Regulatory Changes in the ASC
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ASOA Symposium & Congress
April, 2014

Financial Disclosure

• Crissy is a consultant for Progressive Surgical Solutions, LLC.

Objectives

• Overview of recent regulatory changes
  • CMS
  • HIPAA
  • OSHA
  • TB Plan
  • Surgical Site Infection Surveillance
  • Mandatory Quality Reporting
• Know what to implement in order to assure compliance
CMS

- Revised version of State Operations Manual – Appendix L
- 1/31/14

CMS – Patient Rights

416.50 Patient Rights

- Inform Surrogate, in addition to the patient, of patient rights
- Post the written notice in “a place or places” where it is likely to be noticed by patients waiting for surgery or by the patient’s representative or surrogate

Interpretive Guidelines 416.50

- “Patients representative or surrogate is an individual designated by the patient to make health care decisions on behalf of the individual or to otherwise assist the patient during his/her stay at the ASC.”

CMS – Patient Rights (cont)

416.50 (a) Notice of Rights, Q-0221

- Provide verbal and written notice of the patient rights to the patient and surrogate prior to the start of the procedure.
- Include address and telephone number of the State agency as well as the web site for the Office of the Medicare Beneficiary Ombudsman within the Patient Rights.
- Medicare Beneficiary Ombudsman is to assist Medicare beneficiaries in the receipt of information they need to understand their Medicare options.
  http://www.medicare.gov/ombudsman/resources.asp
CMS – Advance Directives

• A blanket statement of refusal by the ASC to comply with any patient advance directives is not permissible.

CMS – Advance Directives (cont)

• Living Will
  • Legal document used to make wishes known about life prolonging medical treatments

• Medical Power of Attorney
  • Manages medical care

• Power of Attorney
  • Manages financial affairs
  • NOT considered part of an Advance Directive

CMS – Advance Directives (cont)

Interpretive Guidelines 416.50(c):

• Each ASC patient has the right to formulate an advance directive consistent with applicable State law and to have ASC staff implement and comply with the advance directive, subject to the ASC’s limitations on the basis of conscience. The ASC must respect the patient’s wishes and follow that process.
CMS – Advance Directives (cont)

- Basis of Conscience
  - Elements of an Advance Directive may be denied if the provider, in good conscience, does not feel he/she can authorize it
  - Develop a list of limitations for the facility
    - Ensure list of limitations are within those allowed by your State
    - If allowed under state law, include limitation language such as: always attempt to resuscitate a patient and transfer that patient to a hospital in the event of deterioration.
  - Educate your staff and include your Governing Body in this process

CMS – Emergency Equipment

416.44 (c) Emergency Equipment; Q-0105

.....specify the types of emergency equipment required for use in the ASC’s operating room.

- The equipment must meet the following requirements:
  - (1) Be immediately available for use during emergency situations.
  - (2) Be appropriate for the facility’s patient population.
  - (3) Be maintained by appropriate personnel.

CMS – Emergency Equipment (cont)

416.44 (c) Interpretive Guidelines

- No specific list of emergency equipment
- Maintain “comprehensive, current and appropriate set of emergency equipment, supplies and medications that meet current standards of practice and are necessary to respond to a patient emergency in the ASC.”
CMS – Physical Environment

Q-0101 (Temperature and Humidity)

• Temperature: Each operating room should have separate temperature control.
• Humidity: An example of an acceptable humidity standard for ORs is the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. Addendum D of the ASHRAE standard requires RH in ORs to be maintained between 20 - 60 percent.

CMS – Infection Control Surveyor Worksheet

• Medications that are pre drawn include the date and time of the draw, the initials of the person drawing, medication name, strength, and discard date and time.
• The multi-dose vial can be dated with either the date opened or the new expiration date, as long as it is consistent with ASC policy.
• Glucometer: if the manufacturer’s guidelines do not include directions for cleaning and disinfection, it must not be used for more than one patient.

HIPAA Changes

• Changes effective 3/26/13
• HIPAA Compliance date was 9/23/13:
  • Breach Notification of PHI
  • Disclosures to Health Plans
  • Electronic PHI
  • Notice of Privacy Practices
• Business Associate Agreement
  • Compliance date is 9/22/14
• Enforcement Changes
  • Four culpability tiers corresponding to penalty amounts
  • Fines range from $100 - $50,000 per violation
OSHA

- Hazard Communication Standard (HCS)
- Safety Data Sheets (SDS) – formerly known as Material Safety Data Sheets (MSDS)
- Labeling
- Information and Training
  - December 1, 2013
- Manufacturers/Importers/Distributors
  - June 1, 2015

OSHA (cont)

- Safety Data Sheets (SDS)
  - Standardized 16-section format
  - Labeling related to SDS
  - List of Hazardous Substances in Facility
- Labeling
  - Must include the following:
    - Product Identifier
    - Signal Word
    - Pictogram
    - Hazard Statement
    - Precautionary Statement
    - Name/Address/Phone Number of Manufacturer, Distributor or Importer

OSHA (cont)

- OSHA Resources:
  - A Guide to GHS
    - https://www.osha.gov/dsghazcom/ghs.html#1.1
  - Hazard Communication Standard
  - Model Plans & Programs for the OSHA Bloodborne Pathogens & HCS
    - https://www.osha.gov/Publications/osha3186.html
  - HCS QuickCards
    - https://www.osha.gov/dsghazcom/ghsquickcards.html
  - Downloadable Pictograms
The 1994 CDC TB control recommendations were updated in 2005 to maintain momentum to avert another TB resurgence and to eliminate the lingering threat to HCWs, which is mainly from infected patients.

**Source of Policy Change:**

- “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005”, the CDC states transmission to HCWs “varies by setting, occupational group, prevalence of TB in the community, patient population, and effectiveness of TB infection control measures”.

The risk assessment for settings in which patients with suspected or confirmed TB Disease are not expected to be encountered should consist of:

- Community profile review of TB disease in collaboration with the local or state health department
- Consult with the local or state TB control program to obtain surveillance data in order to conduct a TB Risk Assessment
- Determine if persons with unrecognized TB disease were encountered in the setting during the previous 5 years
- Determine if any HCWs need to be included in the TB screening program
- Document procedures that ensure the prompt recognition and evaluation of suspected HCW associated transmission
- Conduct annual reassessments
- Recognize and correct lapses in infection control
TB Plan (cont)

• The facility risk assessment is based on a three-level hierarchy of controls including administrative, environmental and respiratory protection
  • First Level of Hierarchy – Administrative Controls
  • Second Level of Hierarchy – Environmental Controls
  • Third Level of Hierarchy – Respiratory Protection Control

TB Plan (cont)

• Examples of Administrative Controls:
  • Assigning responsibility for TB infection control
  • Conducting a TB risk assessment to confirm low risk status
  • Implementing a written TB infection control program
  • Implementing effective work practices for the management of suspected TB disease
  • Training and educating HCWs regarding TB
  • Screening and evaluating HCWs
  • Using appropriate signage advising respiratory hygiene and cough etiquette
  • Coordinating efforts with the local or state health department

TB Plan (cont)

• Examples of Environmental Controls:
  • Control source of infection
  • Proper ventilation and air exchanges, per HVAC requirements for an ASC
  • Environmental control maintenance procedures and logs should be maintained
• Examples of Respiratory Protection Control:
  • Training patients on respiratory hygiene and cough etiquette procedures
  • Train HCWs in respiratory protection
  • Isolate any patient suspected of a communicable disease

• Employee Education
  • Overview of TB infection control program, including the hierarchy of TB infection control measures, written policies, monitoring and control measures for HCWs at increased risk for exposure
  • Proper implementation and monitoring of environmental controls
  • Roles of CDC and OSHA
  • Reporting responsibility of the facility

• Tuberculin Skin Test (TST) Testing
  • “PPD” has been changed to “TST”
  • Screen all paid and unpaid persons working in the ASC who have potential for exposure to M. tuberculosis through air space shared with persons with infectious TB disease for the presence of inactive or active Tuberculosis at the time of employment. Two-step TB protocol will be utilized for all new HCWs.
Surgical Site Infection (SSI) Surveillance

- Part of IC Program of ASC
- Query surgeons regularly (monthly)
- 30 days surveillance for all surgical procedures
- 30 or 90 days surveillance for Deep Incisional or Organ/Space SSI

SSI Surveillance (cont)

- National Healthcare Safety Network (NHSN) Surgical Site Infection Surveillance (SSI):
  - Use this document as source of facility policy
  - Breast, Gallbladder, Colon, various Orthopedic procedures, Abdominal and Vaginal Hysterectomy (CPT codes) require some 30 and 90 day surveillance
  - Report as required by state:
    - CO, MA, NV, NH, NJ, TX, MD

Mandatory Quality Reporting

- Began 10/1/12
- Claims-Based Measures
- Web-Based Measures
- Outcome Measures
- Process of Care Measures
- 2014 Final Rule
Mandatory Quality Reporting (cont)

• Reporting Period 1/1/14 - 12/31/14
  • ASC-1: Patient Burn
  • ASC-2: Patient Fall
  • ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
  • ASC-4: Hospital Transfer/Admission
  • ASC-5: Prophylactic IV Antibiotic Timing
• 4 outcome measures & 1 process of care measure reported using G-codes
• Payment affected CY 2015

Mandatory Quality Reporting (cont)

• Reporting Period 7/1/15 – 8/15/15 (for 1/1/14 – 12/31/14)
  • ASC-6: Safe Surgery Checklist Use
  • ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures
• 2 web-based measures reported using QualityNet (www.qualitynet.org)
• Payments affected CY 2016

Mandatory Quality Reporting (cont)

• Reporting Period 10/1/14 – 3/31/15
  • ASC-8: Influenza Vaccination Coverage among HCP
  • All HCP including employees, LIPs, students/trainees and volunteers
  • Ancillary contract personnel (optional)
  • Must track reason for declination (as applicable)
• Process of care measure reported via CDC’s National Healthcare Safety Network (www.cdc.gov/nhsn/)
• Payments affected CY 2016
Mandatory Quality Reporting (cont)

- ASC-8: Influenza Vaccination Coverage among HCP
  - Operational Guidance for ASCs (CDC)
    - Encourages monthly updates (i.e., all October data should be added by November 30)

Mandatory Quality Reporting (cont)

- Reporting Period 1/1/15 – 8/15/15 (for 1/1/14 – 12/31/14)
  - ASC-9: Endoscopy/Polyp Surveillance – appropriate follow-up interval for normal colonoscopy in average risk patients
  - ASC-10: Endoscopy/Polyp Surveillance – colonoscopy interval for patients with a history of adenomatous polyps – avoidance of inappropriate use
  - Sampling size specifications have been established
  - Web-based measures reported via QualityNet ([www.qualitynet.org](http://www.qualitynet.org))
  - Payments affected CY 2016

Mandatory Quality Reporting (cont)

- ASC-11: Cataracts – improvement in patient’s visual function within 90 days following cataract surgery
  - Sampling size specifications have been established
  - Web-based measures reported via QualityNet ([www.qualitynet.org](http://www.qualitynet.org))
  - Delayed until January 1, 2015
    - 2015 ASC Final Rule
Mandatory Quality Reporting (cont)

- Currently paid for reporting but will eventually evolve into paid for performance
- Add measure results/benchmarking into your QAPI program to look for improvement opportunities
- Measures will continue to evolve and change

Remain Compliant

- Stay informed and involved!!
- Regulations/Requirements are constantly evolving
- Surveys increasing by multiple government organizations
- Make necessary changes to remain compliant

Resources

- [www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/ASCs.html](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/ASCs.html)
- [www.hhs.gov/ocr/privacy/](http://www.hhs.gov/ocr/privacy/)
- [www.osha.gov/dsg/hazcom](http://www.osha.gov/dsg/hazcom)
- [www.cdc.gov/tb/publications/guidelines/infectioncontrol.htm](http://www.cdc.gov/tb/publications/guidelines/infectioncontrol.htm)
• www.qualitynet.org
• www.ascquality.org
• www.cdc.gov/nhsn/
• www.ooss.org
• www.ascassociation.org

State ASC Associations

Questions?

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