Federal Regulatory Update

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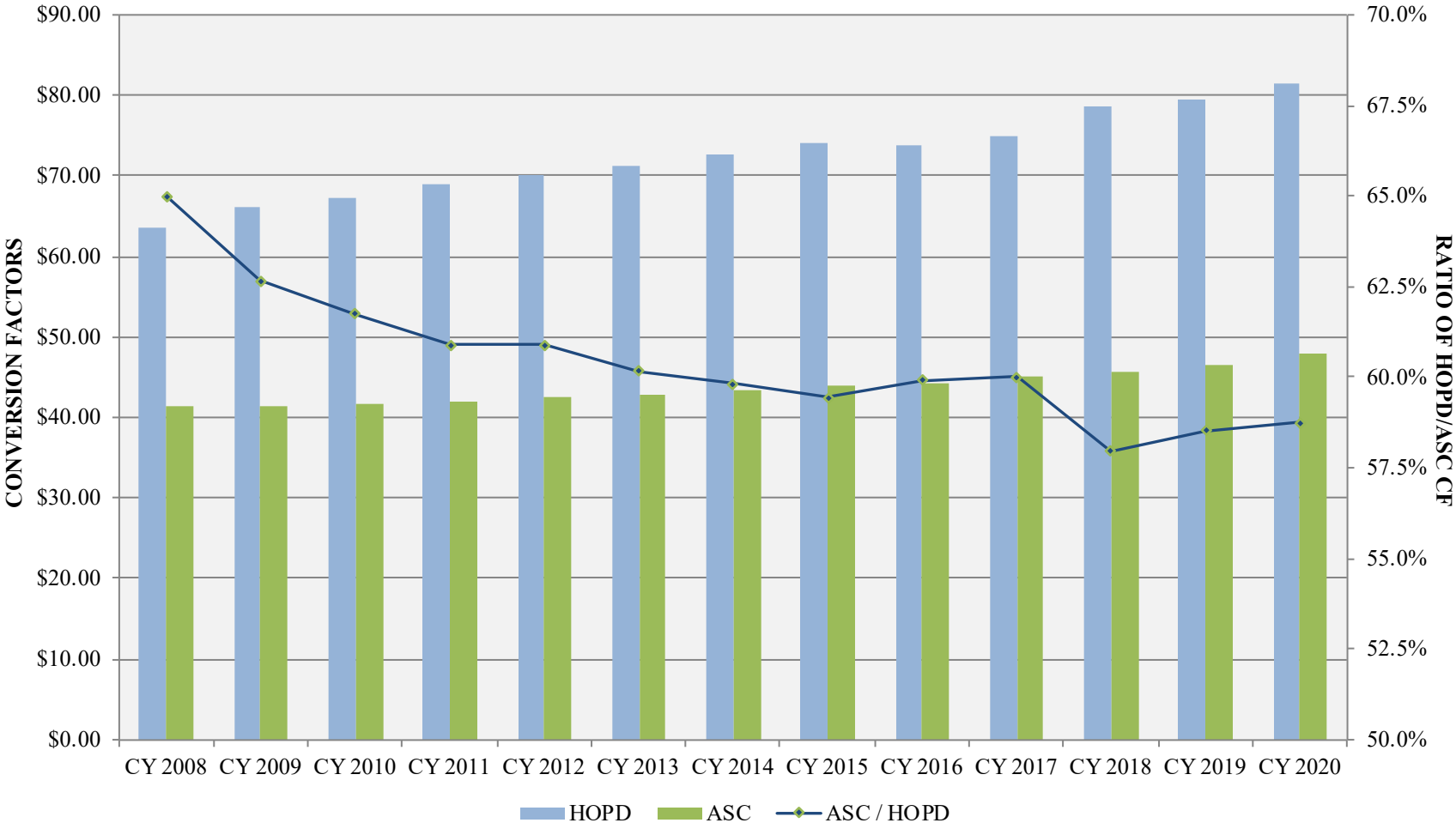
Primary Areas of Focus

- Payment Policy
- Quality & Safety
- Survey and Certification

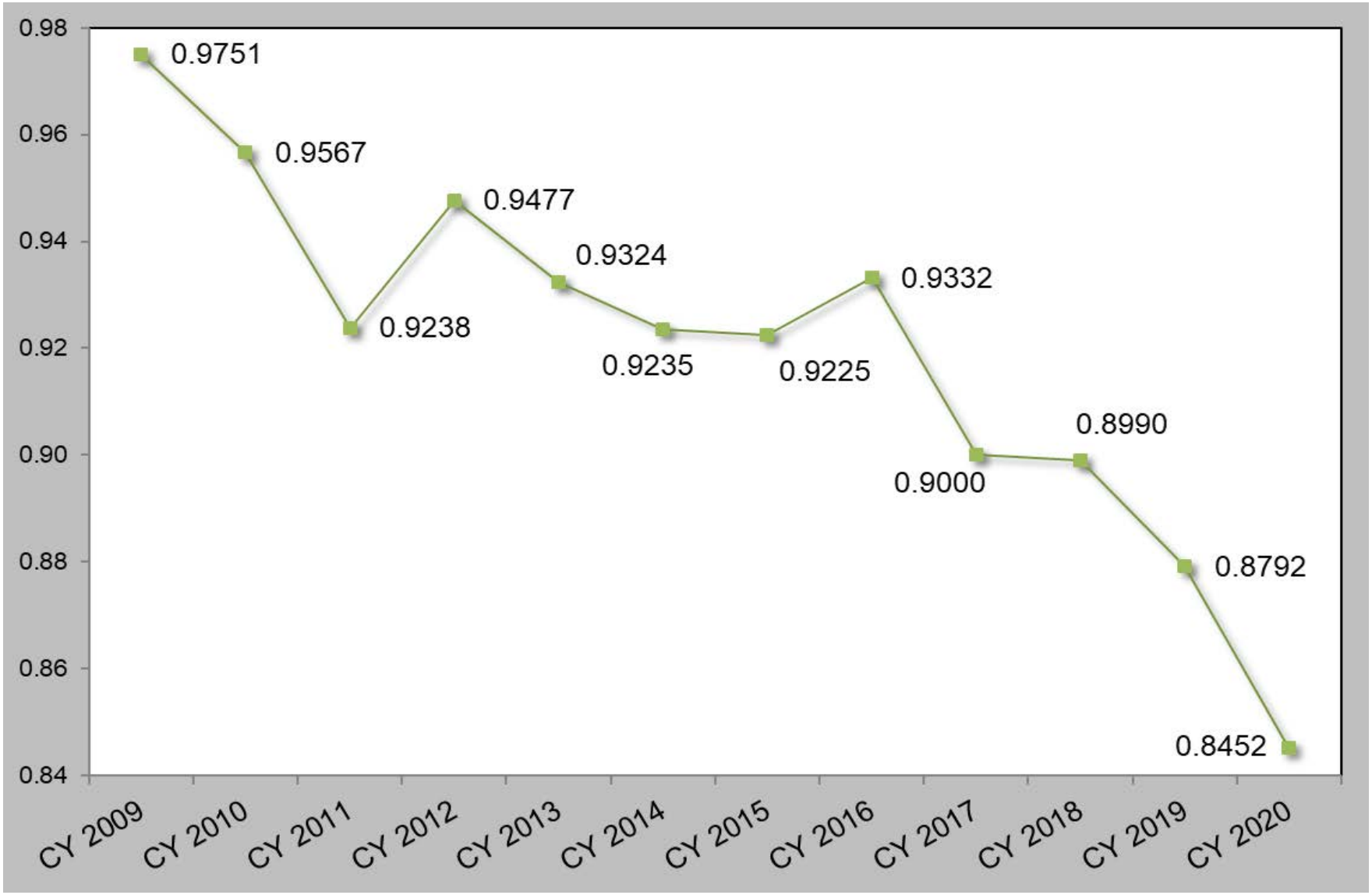
2020 Proposed Payment Update

- **ASC Effective Inflation Update: 2.7%**
  - CMS to use hospital market basket index for 2019 - 2023
  - Hospital Market Basket: 3.2%
  - Multi-factor productivity (MFP) adjustment: 0.5%
- **HOPD Effective Inflation Update: 2.7%**
  - Hospital Market Basket: 3.2%
  - Multi-factor productivity (MFP) adjustment: 0.5%
- **Secondary Rescaling Factor: 0.8452**
  -2020 proposed: 0.8854 (*0.8792 in CY 2019*)
- **Rate change varies by procedure**

HOPD vs ASC Conversion Factor 2008 – 2020 (Proposed)



ASC Weight Scalar: 2009 – 2020 (Proposed)



Top 100 Surgical Procedures by Volume 2020 Proposed Rule

Specialty	Total Codes in Top 100	2017 ASC Volume for Top 100 Codes*	Medicare Savings (2017 Volume)	Δ 2019- 2020 (Proposed)
Cardiovascular	2	12,653	$ 20,356,936	4.02%
Dermatology	9	87,827	$ 39,022,155	1.73%
Gastrointestinal	16	2,050,922	$ 764,305,405	1.16%
General	1	5,344	$ 8,261,730	5.46%
Ophthalmology	22	1,945,507	$ 1,454,971,018	2.54%
Orthopedics	19	313,181	$ 337,099,424	1.80%
Otolaryngology	5	72,161	$ 80,628,205	5.63%
Pain Management	15	1,257,676	$ 504,406,364	4.96%*
Urology	11	172,783	$ 121,422,098	0.68%
Grand Total	**100**	**5,418,762**	**$ 3,330,473,334**	**2.47%**

Top 10 Procedures by Volume
2020 Proposed Rule Impact

HCPCS	Descriptor	Specialty	2017 Volume	2019 Final	2020 Proposed	Δ 2019 F - 2020 P
66984	Cataract surg w/iol 1 stage	Ophthalmology	1,253,883	$977.33	$1,012.55	3.48%
43239	Egd biopsy single/multiple	Gastroenterology	540,264	$392.30	395.98	0.93%
45380	Colonoscopy and biopsy	Gastroenterology	464,614	$504.73	$508.57	0.76%
45385	Colonoscopy w/lesion removal	Gastroenterology	397,729	$504.73	$508.57	0.76%
64483	Inj foramen epidural l/s	Pain Management	320,240	$394.00	401.55	1.88%
66821	After cataract laser surgery	Ophthalmology	283,574	$255.60	$258.75	1.22%
64493	Inj paravert f jnt l/s 1 lev	Pain Management	220,740	$394.00	$401.55	1.88%
62323	Njx interlaminar lmbr/sac	Pain Management	195,708	$308.47	$311.57	0.99%
G0105	Colorectal scrn; hi risk ind	Gastroenterology	137,808	$383.72	$385.65	0.50%
45378	Diagnostic colonoscopy	Gastroenterology	127,204	$383.72	$385.65	0.50%
			3,941,764			**1.29**%

Medicare's ASC-Payable List

- Historically includes surgical procedures CPT 10000-69999 (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 Policy Change

- 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

- Six more cardiology codes proposed for addition in 2020.

2020 Proposed Additions

HCPCS	Short Descriptor	Payment Indicator	2020 Proposed Rate
92920	Prq cardiac angioplast 1 art	G2	$2,125.56
92921	Prq cardiac angio addl art	N1	
92928	Prq card stent w/angio 1 vsl	J8	$6,081.02
92929	Prq card stent w/angio addl	N1	
C9600	Perc drug-el cor stent sing	J8	$6,203.47
C9601	Perc drug-el cor stent bran	N1	

Total Knee Arthroplasty (TKA)

CMS is proposing to add TKA to the ASC-payable list for 2020.

- Proposed J8 payment indicator (device-intensive)
  - **device cost included in rate**
- National ASC proposed rate is $8,639.97
- National HOPD rate proposed is $11,960.25

TKA Continued

CMS soliciting comment on the "appropriate approach to provide safeguards for Medicare beneficiaries who should not receive the TKA procedure in an ASC setting," and requests feedback on the following:

- CMS could issue a new modifier that indicates the physician believes the beneficiary would not be expected to require active medical monitoring and care at midnight following a procedure furnished in the ASC setting;
- CMS could require ASC has a defined plan of care for each beneficiary following a surgical procedure;
- CMS could establish certain requirements for ASCs that choose to perform certain surgical procedures on Medicare patients, such as requiring an ASC to have a certain amount of experience performing a procedure before being eligible for payment for performing the procedure under Medicare.

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 initially set at 31 percent (unless CMS has compelling information indicating it's significantly higher)

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 **264** device-intensive codes in 2019
- There are **265** codes proposed as device-intensive for 2020

No change proposed to device threshold for 2020.

Reimbursement for Non-Opioid Pain Management

- As of 2019, CMS now provides separate payment for non-opioid pain management "drugs that function as a supply" when used in a surgical procedure performed in an ASC
  - Note: This same policy does not extend to HOPDs
- Currently, HCPCS code C9290, Exparel, is the only code that meets these criteria
- No change to this policy proposed for 2020.

Quality Reporting in 2020 OPPS/ASC Proposed Payment Rule

- **Continued suspension of measures 1-4**
  - Testing web-based reporting
- **Continued Delay** of implementation of ASC 15a-e: OAS CAHPS Survey measures
- **Proposed addition of** *ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers*

Medicare ASC Quality Reporting

Description of quality measure	Required in: 2019	2021
ASC–1: Patient burn	Yes[a]	No
ASC–2: Patient fall	Yes[a]	No
ASC–3: Wrong site, wrong side, wrong patient, wrong procedure, wrong implant	Yes[a]	No
ASC–4: Hospital transfer/admission	Yes[a]	No
ASC–5: Prophylactic intravenous antibiotic timing	No[b]	No
ASC–6: Safe-surgery checklist use	No[b]	No
ASC–7: ASC facility volume data on selected ASC surgical procedures	No[b]	No
ASC–8: Influenza vaccination coverage among health care personnel	Yes[c]	No
ASC–9: Endoscopy/polyp surveillance: Appropriate follow-up interval for normal colonoscopy in average-risk patients	Yes	Yes
ASC–10: Endoscopy/polyp surveillance: Colonoscopy interval for patients with a history of adenomatous polyps—avoid inappropriate use	Yes[d]	No
ASC–11: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery	Voluntary	Voluntary
ASC–12: Facility seven-day risk standardized hospital visit rate after outpatient colonoscopy	Yes	Yes
ASC–13: Normothermia outcome: Percentage of patients under anesthesia who are normothermic within 15 minutes of arrival in the post-anesthesia care unit	No[e]	Yes
ASC–14: Unplanned anterior vitrectomy: Percentage of cataract surgery patients who have an unplanned removal of the vitreous	No[e]	Yes
ASC–15: Five patient experience measures from the Consumer Assessment of Healthcare Providers and Systems® survey measures:		
ASC–15a: About facilities and staff		
ASC–15b: Communication about procedure		
ASC–15c: Preparation for discharge and recovery		
ASC–15d: Overall rating of facility		
ASC–15e: Recommendation of facility	No[f]	No
ASC–16: Toxic anterior segment syndrome (TASS)	No[f]	No
ASC–17: Hospital visits after orthopedic ASC procedures	No[g]	No
ASC–18: Hospital visits after urology ASC procedures	No[g]	No

Public Reporting of Facility Specific Quality Reporting Data

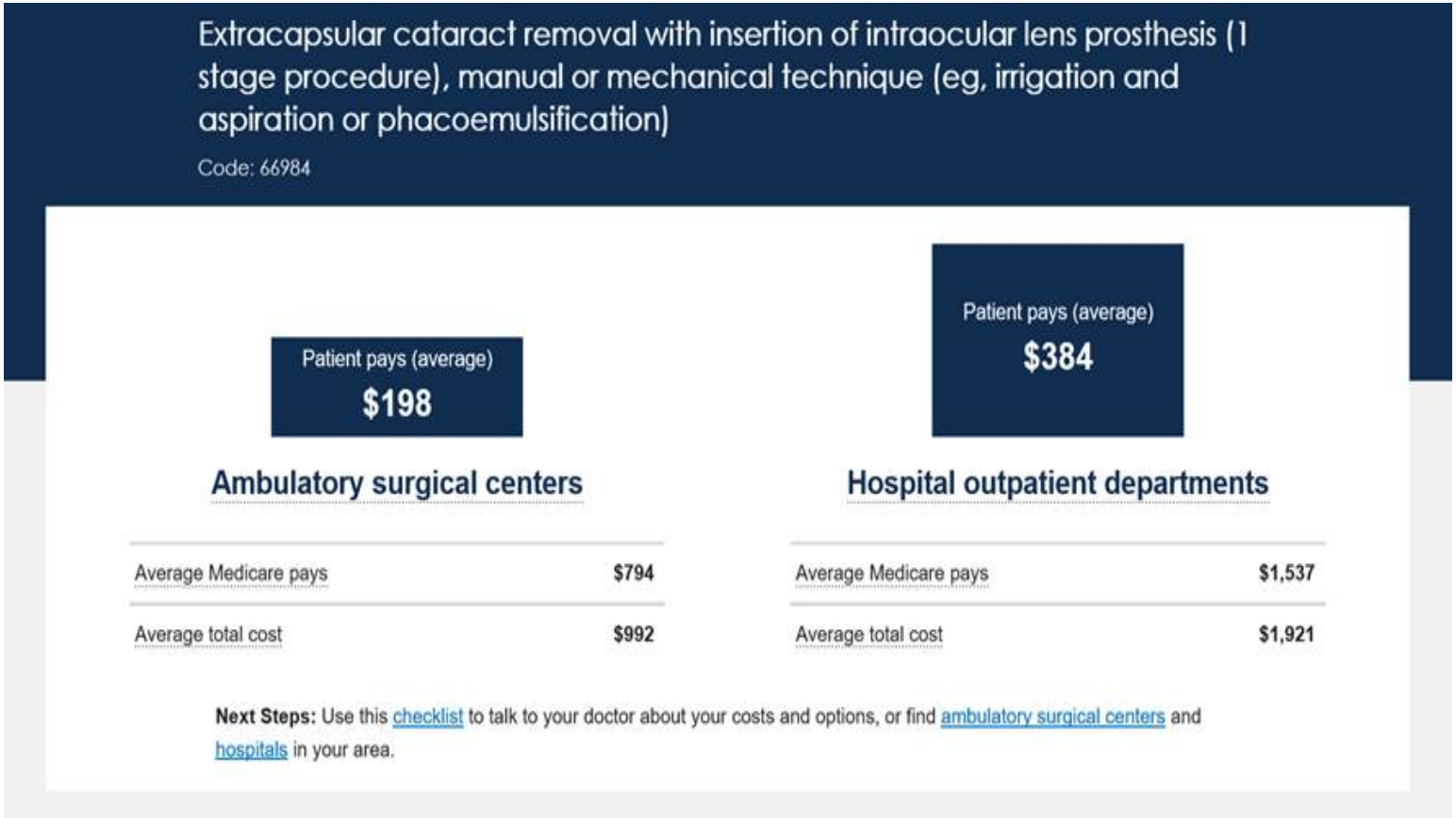
- CMS reports ASC data on *Hospital Compare*, the CMS website for Medicare beneficiaries and the general public at:

  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

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



Survey and Certification

- Top Citations
- Distinct entity language (State Operations Manual)
- Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P)
- Proposal in Medicare Physician Fee Schedule (MPFS)
- Environmental Protection Agency (EPA) Update

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 796 total surveys as of 9/9/19)

Tag #	Tag Description	# Citations	% Surveys Cited
Q0241	SANITARY ENVIRONMENT	185	23.2%
Q0181	ADMINISTRATION OF DRUGS	159	20.0%
Q0242	INFECTION CONTROL PROGRAM	133	16.7%
Q0162	FORM AND CONTENT OF RECORD	78	9.8%
Q0101	PHYSICAL ENVIRONMENT	69	8.7%
Q0261	ADMISSION ASSESSMENT	57	7.2%
Q0141	ORGANIZATION AND STAFFING	57	7.2%
Q0104	SAFETY FROM FIRE	55	6.9%
Q0064	STANDARD LEVEL TAG FOR SURGICAL SERVICES	42	5.3%
Q0240	INFECTION CONTROL	41	5.2%

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 that currently exist in some situations where hospitals providing outpatient surgical services refuse to sign written transfer agreements or grant admitting privileges to physicians performing surgery in an ASC
- The Emergency Medical Treatment and Labor Act emergency response regulations would continue to address emergency transfer of a patient from an ASC to a nearby hospital

Comprehensive Medical History and Physical Assessment (H&P)

- Replace with requirements that defer, to a certain extent, to the ASC policy and operating physician's clinical judgment to ensure that patients receive the appropriate pre-surgical assessments tailored to the patient and the type of surgery being performed.
- Would still require the operating physician to document any pre-existing medical conditions and appropriate test results, in the medical record, which would have to be considered before, during and after surgery.
- Retains requirement that all pre-surgical assessments include documentation regarding any allergies to drugs and biologicals, and that H&P, if completed, 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
  - Providers must participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year.
  - In the opposite years, providers may conduct a testing exercise of their choice, which may include: a community-based full-scale exercise (if available), 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

Proposal in Medicare Physician Fee Schedule (MPFS)

- CMS is proposing a change to the ASC Conditions for Coverage that would align patient anesthetic assessment requirements for pre-surgery [CFR §416(a)(1)] and pre-discharge [CFR §416(a)(2)] evaluations.
- Currently, the post-surgical assessment can be completed by a physician OR CRNA, whereas the pre-surgery anesthesia risk evaluation can only be performed by a physician.
- CMS proposes to allow anesthetists to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure.

Management Standards for Hazardous Waste Pharmaceuticals

- Environmental Protection Agency (EPA) final rule prohibits all facilities subject to the rule from sewering hazardous waste pharmaceuticals.
- **Became effective on August 21, 2019**
- https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075

Questions?

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