OSHA and CMS Requirements: What ASCs Need to Know
Objectives

1. Understand the implications of the OSHA Bloodborne Pathogens (BBP) Standard for ASCs, particularly around sharps safety and exposure avoidance.
2. Write a BBP Exposure Control Plan.
3. Know the purpose of the CMS requirements.
4. Understand the required elements of a CMS survey.

Types of Requirements

- Regulations
  - Federal
  - State & Local
- Accreditation
- Guidelines & Standards

Regulatory Agencies

- Occupational Safety and Health Administration (OSHA)
- Centers for Medicare and Medicaid Services (CMS)
- Environmental Protection Agency (EPA)
- Department of Transportation (DOT)
- Food and Drug Administration (FDA)
- State and local health departments
State & Local Regulations

• Requirements for infection surveillance, prevention and control programs
• Notifiable disease reporting – all states
• Medical waste handling & processing
• Food safety and sanitation
  – State occupational safety & health

OSHA

• Federal Occupational Safety & Health Administration
• Laws regarding worker safety
• Employers must provide a safe & healthful workplace, mitigate hazards, protect employees
• “State Program State” – requirements at least as stringent as OSHA, run by state

Bloodborne Pathogens

29 CFR 1910.1030

• Published in 1991
  Needlestick Safety and Prevention Act
  
• Published in 2001, amended BBP Standard
• Eliminate or minimize employee exposure

Who is Covered?

- Employees, volunteers
- Students covered by school policy
- If ASC is a corporation, the owners (surgeons) are employees of the corporation.
- If not, the owner(s) may not be considered an employee and may not have to comply, but must ensure the employees DO comply

Bloodborne Viral Diseases

- HBV (Hepatitis B Virus)
- HCV (Hepatitis C Virus)
- HIV (Human Immunodeficiency Virus)
- GOK

OPIM- Other Potentially Infectious Materials

- Semen; vaginal secretions
- Synovial, pleural, cerebrospinal, peritoneal, amniotic, or pericardial fluids
- Any fluid with visible blood
- Saliva (dental procedures only)
Not Considered Infectious by OSHA

Per OSHA, UP does NOT apply to:
- Saliva
- Tears
- Urine
- Stool
- Mucus
- Sputum
- Vomit

UNLESS they contain visible blood

BBP Exposure Control Plan

- Exposure determination (jobs with exposure potential, those without)
- Schedule and implementation for
  - Methods of compliance
  - Hepatitis B vaccination & testing
  - Exposure management
  - Communication of hazards to employees
  - Recordkeeping (medical, training)

BBP Exposure Control Plan

- Accessible copy of Plan
- Annual review and revision as needed
  - Updated safety products available
  - Safety products selected, justification
  - Input from front-line users for effective Engineering, Work Practice Controls & Personal Protective Equipment
- If there is a safety product available, you MUST use it!
OSHA Hierarchy of Control Measures

• Engineering Controls - FIRST
  – Hardware: safety sharps devices, sharps containers

• Work Practice Controls - SECOND
  – Policies and procedures: Don’t recap needles, use sharps containers, use safety devices

• Personal Protective Equipment- LAST
  – Gloves, gowns, masks, eye protection, etc.

Methods of Compliance

• Universal (Standard) Precautions
• Engineering & Work Practice Controls- if risk still remains, use PPE
• Handwashing stations, alcohol hand rinse
  – Must clean hands on removing gloves/PPE
  – Must wash off any blood or OPIM ASAP

Methods of Compliance

• Contaminated Sharps
  – Do not recap; if no alternative use recapping device
  – Do not remove needle unless no alternative, use mechanical means, e.g. Kelly clamp
• Immediately place in sharps container
  – Rigid, puncture-resistant, labeled, leak proof
Work Practice Controls

- Eating, drinking, smoking, applying lip balm, handling contacts prohibited in areas where exposure to BBP is likely
- Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood/OPIM are present
- Perform all procedures to minimize spraying, splashing, aerosolizing

Work Practice Controls

- Mouth pipetting blood/OPIM prohibited
- Specimen containers must prevent leaking during collection, handling, processing, storage, transport, or shipping

Work Practice Controls

- The container for storage, transport, or shipping shall be labeled or color-coded and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding is not necessary provided containers are recognizable as containing specimens.
- This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding is required when such specimens/containers leave the facility.
Work Practice Controls

• If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

Universal Precautions

• Standard Precautions- CDC
• Method of infection control
• All blood & body fluids considered infectious
• Measures taken to reduce risk of exposure

Standard Precautions
Personal Protective Equipment

• If it’s wet and not yours, wear gloves!
• Gown if soiling clothing is likely
• Face, eye protection if spraying likely
• When handling soiled instruments
• Handling soiled linens
Hepatitis B Vaccine

- All workers with exposure potential
- After initial training, within 10 days of starting
- 3 doses, 0, 1 & 6 months, test for antibody
- 80-95% effective
- Soreness at injection site
- Will not cause HIV or HBV
- No booster required (yet!)

Exposures to BBP

- Stuck/cut by contaminated needle or other sharp
- Blood/OPIM in cut or sore
- Sprayed or splashed in face
- Must have procedure for management
- Recommend contract with Occupational Medicine Clinic

Post-Exposure Evaluation

- Test source for HBsAg, HCV, HIV
- Test worker for HBsAb, HCV, HIV
- Rapid HIV if possible
- If source HIV+, start treatment with antivirals
- If source HBV+ & worker not vaccinated, give HBIG and vaccine
- No treatment for HCV, test at 1 & 6 months
Information Provided to Medical Professional

• Copy of regulation
• Employee’s duties around exposure
• Routes and circumstances of exposure
• Results of source patient testing if available
• Employee HBV vaccine status, testing

Medical Professional’s Opinion

• Written report within 15 days of evaluation
• Include only that employee has been informed of results of the evaluation
• The employee has been told of any medical conditions resulting from exposure that require follow-up and treatment
• All other diagnoses remain confidential

Employee Medical Records

• Each employee with occupational exposure
• Name, SSN, Hep B vaccine dates, testing
• Results of exams, medical testing, follow-up post exposure, opinion of medical professional, copy of information provided to medical professional
• Confidential
• Keep for duration of employment +30 years
### Sharps Injury Log
- Percutaneous injuries with contaminated sharp
- Type and brand of device
- Dept or work area where injury occurred
- How injury occurred
- NAMES kept confidential
- Maintain log per 29CFR1904.6
- Look for trends and patterns

### Infection After Needlestick
Percent + as result of exposure:
- HBV 6 - 30% (unvaccinated)
- HCV 0.2 - 2%
- HIV 0.3% (with meds, 0.01)

### Contaminated Sharps
Anything contaminated that can puncture skin:
- Used needles
- Razor blades
- Broken glass, metal
- Place in sharps box
- Containers must be appropriate for the size of the sharp
Regulated Medical Waste

- Definitions may vary by location
- Sharps can cause disease, trash no
- ONLY put in red bag what is required by law
- Blood/OPIM-caked, -soaked, would extrude if compressed or flake off
- ONLY use red bags for infectious waste

Laundry

- Bag at point of use, minimize handling
- Impermeable bag if wet, double bag if needed
- Minimum of agitation, no sorting, rinsing
- Color-coded bags or tags if sent off site and laundry doesn’t use Universal Precautions
- Employees use proper PPE (gloves)

Training

- Initial- within 10 days of start date
- Whenever job exposure risks change
- Annually (within 365 days) thereafter
- Language appropriate to level of worker
- Documented- keep 3 years
  - Names, job titles, dates, summary, name(s) & qualifications of instructor(s)
Training - Must Include

• Explanation of BBP Standard and contents
• Epidemiology and symptoms of BBP
• Modes of transmission
• Employer’s BBP Exposure Control Plan, where employee can get written copy
• Methods for recognizing risky tasks
• Engineering, Work Practice Controls
• PPE - type, location, limitations, disposal

Training - Must Include

• Basis for selection of PPE
• HBV vaccine safety, benefits, offered free
• Exposure incident, what to do, who to call
• Medical follow-up available post-exposure
• Signs, labels, color-coding
• An opportunity for interactive questions and answers with the person conducting the training session

OSHA Compliance Directives

• Used by OSHA inspectors - specify OSHA requirements for each standard
  - CPL 2-2.44D. Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens; Nov. 27, 2001

OSHA Inspections

• Some planned; many unannounced in response to:
  – Catastrophes and fatal accidents
  – Complaints, either employee or patient

OSHA Inspections

• Inspection process
  – request to see specific personnel
  – review documents & records, inspect site (walk around), interview employees
  – evaluate compliance
  – issue written findings
• Can result in citation, fines, and adverse publicity

Bloodborne Pathogens - Summary

• Written Exposure Control Plan
• Hand hygiene
• Safety sharps devices- employee input
• Appropriate PPE- employee input
• Exposure evaluation & follow-up procedure
• Plan updated annually
• Initial and annual training
• Record keeping- medical & training
Centers for Medicare and Medicaid Services (CMS)

- Federal agency that administers:
  - Medicare and Medicaid
  - HIPAA (Healthcare Insurance Portability and Accountability Act of 1996)
- Enforces federal quality standards for various healthcare settings

Centers for Medicare and Medicaid Services (CMS)

- Maintains oversight of ASCs, long term care facilities, home health agencies, intermediate care facilities, mental health facilities and hospitals
- Administers Quality Improvement Organizations (QIOs) at state level
- Conditions of Participation (COP) and Conditions for Coverage (CfC)

CMS Conditions for Coverage: Ambulatory Surgical Centers (ASC)

- New ASC Conditions for Coverage (CfC) effective May 18, 2009
- Interpretive Guidelines extensively updated to reflect new and revised CfC
- Added a CfC on “Infection Control”
What is an Ambulatory Surgical Center or ASC (per CMS)?

- Any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.
- The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the Conditions for Coverage (42 CFR 416.2 – 416.52)

What is Surgery per CMS? (1)

- Procedure performed for purpose of structurally altering the human body by incision or destruction of tissues
- Also: diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles

What is Surgery per CMS? (2)

- Also: Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system
CMS Conditions for Coverage: Ambulatory Surgical Centers (ASC)

- 416.51(a): Provide functional and sanitary environment
  - food sanitation
  - cleaning and disinfecting environmental surfaces, carpeting, and furniture
  - disposal of regulated and non-regulated waste
  - pest control
- Must monitor compliance

Policies And Procedures For Environment Should Also Address:

- Ventilation and water quality control, including measures taken to maintain a safe environment during internal or external construction/renovation;
- Maintaining safe air handling systems in areas with special ventilation, such as operating rooms

CMS Conditions for Coverage: ASC

- 416.51(b): Infection control program
  - Designed to prevent, control and investigate infections and communicable diseases
  - Based on nationally recognized guidelines
  - Led by individual who has training in principles and methods of infection prevention and control
CMS Conditions for Coverage: ASC

• 416.51(b): Infection control program
  – Must be integral part of ASC’s quality assessment & performance improvement program
  – Provides plan of action for preventing, identifying, and managing infections & communicable diseases & for immediately implementing corrective and preventive measures that result in improvement

CMS Conditions for Coverage: ASC

• §416.44(a)(3) retained: Physical environment. The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

Strategies for Complying with CMS Conditions of Coverage

• Review Conditions for Coverage and Interpretive Guidelines
  – Base strategies on interpretive guidelines
• Use CMS IC Surveyor’s Worksheet for self assessment
Survey Processes

• Focus on staff that do procedures
• Case tracer methodology
  – Surveyors required to follow at least one patient from admission through surgery and recovery to discharge
  – Observe for compliance with multiple CfC throughout, particularly at transition points
• Infection control survey tool

Surveyors Will Look for…(1)

• Explicit infection control program that follows nationally recognized guidelines
  • Consideration and selection documented
  • CDC/HICPAC guidelines for isolation, hand hygiene; disinfection/sterilization; AORN Perioperative Standards; others as appropriate
• Designated, qualified program director

Surveyors Will Look for…(2)

• System to actively identify infections related to ASC procedures
  – How information is obtained; documentation of tracking activity
  – Policy/procedure for notifiable diseases
• Staff receive IC training
  – How, who, frequency, documentation
Surveyors Will Look for…(3)

- Hand hygiene
  - Availability of soap and water and alcohol-based hand rubs
  - Will observe staff performance
    - After removing gloves, after direct patient contact, before invasive procedures, after contact with blood, body fluids, or contaminated surfaces
  - Glove use by staff

Surveyors Will Look for…(4)

- Appropriate injection practices (injectable medications, saline, other infusates) including anesthesia
  - Needles and syringes used for only one patient, one time
  - Medication vials entered with new needle and new syringe

Surveyors Will Look for…(5)

- Injection practices
  - Pre-drawn medications labeled with time drawn, initials person drawing, medication name, expiration date or time
  - Proper use of single and multi-dose vials, prefilled syringes, bags of IV solution and administration tubing
Surveyors Will Look for…(6)

• Appropriate practices for single use devices, sterilization and high-level disinfection
  – Single use device reprocessing
  – Critical devices/equipment sterilized
    • If on-site: methods; precleaning done; biological and mechanical quality monitoring done and documented
    • Handling/storage of sterilized items

Surveyors Will Look for…(7)

  – Semi-critical devices/equipment are high-level disinfected or sterilized
  – If on-site:
    • methods
    • precleaning done
    • chemicals prepared, tested and used according to manufacturer's instructions
    • items allowed to dry and properly stored
  • Will observe practices and check logs

Surveyors Will Look for…(8)

• Environmental infection control
  – ORs cleaned and disinfected after each surgical or invasive procedure with EPA registered disinfectant
  – ORs terminally cleaned daily
  – High-touch surfaces cleaned, disinfected
  – Procedure to decontaminate gross spills of blood
  – Overall maintenance and cleanliness
Surveyors Will Look for…(9)

• Point of Care Testing Devices
  – Use of blood glucose meter & fingersticks
    • New, single-use, auto-disabling lancing device used for each patient
    • Meter not used on more than one patient unless manufacturer’s instructions indicate this is permissible
    • Meter cleaned & disinfected after every use
  – Other devices can be assessed

Surveyors Will Also Look for… (10)

• Under §416.44 “Safe environment”
  – Conformance to aseptic and sterile technique by all individuals in surgical area
  – OR room attire suitable for surgical case performed; persons working in operating suite wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage

Surveyors Will Also Look for… (11)

• Under §416.44 “Safe environment”
  – Equipment available for rapid “emergency” high-level disinfection or sterilization
  – Policies/procedures for expiration dates developed and followed in accordance with accepted standards of practice
  – Temperature and humidity are monitored and maintained within accepted standards
Environmental Protection Agency (EPA)

- Pesticides
  - Includes disinfectants and sterilants used on inanimate objects and environmental surfaces
- Medical waste incinerators

Food and Drug Administration

- Regulates:
  - Medical devices, including reuse
  - Drugs for human and animal use
  - High level disinfectants and sterilants
  - Blood products
- Has oversight of glove testing, quality control and inspection

Food and Drug Administration

- Issues recall notices and safety alerts
  - e.g., Jan. 2009 - one brand of trays and kits recalled due to weakness in sterile package sealing
- You can subscribe to FDA MedWatch email alerts and Safety Alert RSS feeds at http://www.fda.gov/Safety/MedWatch
Department of Transportation (DOT)

- Regulates packaging and transport of regulated (infectious) medical waste

Mandatory & Public Reporting

- In addition to CMS, many states require reporting:
  - HAI related data
  - Some have public reporting
- Reporting indicators differ by state
  - Know your state reporting requirements
- APIC legislative map: www.apic.org
  - Click on “Public Policy” & “legislative map”

Surgical Care Improvement Project (SCIP)

- National partnership of organizations
- Improving surgical care quality by reducing surgical complications
- Not regulation but many SCIP measures have been incorporated into mandatory and public reporting program requirements
SCIP Measures

• Evidence-based practices
• Prophylactic antibiotic:
  • infused within one hour prior to incision
  • appropriate antibiotic selection for specified surgical procedure
  • discontinued within 24 hours after surgery (48 hours for cardiac surgery)

SCIP Measures

• Cardiac surgery patients with controlled 6 a.m. postoperative serum glucose
• Surgery patients with appropriate hair removal (clippers, not razors)
• Colorectal surgery patients with immediate postop normothermia

Accreditation Survey Prep

• Know standards requirements related to surveillance, prevention, and control of infection
• Conduct self assessment
  – Use forms and checklists
  – Conduct mock survey
• Prepare documents for review
• Educate self, staff and administration
• Network with colleagues
Guidelines and Standards

- Are not regulations
  - Often cited in regulations
- Are cited by accrediting agencies
- May become “Standard of Care”
- Based on scientific research or consensus if no research available
- Graded by level of evidence

Guidelines and Standards Agencies

- Centers for Disease Control & Prevention (CDC)
- Association for periOperative Registered Nurses (AORN)
- American Institute of Architects (AIA)
- Association for Professionals in Infection Control and Epidemiology (APIC)

Guidelines and Standards Agencies

- Association for the Advancement of Medical Instrumentation (AAMI)
- Advisory Committee on Immunization Practices (ACIP)
- Society for Healthcare Epidemiology of America (SHEA)
Centers for Disease Control and Prevention (CDC)

- Division of Healthcare Quality Promotion (DHQP)
  - Healthcare Infection Control Practices Advisory Committee (HICPAC)
  - National Healthcare Safety Network (NHSN)
- National Institute for Occupational Safety and Health (NIOSH)

Some CDC HICPAC Guidelines

- Hand Hygiene (2002)
- Isolation Precautions (2007)
- Environmental Infection Control (2003)
- Disinfection and Sterilization in Healthcare Facilities
- Prevention of Surgical Site Infections (1999)
- Management of Multidrug-resistant Organisms (2006)

Some CDC HICPAC Guidelines

- Management of Occupational Exposures to HIV (2005)
- Prevention of Transmission of M. tuberculosis (2005)
American Institute of Architects (AIA)

• Guidelines for the Design & Construction of Hospital and Health Care Facilities, 2009 (Paperback and CD-ROM)
  –Cited in many state construction regulations
  –Infection Control Risk Assessment (ICRA) cited by many state regulations

www.aia.org

Association for Advancement of Medical Instrumentation (AAMI)

• Consensus organization founded 1967
• Manufacturers and users of medical devices
• Guidelines for decontamination and sterilization (hospitals, ambulatory care)

www.aami.org

Association for Professionals in Infection Control and Epidemiology (APIC)

• Professional and Practice Standards
  –APIC/CHICA-Canada infection prevention, control, and epidemiology: Professional and practice standards

www.apic.org
Advisory Committee on Immunization Practices (ACIP)

- Recommendations for adult, adolescent, pediatric immunization
  - published in MMWR
  - Vaccine Information Sheets (VIS)
- We can assist in implementing immunization programs
  - patients & personnel
  
  www.cdc.gov/vaccines/recs/acip

Other Guidelines & Standards

- American Society for Gastrointestinal Endoscopy (ASGE)
  
  http://www.asge.org/WorkArea/showcontent.aspx?id=4300
- American Academy of Pediatrics
  - “Red Book” for infectious diseases

How Can We Ensure Compliance?

- Know requirements applicable to our setting
  - Obtain and disseminate copies of regulations, standards, and guidelines
- Educate self, administration and staff
How Can We Ensure Compliance?

• Monitor new and changing requirements
  – APIC, network with colleagues, monitor websites, receive electronic alerts
• Assist during surveys and inspections
• Serve as leader or member of performance improvement teams

How Can We Ensure Compliance?

• Assess compliance by observation, checklists, rounds, interviews
  – involve stakeholders
• Develop and implement action plan if:
  – new or changing requirements
  – non-compliance
  – infection rates unacceptable

Summary

• Requirements affecting infection prevention and control programs include:
  – government regulations
  – accrediting agency standards
  – guidelines, standards, other organizations
• There are recognized strategies for ensuring compliance with these requirements
• We must identify our role in ensuring compliance
Any Questions?