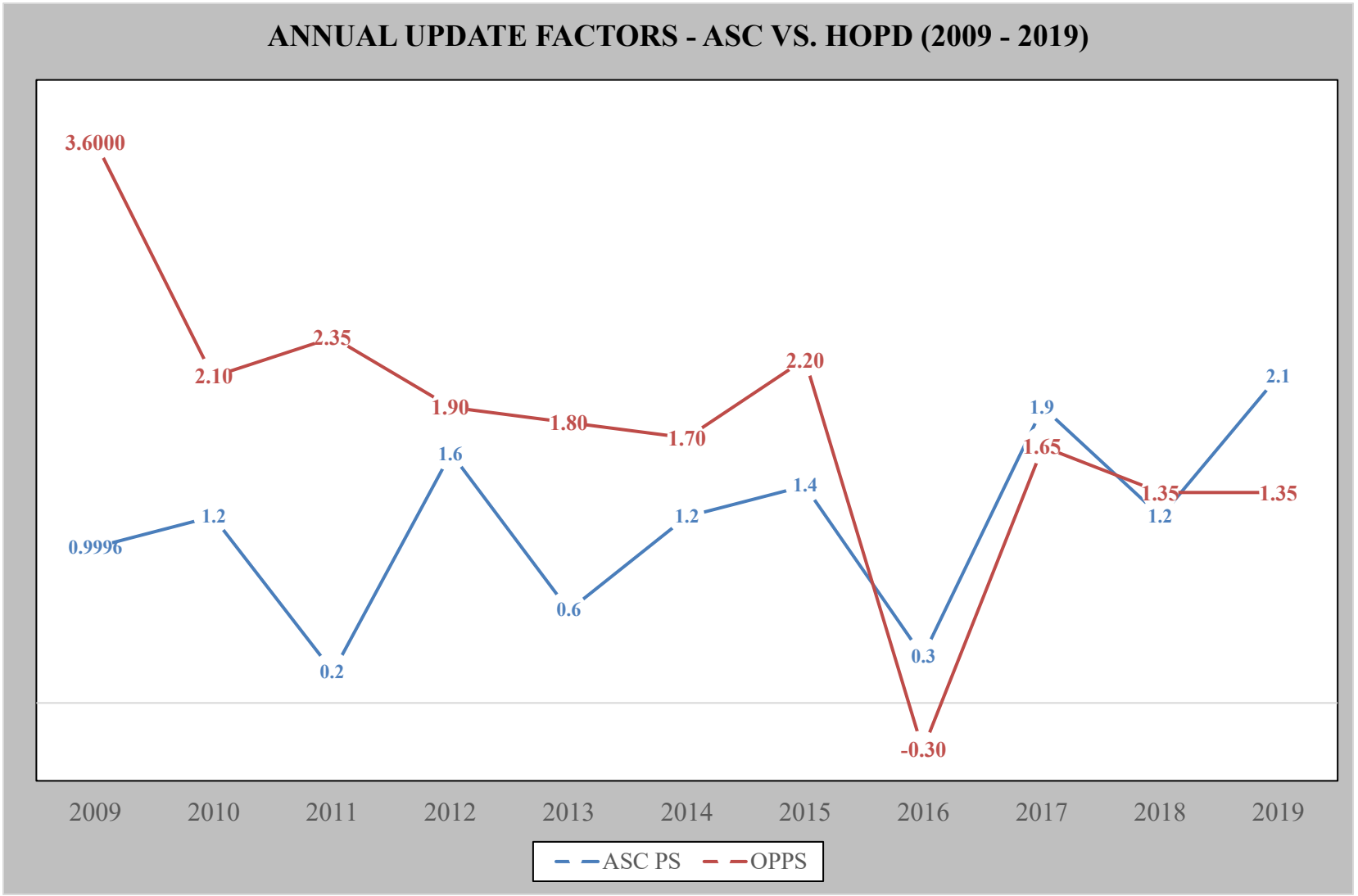
Objectives

- Discuss CMS payment policies finalized in the 2019 payment rule and look ahead to 2020.
- Outline requirements for the ASC Quality Reporting program, focusing on recent changes finalized in the 2019 payment rule.
- Review common citations and proposed changes to CMS Conditions for Coverage (CfCs), Interpretive Guidelines and Affordable Care Act (ACA) Section 1557 requirements.

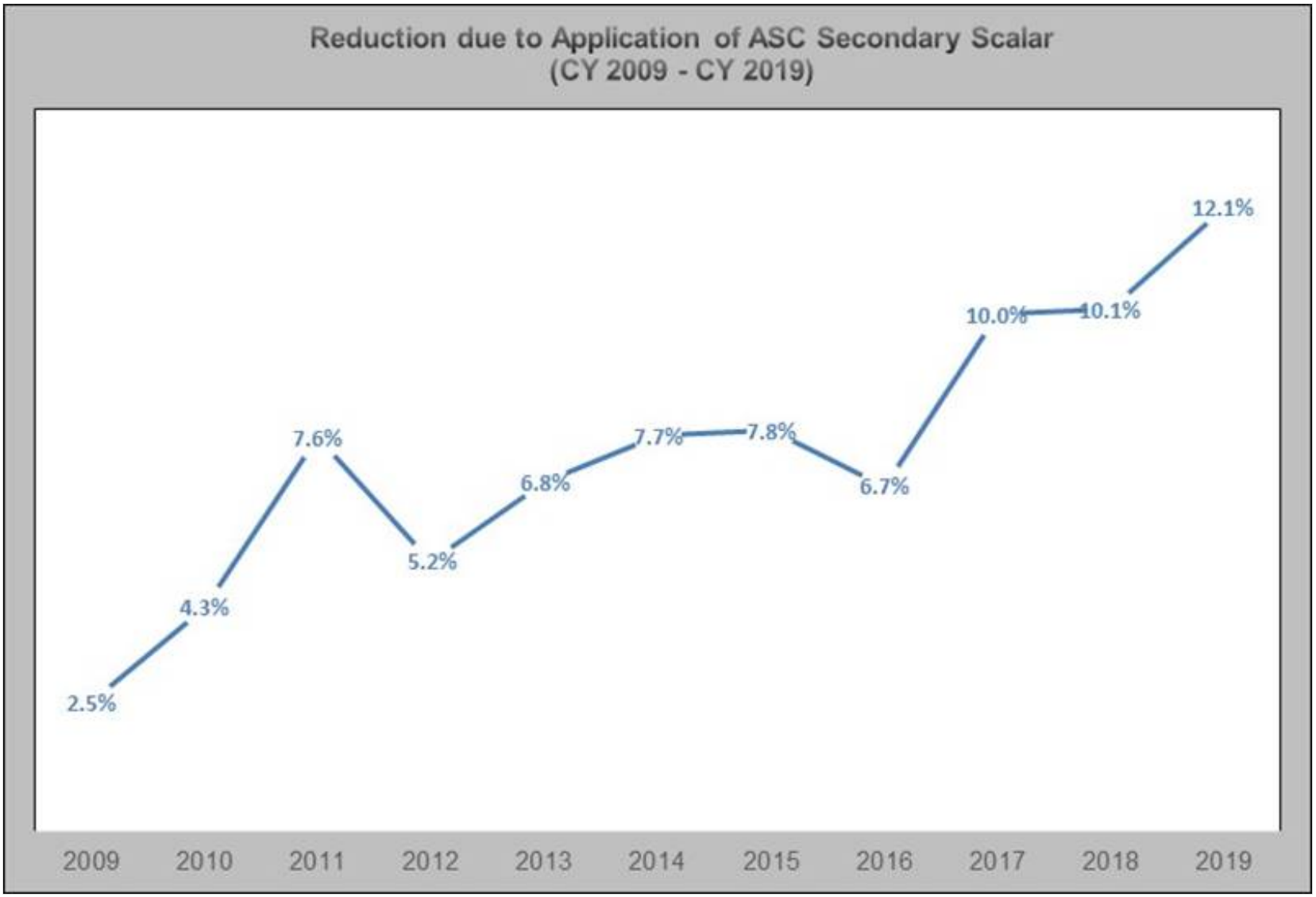
2019 FINAL Payment Update Changes

- **ASC Effective Inflation Update: 2.1%**
  - CMS to use hospital market basket index for 2019 - 2023
  - Hospital Market Basket: 2.9%
  - Multi-factor productivity (MFP) adjustment: 0.8%
- **HOPD Effective Inflation Update: 1.35%**
  - Hospital Market Basket: 2.9%
  - Multi-factor productivity (MFP) adjustment: 0.8%
  - ACA adjustment: 0.75%
- **Secondary Rescaling Factor: 0.8800**
  -2019 proposed: 0.8854 (*0.8990 in CY 2018*)
- **Rate change varies by procedure**

HOPD vs. ASC Update Factors 2009 – 2019

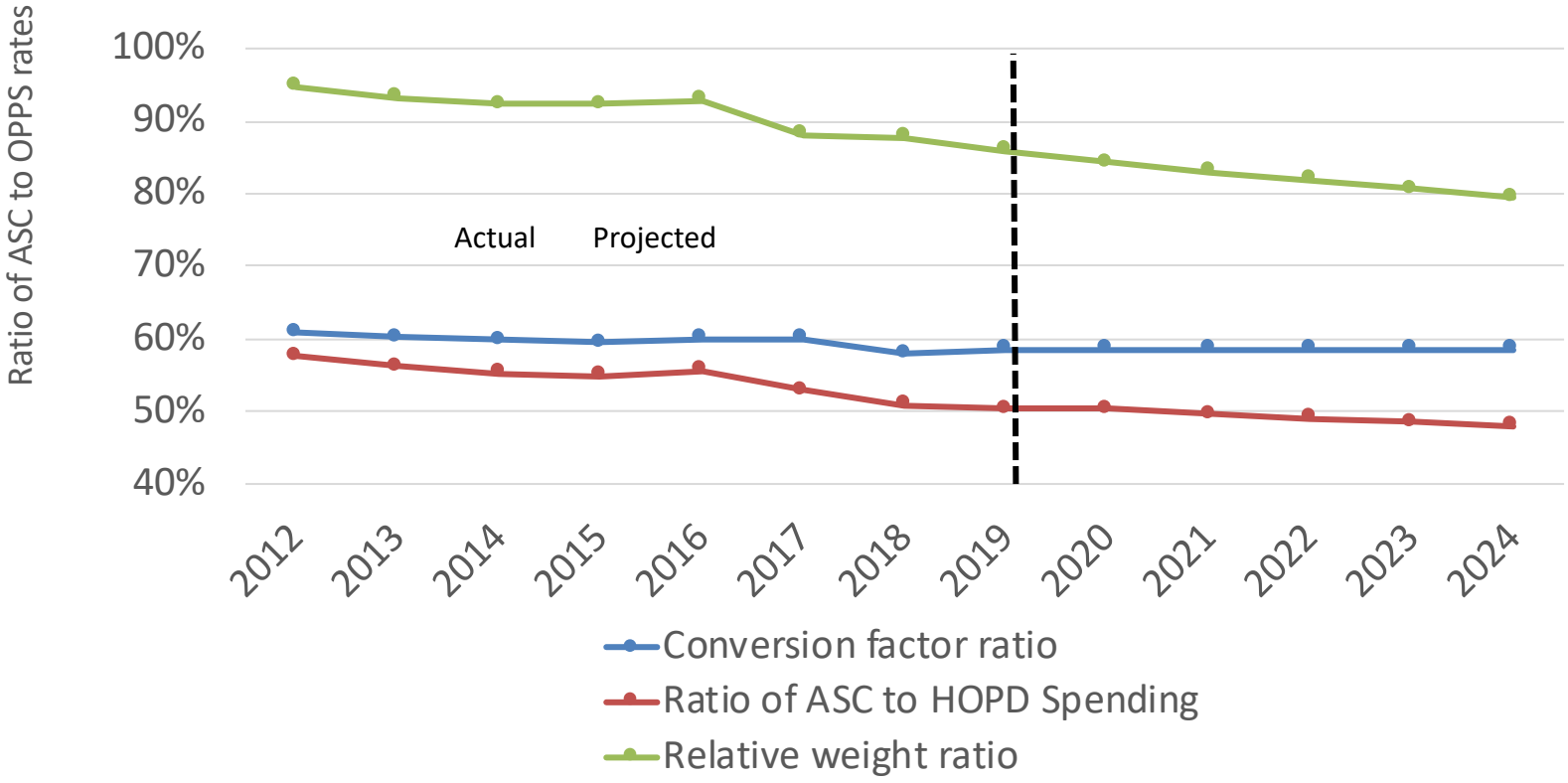


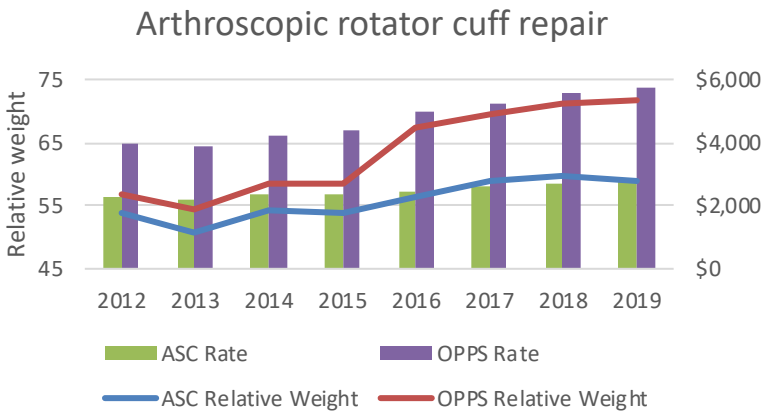
ASC Weight Scalar: 2009 – 2019



Relationship of ASC and Hospital Outpatient Payments (2012-2024p)

Top 75 ASC Codes by Volume with
Payment Based on OPPS Relative Weight

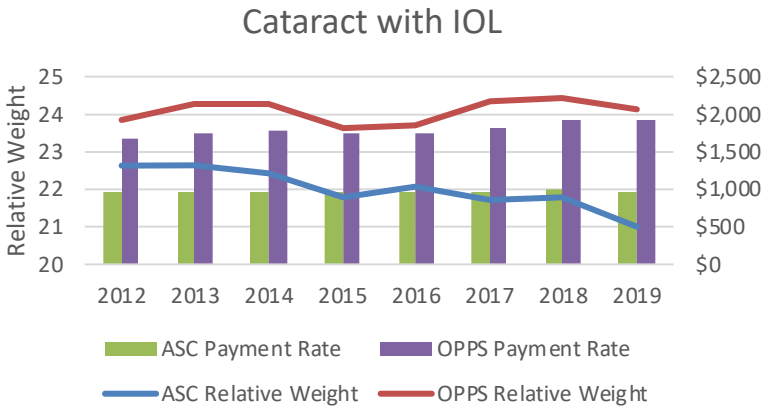




Example: Rotator Cuff Repair (HCPCS 29827)

2012: ASCs were paid 58% of OPPS Rate, and the relative weight for the code was just 5.4% higher in the OPPS.

2019: ASC payment for a rotator cuff repair had dropped to 48% of the amount paid to a hospital. Driving that decline is that the relative weight is now **21% higher** in the OPPS.



Example: Cataract Surgery with IOL (HCPCs 66984)

2012: ASCs were paid 58% of OPPS Rate, and the relative weight for the code was just 5% higher in the OPPS.

2019: ASC payment for a cataract surgery with lens replacement had dropped to 51% of the amount paid to a hospital. Driving that decline is that the relative weight is now **12% higher** in the OPPS.

2019 Final Rule Impact: Top 100 Procedures by Volume in ASC

Specialty	Total Codes in Top 100	2017 ASC Volume for Top 100 Codes*	2018 Payment (2017 Volume)	2019 Final Payment (2017 Volume)	Difference, 2018- 2019
Cardiovascular	2	12,550	$ 25,053,894	$ 21,353,080	-14.8%
Dermatology	9	114,284	$ 76,118,511	$ 74,655,795	-1.9%
Gastrointestinal	17	1,842,821	$ 801,429,463	$ 824,201,038	2.8%
Male Genital System	1	20,494	$ 15,969,122	$ 16,093,869	0.8%
Neurology	17	1,143,047	$ 834,231,882	$ 857,216,223	2.8%
Ophthalmology	24	1,855,171	$ 1,655,596,163	$ 1,643,849,225	-0.7%
Orthopedics	17	246,683	$ 270,894,352	$ 267,389,711	-1.3%
Radiology	2	30,004	$ 4,216,285	$ 3,658,094	-13.2%
Respiratory	2	11,934	$ 15,492,740	$ 15,726,227	1.5%
Urology	9	141,774	$ 93,941,976	$ 91,857,205	-2.2%
Grand Total	**100**	**5,418,762**	**$ 3,792,944,386**	**$ 3,816,000,467**	**0.6%**

2019 Final Rule Impact: Top 10 Codes by Volume in ASC

Codes	Descriptor	Specialty	2017 Volume	2018 Rate	2019 Rate	Δ, '18-'19
66984	Cataract surg w/iol 1 stage	Ophthalmology	1,228,887	$ 991.95	$ 977.33	**-1.5%**
43239	Egd biopsy single/multiple	Gastrointestinal	465,461	$ 387.30	$ 392.30	1.29%
45380	Colonoscopy and biopsy	Gastrointestinal	462,305	$ 487.78	$ 504.73	3.47%
45385	Colonoscopy w/lesion removal	Gastrointestinal	319,962	$ 487.78	$ 504.73	3.47%
64483	Inj foramen epidural l/s	Neurology	284,658	$ 350.15	$ 394.00	12.52%
66821	After cataract laser surgery	Ophthalmology	277,500	$ 254.19	$ 255.60	0.55%
62323	Njx interlaminar lmbr/sac	Neurology	192,112	$ 283.06	$ 308.47	8.98%
64493	Inj paravert f jnt l/s 1 lev	Neurology	180,422	$ 350.15	$ 394.00	12.52%
G0105	Colorectal scrn; hi risk ind	Gastrointestinal	129,346	$ 369.84	$ 383.72	3.75%
G0121	Colon ca scrn not hi rsk ind	Gastrointestinal	112,279	$ 369.84	$ 383.72	3.75%

Medicare's ASC-Payable List

- Historically includes surgical procedures CPT 1,000-6,999 (unless excluded)
- Ancillary services (when provided on conjunction with surgical code)
- List updated annually (mid-year coding changes)
- Evaluates excluded procedures & procedures newly removed from the inpatient list
- Determine if any codes currently excluded should be added to the ASC-payable list, using the ASC List Exclusion Criteria

Reasons for Exclusions

- Pays for unless meets one or more of the following:
  - **ASC List Exclusion Criteria**
    - ☒ Is on the inpatient only list
    - ☒ Poses a significant safety risk to the beneficiary
    - ☒ Typically requires active medical monitoring and care past midnight
    - ☒ Directly involves major blood vessels
    - ☒ Requires major or prolonged invasion of body cavities
    - ☒ Generally results in extensive blood loss
    - ☒ Is emergent in nature
    - ☒ Is life-threatening in nature
    - ☒ Commonly requires systemic thrombolytic therapy
    - ☒ Can only be reported using an unlisted surgical procedure code

2019 ASC-Payable List

- Broadening definition of surgical procedures
  - CMS revised the definition of "surgery" to account for surgery-like procedures that fall outside of the CPT surgical range (10000 – 69999)

- Seventeen cardiac catheterization codes added:
  - CPT procedures 93451 through 93462 (in proposed rule)
  - CPT codes 93566, 93567, 93568, 93571 and 93572

No other codes finalized for addition outside cardiac catheterization

No discussion or changes to total joint procedures from CY 2018

Review of Codes Recently Added to ASC-Payable List

- CMS KEPT on ASC-payable list all codes under review
- Codes added in the last three years (2015 – 2017)
  - Constitutes 38 codes
  - Seventeen codes had no volume
    - Two codes were deleted as of January 1, 2017
    - Twelve codes were add-on codes where payment was bundled (“N1” indicator)
    - Three codes (including two gynecology codes) had no volume report from ’15 – ‘17

Recently-Added Spine Codes

Codes	2017 Descriptor	Volume			ASC Payment Rates		
		CY 2015	CY 2016	CY 2017	CY 2015	CY 2016	CY 2017
22551	Neck spine fuse&remov bel c2	369	540	731	$ 7,843.67	$ 7,886.65	$ 7,008.82
22554	Neck spine fusion	18	17	11	$ 7,843.67	$ 7,886.65	$ 6,940.69
22612	Lumbar spine fusion	113	119	102	$ 7,843.67	$ 3,532.70	$ 4,981.42
63020	Neck spine disk surgery	24	66	55	$ 2,253.83	$ 2,486.22	$ 2,651.09
63030	Low back disk surgery	1,299	1,697	1,821	$ 2,253.83	$ 2,486.22	$ 2,651.09
63042	Laminotomy single lumbar	193	237	249	$ 2,253.83	$ 2,486.22	$ 2,651.09
63045	Remove spine lamina 1 crvl	65	70	81	$ 2,253.83	$ 2,486.22	$ 2,651.09
63046	Remove spine lamina 1 thrc	0	15	27		$ 2,486.22	$ 2,651.09
63047	Remove spine lamina 1 lmbr	1,449	1,997	2,453	$ 2,253.83	$ 2,486.22	$ 2,651.09
63055	Decompress spinal cord thrc	0	3	3		$ 2,486.22	$ 2,651.09
63056	Decompress spinal cord lmbr	287	299	302	$ 2,253.83	$ 2,486.22	$ 2,651.09
Total		**3,817**	**5,060**	**5,835**			

Device Intensive Policies

1) Codes designated as device-intensive in 2019 if device offset at HCPCS-code level is greater than 30 percent of overall costs

- For new HCPCS codes, device offset would be initially set at 31 percent

2) Procedures with single-use devices that do not remain implanted or inserted in the body following the procedure can be device intensive.

There are **263** Device-intensive codes in 2019

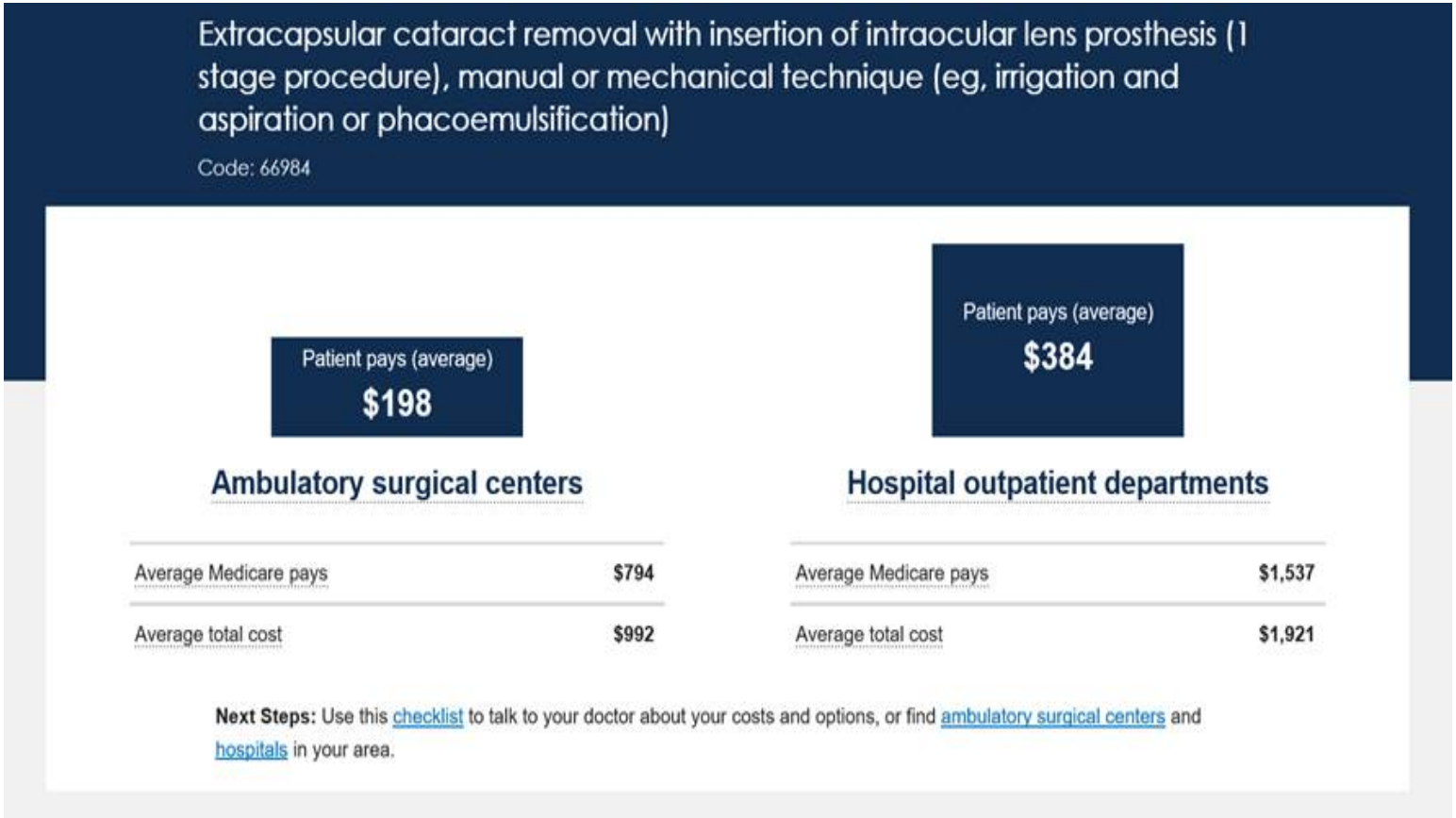
Reimbursement for Non-Opioid Pain Management

- CMS will provide separate payment for non-opioid pain management "drugs that function as a supply" when used in a surgical procedure performed in an ASC
- Currently, HCPCS code C9290, Exparel, is the only code that meets these criteria

New Medicare Cost Transparency Tool for Certain Surgical Procedures

- Mandated by the 21st Century Cures Act (signed into law December 13, 2016)
  - https://www.medicare.gov/procedure-price-lookup/
- Outpatient facility checklist: Which facility is best for my outpatient procedure? https://www.medicare.gov/what-medicare-covers/outpatient-facility-checklist
  - Also a hospital and ASC look up tool

Cost Transparency Tool: ASC to HOPD Comparison



Quality Reporting in 2019 OPPS/ASC FINAL Payment Rule

- ***Remove*** measures 8 & 10
- ***Maintain*** measures ASC 9, 11,* 12-14; 17 and 18
- ***Maintain but Suspend*** measures 1-4
- ***Continued Delay*** of implementation of ASC 15a-e: OAS CAHPS Survey measures

*Still voluntary

Two Measures Removed in 2019 Final Rule

- Removed ~~eight~~ two measures across CY 2020 and CY 2021 payment determinations:

CY 2020 Payment Determination (Data Collection 2018)

  - ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel

CY 2021 Payment Determination (Data Collection 2019)

  - ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use

Four measures suspended in 2019 Final Rule

- Suspended four measures for CY 2021 payment determinations:(Data Collection 2019)
  - ASC-1: Patient Burn
  - ASC-2: Patient Fall
  - ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
  - ASC-4: All-Cause Hospital Transfer/Admission

(Suspended data collection starting January 1, 2019 until further rulemaking)

Other Quality Reporting Aspects of 2019 Final Rule to Know

- **Continued delayed** implementation of (ASC 15a-e): OAS CAHPS Survey measures

- Changed the reporting period for ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years. For example, for CY 2020 payment determination claims data from January 1, 2016 through December 31, 2018 would be utilized.

ASC Quality Reporting Program Measures

- ASC 13 Normothermia Outcome
  Data submitted for ***a Sampling*** that meet the denominator criteria.
- ASC 14 Unplanned Anterior Vitrectomy
  Data submitted for ***All Patients*** that meet the denominator criteria.

Web Based Reporting via QualityNet Secure Portal (www.qualitynet.org)

- Data ***collection***: January 1 through December 31, 2018
- Data ***reporting***: January 1 through May 15, 2019

ASC 17: Hospital Visits after Orthopedic ASC Procedures

- Data *pulled by CMS* from the Medicare Fee for Service *administrative* claims billed by the center.
- **No data submission** or reporting required from the ASC.
- Data collection period for the CY 2022 payment determination would be CY 2019 to 2020 (two calendar years).
- The measure outcome is all-cause, unplanned hospital visits (Emergency Department Visit, Observation Stays, Unplanned Inpatient Admission) within seven days of an orthopedic procedure performed at an ASC.
- **Claims Detail Reports (CDR)** will be uploaded to QualityNet secure portal for facility review.

ASC 18: Hospital Visits after Urology ASC Procedures

- Data *pulled by CMS* from the Medicare Fee for Service *administrative* claims billed by the center.
- **No data submission** or reporting required from the ASC
- Data collection period for the CY 2022 payment determination would be CY 2019 to 2020 (two calendar years).
- The measure outcome is all-cause, unplanned hospital visits (Emergency Department Visit, Observation Stays, Unplanned Inpatient Admission) within seven days of an urology procedure performed at an ASC.
- **Claims Detail Reports (CDR)** will be uploaded to QualityNet secure portal for facility review.

ASC-17 and ASC-18

- The dry run occurred from **August 1, 2018 through August 30, 2018** and the measure results provided during the dry run will not be used for public reporting or payment determination.
- A dry run is a period of confidential feedback during which ASCs may:
  - Allow facilities to review the data used to calculate their 7-day results;
  - Inform facilities of how to interpret their measure results; and
  - Provide an opportunity for facilities to ask questions about the measures.
- For the dry-run, the most current 2-year set of data available was August 2015 to August 2017
- Reports uploaded to QualityNet secure portal

Public Reporting of Facility Specific Quality Reporting Data

- CMS reports ASC data on *Hospital Compare*, at:

  https://www.medicare.gov/hospitalcompare/asc-ambulatory-surgical-measures.html
- Facility, state, and national data is displayed.
- ASC 1-12 Facility Specific Data submitted for calendar year **2017** publicly reported February 2019
- CMS announced updates to occur October 2019

ASCQR Program: Public Reporting Comparison

Measure	National	Colorado
ASC-1: Patient Burn	0.162	0.244
ASC-2: Patient Fall	0.106	0.058
ASC-3: Wrong Site, Side, Patient, Procedure, Implant	0.036	0.019
ASC-4: Hospital Transfer/Admission	0.350	0.273
ASC-12: Facility Seven-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy	**1801:** no different than average; **259:** too small; **3**: outside of average range (1 better; 2 worse)	**39** facilities – no different than average **3** facilities: too small sample size

Survey and Certification

- Top Citations
- Distinct entity language (State Operations Manual)
- Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P)
- Affordable Care Act (ACA) Section 1557

Overall Survey & Certification Recommendations

- Periodically review state regulations for revisions
- State vs Medicare: More restrictive regulation must be followed
- ASC policies must be updated when any revision is made to a process or procedure at the center
- Revised policies must be approved by the center's Governing Board
  - This should be documented in meeting minutes

2019 CMS Health Survey Citations
(Based on 332 total surveys as of 6/7/2019)

Tag #	Tag Description	# Citations	% Surveys Cited
Q0241	SANITARY ENVIRONMENT	69	20.8%
Q0181	ADMINISTRATION OF DRUGS	64	19.3%
Q0242	INFECTION CONTROL PROGRAM	47	14.2%
Q0101	PHYSICAL ENVIRONMENT	25	7.5%
Q0104	SAFETY FROM FIRE	24	7.2%
Q0261	ADMISSION ASSESSMENT	22	6.6%
Q0162	FORM AND CONTENT OF RECORD	22	6.6%
Q0100	ENVIRONMENT	17	6.1%
Q0221	NOTICE OF RIGHTS	16	5.1%
Q0141	ORGANIZATION AND STAFFING	15	4.8%

Distinct Entity Language in State Operations Manual

- "Furthermore, care must be taken when such an arrangement is in use to ensure that the ***ASC's medical and administrative records are physically separate***."

- Revised SOM should be released soon

Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P)

- Changes to many provider types
- ***Removal of Requirements*** at 42 CFR 416.41(b)(3), "Standard: Hospitalization."
- ***Remove current requirements*** at § 416.52(a) (comprehensive history & physical assessment)
- ***Revises some emergency preparedness requirements***

42 CFR 416.41(b)(3) "Standard: Hospitalization"

- Addresses competition barriers
  - hospitals refusing to sign written transfer agreements or grant admitting privileges to physicians performing surgery in an ASC

- The Emergency Medical Treatment and Labor Act (EMTALA) emergency response regulations address emergency transfer of a patient from an ASC to a nearby hospital

Comprehensive Medical History and Physical Assessment (H&P)

- Would defer, to a certain extent, to ASC policy and operating physician's clinical judgment. Must ensure patients receive the appropriate pre-surgical assessments tailored to the patient and the type of surgery being performed.
- Retain requirement that operating physician to document pre-existing medical conditions and appropriate test results in the medical record (to be considered before, during and after surgery)
- Retain requirement that pre-surgical assessments include documentation regarding allergies to drugs & biologicals
- H&P, if completed, must be placed in the patient's medical record prior to the surgical procedure.

Proposed Changes to Emergency Preparedness Requirements

- Requires review of Emergency Plan (EP) every two years (currently annual requirement);
- Eliminates requirement that facilities document efforts to contact local, tribal, regional, State, and Federal EP officials;
  - Still need to reach out and try to coordinate with them, just don't have to document contact was made
- Training requirement changed from every year to every two years (or when EP is significantly updated)

Proposed Changes to EP Requirements, Contd.

- Outpatient providers only need one testing exercise per year
  - Must participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year.
  - For opposite years, may conduct a testing exercise of your choice, which may include: a community-based full-scale exercise, an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.
- Providers are exempt from the next required exercise after an event requiring activation of EP plan

Section 1557 of the Affordable Care Act (ACA)

- Final rule (45 CFR 92) implementing Section 1557, the nondiscrimination provision of the ACA required compliance by October 16, 2016.
- Section 1557 requires covered entities to:
  - post a nondiscrimination notice containing information such as how to obtain language interpretation services offered by the provider, how to file a grievance with the provider, and how to file a discrimination complaint with Office for Civil Rights (OCR)

Section 1557, Cont'd

- Post in their significant publications and communications nondiscrimination notices in English, as well as taglines in at least the top 15 languages spoken by individuals with limited English proficiency (LEP) in their state
- https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html
- **Proposed regulation would remove this requirement.**

Questions?

- Contact the speaker at:

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