Federal Regulatory Update: Recent Changes That Could Impact Your Facility

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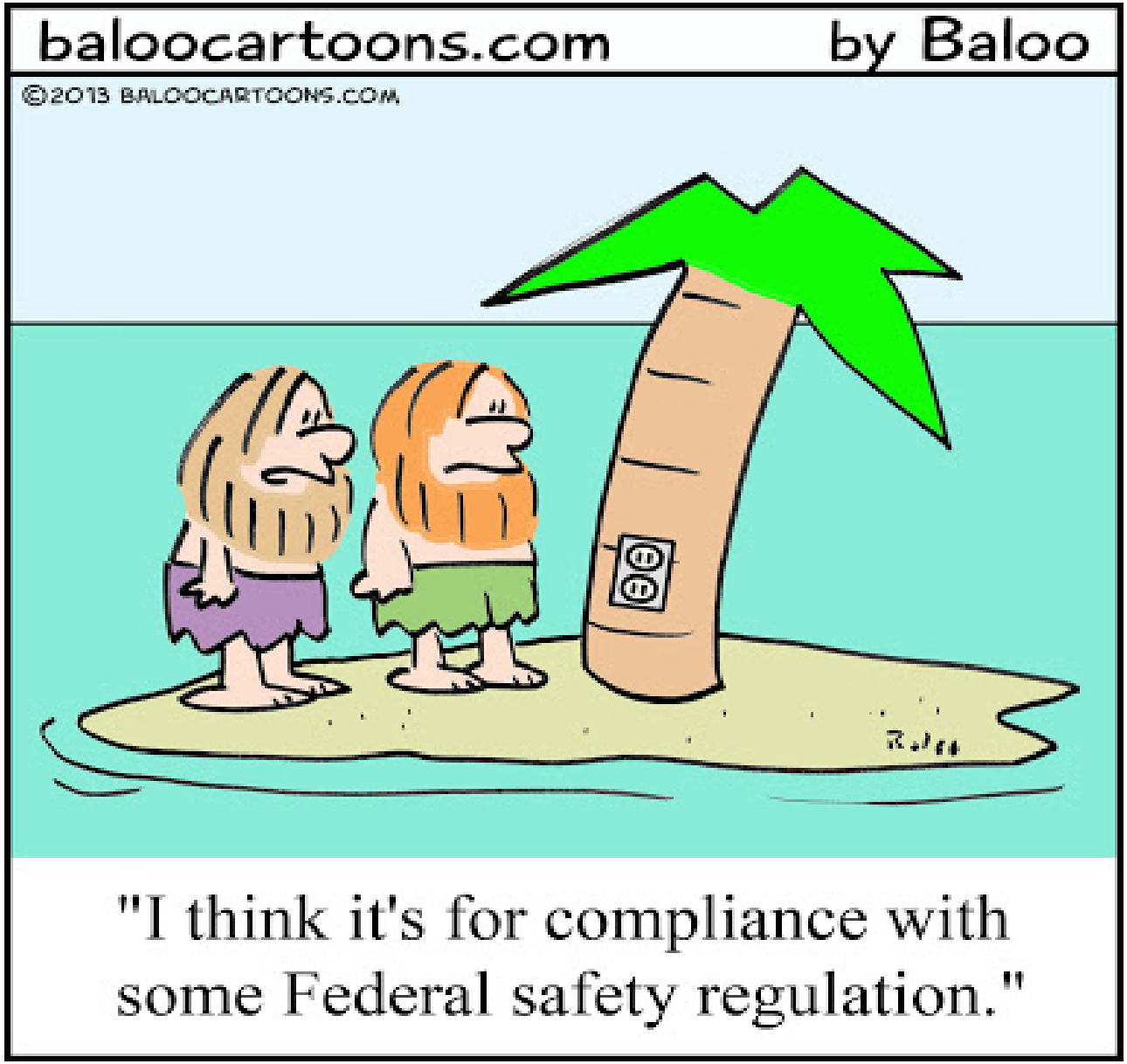
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"I think it's for compliance with some Federal safety regulation."

Regulatory Alphabet Soup

- Agency for Healthcare Research & Quality (AHRQ)
- Centers for Disease Control & Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Drug Enforcement Agency (DEA)
- Facility Guidelines Institute (FGI)
- Food & Drug Administration (FDA)
- Medicare Payment Advisory Commission (MedPAC)
- Office of Civil Rights (OCR)
- Office of the Inspector General (OIG)
- Office of the National Coordinator of Health Information Technology (ONC)
- Occupational Safety & Health Administration (OSHA)
- Office of Management & Budget (OMB)

Primary Areas of Focus

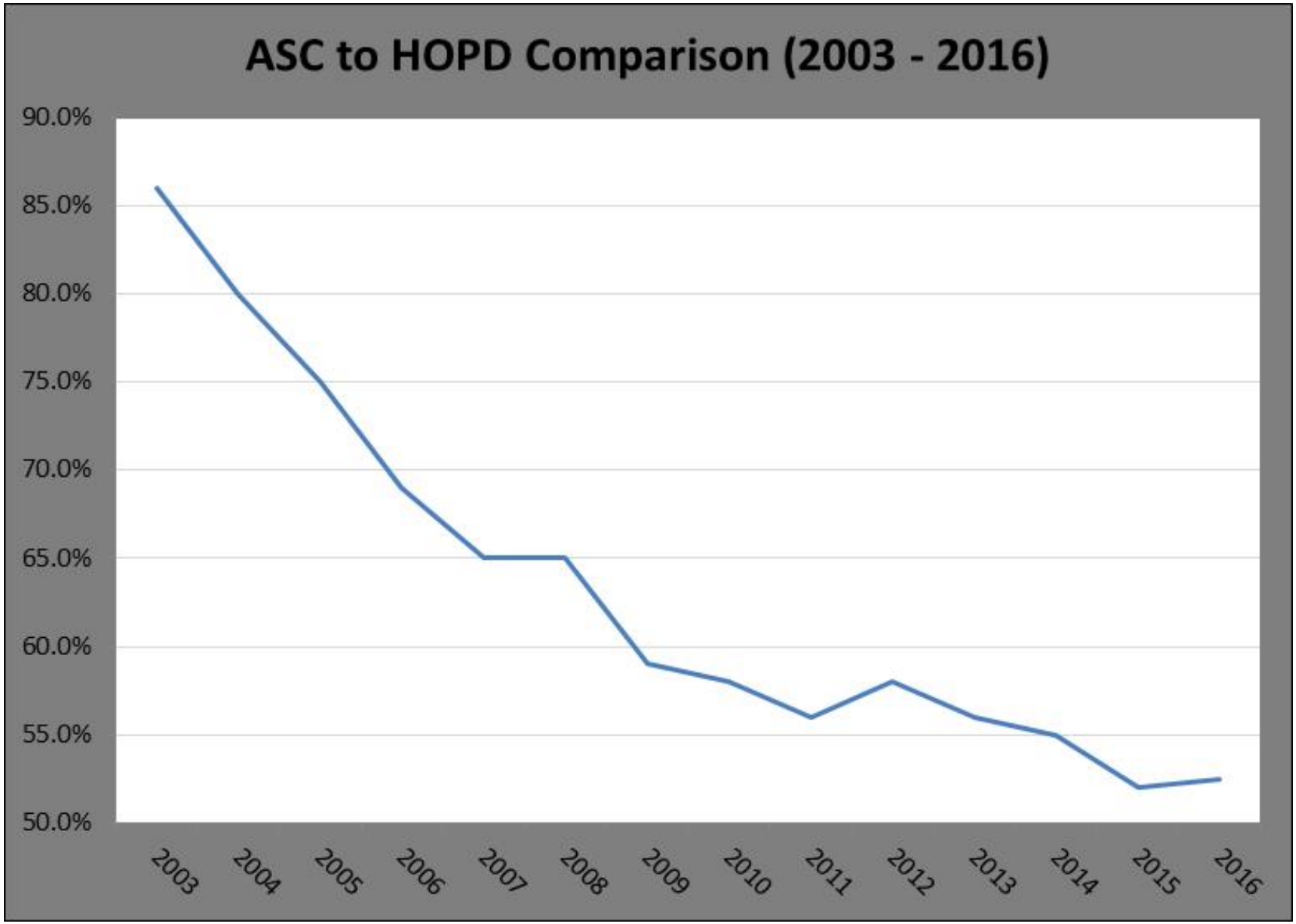
- Payment Policy
  - CMS, MedPAC, OIG, OMB, ONC
- Survey and Certification
  - CMS, DEA, FDA, FGI, NFPA, and OCR
- Quality & Safety
  - AHRQ, CDC, CMS, OSHA

Payment Policy

- Annual update: ASC update factor
- Procedures: ASC-payable list
- Device-intensive policy
- Shift to payment for episode of care
- Physician payment rule proposals

Final Rule Recap

- 0.3% rate update for ASCs, -0.3% rate update for HOPDs*
- Seventeen additional procedures added
- Major APC Restructuring
- No new measures added to ASC Quality Reporting Program


ASC to HOPD Comparison (2003 - 2016)
90.0%
85.0%
80.0%
75.0%
70.0%
65.0%
60.0%
55.0%
50.0%
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016

ASC Rate as Percentage of HOPD Rate

Top 10 ASC Codes by Volume for 2013

CPT/HCPCS Code	Short Descriptor	ASC Rate as % of HOPD Rate
43239	Upper GI endoscopy, biopsy	55.9%
45378	Diagnostic colonoscopy	55.9%
45380	Colonoscopy and biopsy	55.9%
45385	Lesion removal colonoscopy	55.9%
62311	Inject spine l/s (cd)	55.9%
64483	Inj foramen epidural l/s	55.9%
64493	Inj paravert f jnt l/s 1 lev	55.9%
66821	After cataract laser surgery	55.9%
66982	Cataract surgery, complex	55.9%
66984	Cataract surg w/iol, 1 stage	55.9%

2016 Final Rule Impact on Top 100 Procedures by Volume

Specialty	Total Codes in Top 100	2013 PSPS Volume	2015 Dollars	2016 Dollars	Differences, 2015 - 2016
Dermatology / Integumentary	8	133,866	$ 85,138,150	$ 86,860,106	2.0%
Orthopedics / Hand	20	309,500	$ 318,500,683	$ 299,677,446	-5.9%
ENT	4	30,977	$ 38,706,500	$ 41,147,356	6.3%
Cardiology	1	5,946	$ 7,286,109	$ 7,472,219	2.6%
Gastrointestinal	15	1,780,106	$ 763,474,192	$ 758,539,764	-0.6%
Urology	7	130,562	$ 84,362,170	$ 84,246,429	-0.1%
Male Genital	1	18,282	$ 14,648,818	$ 15,400,208	5.1%
Pain Management	19	1,470,461	$ 395,028,659	$ 391,254,982	-1.0%
Neurology/Neurosurgery	2	53,434	$ 40,524,880	$ 41,609,056	2.7%
Ophthalmology	20	1,782,369	$ 1,474,663,798	$ 1,484,745,658	0.7%
Ancillary	2	24,814	$ 2,489,313	$ 3,090,196	24.1%
Packaged Code	1	16,756			
TOTAL	**100**	**5,757,073**	**$ 3,224,823,272**	**$ 3,214,043,422**	**-0.3%**

Procedure List: Seventeen New Codes

- 0171T (Lumbar spine proces distract)
- 0172T (Lumbar spine process addl)
- 37241 (Vasc embolize/occlude venous)
- 37242 (Vasc embolize/occlude artery)
- 37243 (Vasc embolize/occlude organ)
- 49406 (Image cath fluid peri/retro
- 57120 (Closure of vagina)
- 57310 (Repair urethrovaginal lesion)
- 58260 (Vaginal hysterectomy)
- 58262 (Vag hyst including t/o)
- 58543 (Lsh uterus above 250 g)
- 58544 (Lsh w/t/o uterus above 250 g)
- 58553 (Laparo-vag hyst complex
- 58554 (Laparo-vag hyst w/t/o compl)
- 58573 (Tlh w/t/o uterus over 250 g)
- 63046 (Remove spine lamina 1 thr)
- 63055 (Decompress spinal cord thc)

Nine Codes Removed from Inpatient-Only List

- 0312T (Laps impltj nstim vagus)
- 20936 (Sp bone agrft local add-on)*
- 20937 (Sp bone agrft morsel add-on)*
- 20938 (Sp bone agrft struct add-on)*
- 22552 (Addl neck spine fusion)*
- 27477 (Surgery to stop leg growth)
- 27485 (Surgery to stop leg growth)
- 54411 (Remov/replc penis pros comp)
- 54417 (Remv/replc penis pros compl)

*Packaged

2016 ASC Device-Intensive Codes

- Maintains 2015 policy change
  - Device offset percentage greater than 40 percent based on the device cost in HOPD setting
- Device intensive codes decreased from 137 in 2015 to 131 in 2016
- CMS will deduct device offset amount if procedure discontinued prior to anesthesia

Packaged Codes

- Packaged surgical codes:
  - 349 in 2016 up from 330 in 2015
- N1 ancillary codes:
  - 891 in 2016 up from 882 in 2015

OPPS APC Restructuring

- Continued restructuring from 2015, CMS proposes to restructure APCs into nine clinical families
- Move to consolidate codes into fewer APCs
- Consistent with other CMS policies to move toward episodic payments and less procedure-specific

2016 Final Physician Payment Rule

- Cataract and Endoscopic Sinus Surgery in an Office-Based Setting

- Merit-Based Incentive Payment System and EHR Technology

No action taken regarding office-based payment for certain procedures

- CMS sought stakeholder feedback on the ability to perform cataract surgeries in a physician office.
  - Also seeking input on appropriate direct practice expense (PE) inputs for non-facility setting

- CMS requested stakeholder input on appropriate direct PE inputs when endoscopic sinus surgery performed in non-facility setting.
  - Previous stakeholder feedback indicated changes in technique and technology allow for these procedures to be performed in non-facility setting

Merit-Based Incentive Payment System (MIPS) and Electronic Health Record (EHR) Technology

- CMS has started outlining plan for MIPS created under recent legislation.
- CMS is also making changes regarding EHR technology certification and submission of data through EHR technologies.
- Concerns regarding impact on ASC physicians due to lack of ASC EHR technology

Survey and Certification

- Top Citations in 2015
- Conditions for Coverage (CfCs)
  - Emergency preparedness?
  - Life Safety Code?
- Drug Supply Chain Security Act (DSCSA)
- Interpretive Guidelines
  - Radiologist on staff
  - Physician discharge
  - OR/Procedure Room Language
  - Hospital transfer agreement
  - Distinct entity language?
  - Infection control worksheet

2015 CMS Health Survey Citations
(Based on 1256 total surveys)

Q0241	SANITARY ENVIRONMENT (394)
Q0181	ADMINISTRATION OF DRUGS (342)
Q0242	INFECTION CONTROL PROGRAM (286)
Q0162	FORM AND CONTENT OF RECORD (220)
Q0101	PHYSICIAL ENVIRONMENT (181)
Q0141	ORGANIZATION AND STAFFING (153)
Q0221	NOTICE OF RIGHTS (138)
Q0261	ADMISSION ASSESSMENT (133)
Q0043	DISASTER PREPAREDNESS PLAN (119)
Q0104	SAFETY FROM FIRE (119)

Emergency Preparedness Proposal ASCA Concerns

- Community-based requirements
- Arrangements with other ASCs and providers to receive patients?
- Track patients & release patient information to family and others in a timely manner

Life Safety Code (LSC) Proposal

- Proposed adoption of 2012 edition of the LSC
- Windowless anesthetizing locations: “ASC must have a supply and exhaust system that:
  - (i) Automatically vents smoke and products of combustion,
  - (ii) Prevents recirculation of smoke originating within the surgical suite, and
  - (iii) Prevents the circulation of smoke entering the system intake.”

Drug Supply Chain Security Act (DSCSA) Track and Trace Implications for ASCs

Legal Requirements for Dispensers

ASCs as Dispensers: Assuming an ASC is "authorized by law to dispense or administer prescription drugs," it **would** meet the definition of "dispenser" under the DSCSA.

- As of **January 1, 2015**, dispensers must be "authorized" trading partners (have a valid license under state law).
- Drug Manufacturers and repackagers: Must register with FDA. State registration or licensure requirements may apply.
- Wholesale distributors: Must have valid license under state law.

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm

Track and Trace Cont'd

Exemption that May Apply to ASCs

- Dispenser requirements for product tracing and verification do not apply to "licensed health care practitioner"
  - "any person licensed or authorized by State law to prescribe drugs." 21 CFR 203.3(r)

Future Requirements

- November 27, 2020: Unique product identifier on certain prescription drug packages (i.e., bar code that can be easily read electronically)
- November 27, 2023: Dispensers must exchange transaction information and transaction statements, including product identifier at the package level, in an interoperable electronic manner.

CMS' Interpretive Guidelines (IGs)

- Revised April 2015
- First revision since 2013
- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf

§416.49 (b)(1) Radiologic Services, Q-0203

- ASC providing radiologic services must comply with following hospital Condition of Participation (CoP) for radiologic services:
  - §482.26(b) (Safety for patients and personnel),
  - (c)(2) (Only qualified personnel may use radiologic equipment and administer procedures) and
  - (d)(2) (Maintenance for at least 5 years of certain records of radiologic services).

*Prior regulation required the ASC to comply with the entire hospital radiologic services CoP.

§416.49 (b)(2) Radiologic Services, Q-0204

- *If radiologic services are utilized:*
  - *governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.*

§416.52 (c)(2) Discharge, Q-0266

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

§416.52 (c)(2) Discharge, Q-0266

- *It is permissible for the operating physician to write a discharge order indicating "the patient may be discharged when stable."*

- *In such cases there must be documentation of when patient was stable.*

Physician Discharge, Cont'd

- Discharge order must be signed by the operating physician

- Interpretive Guidelines : It is expected patient will leave ASC within 15-30 minutes of physician signing discharge order *or when he or she was found to be stable, whichever happens later*.

Procedure Room Clarification

Interpretive Guidelines: §416.44(a)(1)

"State Agencies may wish to assign surveyors who are trained in evaluating healthcare facility design and construction assist in evaluating compliance with this standard. "Operating room" (*OR*) in an ASC includes *not only traditional ORs, but also* procedure rooms, *including those where surgical procedures that do not require a sterile environment are performed*.

Procedure Room Clarification Cont'd.

ORs must be designed in accordance with industry standards for the types of surgical procedures performed in the room, *including whether the OR is used for sterile and/or non-sterile procedures.*

Existing ORs must meet the standards in force at the time they were constructed, while new or reconstructed ORs must meet current standards. Although the term "OR" includes both traditional ORs and procedure rooms, this does not mean that procedure rooms must meet the same design and equipment standards as traditional operating rooms. In all cases, the OR design and equipment must be appropriate to the types of surgical procedures performed in it."

Hospital Transfers - §416.41(b)(1) Local Requirement

- **When closest hospital cannot accommodate**: "***another hospital that is able to do so and which is closer than other comparable hospitals***"
- **Appropriate type of hospital:** ***Long term care hospital within five miles and short-term acute care hospital with emergency services within fifteen miles, ASC expected to transfer to short-term acute care hospital.***
- **Multiple appropriate hospitals*: "Three comparable, appropriate hospitals within ten mile radius of the ASC, transfer to any acceptable."***
- **Hospital Transfer Agreements:** ***Emergency transfers ordinarily made to hospital ASC has arrangement to meet §416.41(b)(2) and (3).***

Distinct entity

ASC Infection Control Surveyor Worksheet (revised 6/26/15)

- Surveyors will use this document during the on-site survey in order to determine compliance with the Infection Control Condition for Coverage.

- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-43.pdf

New Language in the ASC Infection Control Worksheet

- When observation of a practice is not available, the surveyor “should attempt to assess the practice by interview or documentation review;
- No artificial fingernails and/ or extenders when having direct contact with patients;
- Recording the beyond use date;
- Multi-dose medication vials;
- Immediate Use Steam Sterilization;
- Point of care testing devices;
- Obligation on the surgery center to report identified breaches to state authorities.

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

Quality Reporting Update

- No new measures
- 2% reduction continues for 2016
- ASC-1 through ASC-5: Continuation of 50% threshold for claims-based measures
- ASC-8: May 15, 2016 reporting deadline
- ASC-6 – ASC-10: August 15, 2016 reporting deadline maintained
  - Sample sizes remain for ASC-9 and ASC-10
- Exemption for low Medicare volume remains
  - fewer than 240 claims

Quality Measure Summary

Measure	Where to Report
1. Patient Burn	Claims
2. Patient Fall	Claims
3.Wrong Site, Side, Patient, Procedure, Implant	Claims
4.Hospital Admission/Transfer	Claims
5. Prophylactic IV Antibiotic Timing	Claims
6. Safe Surgery Check List Use	QualityNet
7. Volume of Certain Procedures	QualityNet
8.Influenza Vaccination Coverage Among Health Care Workers	NHSN
9. Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients	QualityNet
10. Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	QualityNet
11. Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	QualityNet
12. Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	NA

Key Points to Remember

- Log into QualityNet secure portal (ASC 6-, 7, 9 & 10) & NHSN (ASC-8) to keep passwords active
- ASC 7 (volume data measure): need to fill in all procedures listed in QualityNet even if your volume is zero
- ASC 9 and 10 (colonoscopy measures): need to fill in the numerator and denominator even if the number is zero and your facility does not perform colonoscopies

ASC 12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

- Administrative Claims based measure
  - Utilizes paid Medicare Fee for Service (FFS) claims
- No additional data submission from ASCs
- Finalized for CY 2018 payment determination
- Measure **outcome** is all unplanned hospital visits (admissions, observation stays, and emergency department [ED] visits) within 7 days of procedure

When does data become public?

- ASC-6 & ASC-7 data from 2012 (reported in 2013) became publicly available in October.
- ASC-1 through ASC-5 data becomes publicly available April 2016 for data submitted in 2013, 2014 and *maybe* 2015
  - Unless facilities chose to suppress this data

Data Suppression

- CMS announced ASCs could choose to suppress ASC-1 through ASC-5 data for 2013 and/or 2014
- There were 332 requests
  - CY 2013 only = 242
  - CY 2014 only = 8
  - Both years = 82

Measures Under Consideration

- **Outpatient and Ambulatory Patient Experience of Care Survey Instrument**

- **Normothermia**
  - ASC patients receiving general, spinal or epidural anesthesia lasting 60 minutes or greater are normothermic (96.8F) within 15 minutes of arrival to the PACU

- **Unplanned anterior vitrectomy**
  - ASC patients having cataract surgery who have experienced an unplanned anterior vitrectomy

What is an ASC? Video

Contact Information

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