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CMS Regulatory Update at a Glance

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Outline

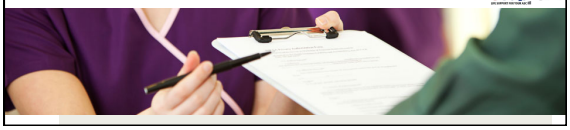
- CMS
  - **Patient Rights**
    - Notice of Patient Rights
    - Advance Directives
  - **Emergency Equipment**
  - **Physical Environment**
    - Humidity
    - MSDS/SDS
  - **Infection Control**
    - IC Surveyor Worksheet
    - SSI Surveillance
    - TB

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Patient Rights

416.50 Patient Rights

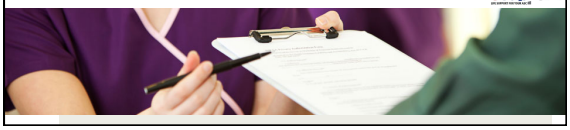
- Inform Surrogate, in addition to the patient, of patient rights
- Post the written notice in "a place or places" where it is likely to be noticed by patients waiting for surgery or by the patient's representative or surrogate



Patient Rights (cont.)

Interpretive Guidelines 416.50

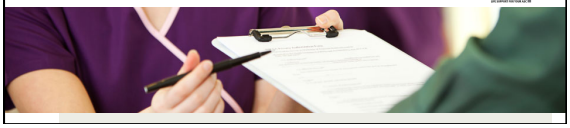
- "Patients representative or surrogate is an individual designated by the patient to make health care decisions on behalf of the individual or to otherwise assist the patient during his/her stay at the ASC."



Patient Rights (cont.)

416.50 (a) Notice of Rights, Q-0221

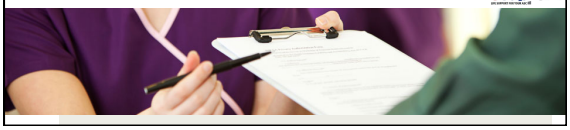
- Provide verbal and written notice of the patient rights to the patient and surrogate prior to the start of the procedure.
- Include address and telephone number of the State agency, as well as the web site for the Office of the Medicare Beneficiary Ombudsman within the Patient Rights for submission of complaints and grievances.



Patient Rights (cont.)

- 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

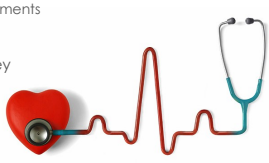


Advance Directive Interpretive Guidelines

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

Advance Directive (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



Advance Directive Interpretive Guidelines

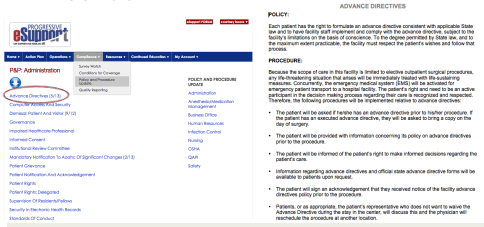
- Each ASC patient has the right to formulate an advance directive consistent with applicable State law and to have ASC staff implement and comply with the advance directive, subject to the ASC's limitations on the basis of conscience. The ASC must respect the patient's wishes and follow that process.

Advance Directive Interpretive Guidelines (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

Advance Directive Interpretive Guidelines (cont.)

- Available on eSupport:
  - Compliance/ Policy and Procedure Update/Administration/ Advance Directives
  - Compliance/Conditions for Coverage/Interpretive Guidelines March 2013



Emergency Equipment

416.44 (c) Emergency Equipment; Q-0105

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

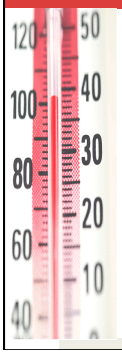
- The equipment must meet the following requirements:
  - (1) Be immediately available for use during emergency situations.
  - (2) Be appropriate for the facility's patient population.
  - (3) Be maintained by appropriate personnel.

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.

Physical Environment (cont.)



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.

Safety Data Sheets

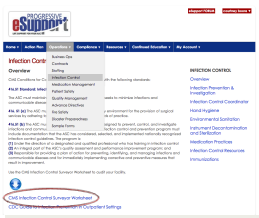
- Safety Data Sheets (formerly known as Material Safety Data Sheets)
  - Written March 26, 2012
  - Effective December 1, 2013
    - Must train employees on new labeling requirements
    - List all chemicals, as before
    - Change verbiage to Safety Data Sheets

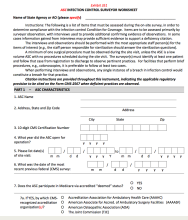
Infection Control Surveyor Worksheet

- 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 manufacturers guidelines do not include directions for cleaning and disinfection, it must not be used for more than one patient

Infection Control Surveyor Worksheet (cont.)

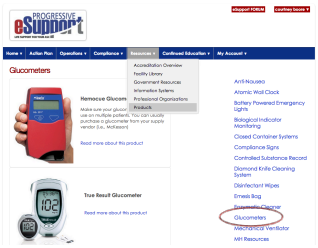
- http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf
- Available on eSupport:
  - Operations/Infection Control/Overview





Infection Control Surveyor Worksheet (cont.)

- Available on eSupport:
  - Resources/Products/Glucometers



CDC National Healthcare Safety Network

- CDCs National Healthcare Safety Network revision for acute care
  - Report by CPT code
  - Breast, Gallbladder, Colon, Hernia, various Orthopedic procedures, Abdominal and Vaginal Hysterectomy
  - Reporting is required for 30 and/or 90 days depending on procedure

Surgical Site Infection (SSI)

"Wait, this one's a lawyer. We'd better wash our hands."

- Part of IC Program of ASC
  - Monitor all cases, as before
    - 30 days surveillance for Superficial SSI
    - 90 days surveillance for Deep Incisional and Organ/Space SSI
  - Implant surveillance for 90 days instead of 1 year

SSI State Based Reporting Requirements to NHSN

- Colorado
- Massachusetts
- Nevada
- New Hampshire
- New Jersey
- Texas

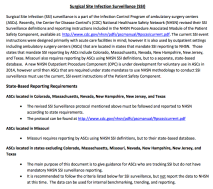
http://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf

SSI State Based Reporting Requirements

- Missouri
  - Need to measure the same NHSN SSI definitions
  - No need to report to NHSN
  - Report to state based database

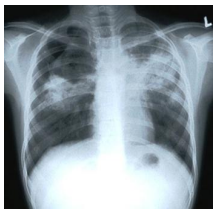
SSI State Non Mandatory Reporting

- Can follow definition for CPT Code Reporting but use internally; no need to report
- Available on eSupport:
  - Operations/Infection Control/Infection Prevention & Investigation



TB

- 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".

TB Control Program Hierarchys

- The facility TB infection control program is based on a three-level hierarchy of controls including administrative, environmental and respiratory protection

Administrative Controls: first level of hierarchy

1
2
3

- 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

Environmental Controls: second level of hierarchy

1
2
3

- Control source of infection
- Proper ventilation and air exchanges, per HVAC requirements for an ASC
- Environmental control maintenance procedures and logs should be maintained

Respiratory Protection Control: third level of hierarchy

1
2
3

- The ASC will implement the following respiratory controls:
  - Training patients on respiratory hygiene and cough etiquette procedures
  - Train HCWs in respiratory protection
  - Isolate any patient suspected of a communicable disease
- **ISOLATION OF THE PATIENT:**
  - Patients with known active cases of TB will not be admitted to this facility. Should a patient be identified after admission, he/she must be isolated until transfer to another facility can be arranged. The isolation is designed to prevent airborne spread of the bacillus. The isolation will be in a previously identified room with a door that can be closed until the patient can be assessed and transferred. Adequate time should elapse to ensure removal of M. tuberculosis contaminated room air before allowing entry by staff or another patients.

Low Risk Facility

1
2
3

- A facility is considered low risk if persons with TB disease are not expected to be encountered. Outpatient settings are considered low risk if there were less than 3 TB patients for the previous year cared for at the facility.
  - Respiratory masks will not be provided as it is not recommended by the CDC for low risk environments.

TB Risk Assessment

- 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 date 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
  - Determine the types of administrative and environmental controls are in place
  - Document procedures that ensure the prompt recognition and evaluation of suspected HCW associated transmission
  - Conduct annual reassessments
  - Recognize and correct lapses in infection control

TST Testing

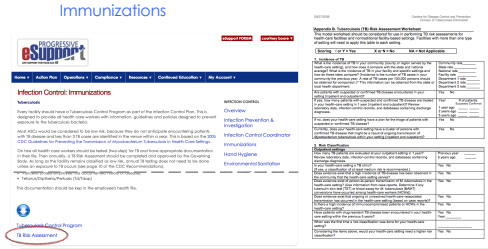
- "PPD" has been changed to "TST"
- Screen all paid and unpaid persons working in the ASC who have potential for exposure to M. tuberculosis through air space shared with persons with infectious TB disease for the presence of inactive or active Tuberculosis at the time of employment. Two-step TB protocol will be utilized for all new employees.
- Testing upon hire only unless symptomatic or exposure has occurred.

Employee Education - TB

- 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

PSS TB Policy Changes

- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm
- Available on eSupport: Operations/Infection Control/ Immunizations



Coming Attractions

- Radiology Supervision
- Compounding
  - 797 and immediate use
  - Manufacturing?
  - Compounding
    - Who
    - Per patient?
    - Hood?
  - State by State?
  - FDA?

Coming Attractions

- Infection Tracking
  - CDCs National Healthcare Safety Network (NHSN)Outpatient Procedure Component (OPC) projected to be released in 2014

Questions?

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