



*Presented by:*

**Gary Purvines, MA, District 1 Manager,  
Health Facility Licensing & Certification Bureau**

# Don't Shoot the Messenger

**“Complying with CMS’ New Conditions of Participation (CfCs)  
for Ambulatory Surgery Centers (ASCs)”**

**Wednesday, September 16, 2009  
10:30 a.m.—12:00 Noon  
Embassy Suites**



# WHY HAVE THE REGULATIONS BEEN CHANGED?

- Rapid growth of ASCs
- 61% increase CY 2000 – CY 2009
- 43% of all same day surgeries
- 15% of FY 08 surveys had condition-level problems
- Incident at Nevada ASC – 50,000 former patients notified of potential exposure to infectious diseases



# FY 2008 ASC PILOT

- Maryland, North Carolina, and Oklahoma
- TOTAL OF 68 ASCs SURVEYED
- Identified widespread deficiencies, particularly in infection control



# CHANGES TO SURVEY PROCEDURE

- Survey procedure will change significantly from past survey procedure
- Changes in
  - length of survey
  - survey process
  - level of scrutiny



# LENGTH OF SURVEY

- Prior survey time was:
  - 1 or 2 health surveyors for 6 to 12 hours total
  - 1 life safety surveyor
- New survey time:
  - 2 health surveyors for 23 hours each
  - 1 life safety surveyor



# FEDERAL REGULATIONS FOR ASCs

- Conditions of coverage
- Standards
- Elements
- Interpretive guidelines (for surveyors but give valuable information to provider)



# NEW SURVEY PROCESS

- 4 new conditions of coverage
- 23 new/revised standards
- Case observation – from curb to curb
- Comprehensive infection control evaluation – 16 page tool
- Record review on 20 medical records



# DEFINITION OF ASC

“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.”



New Mexico  
Hospital Association

# AGREEMENT WITH CMS

Entity must have agreement with CMS to participate in Medicare as an ASC and meet the conditions of coverage.



**New Mexico  
Hospital Association**

# CHANGES IN ASC REGULATIONS

## 4 new 800 lb. Gorillas

- Quality assessment & performance improvement
- Patient rights
- Infection control
- Patient admission, assessment and discharge



# GOVERNING BODY AND MANAGEMENT CC

Q-0040

Condition Statement has added material:

1. Governing body has oversight and accountability for the QAPI program
2. Ensures that facility policies and procedures & programs are administered so as to provide quality healthcare in a safe environment
3. Develops and maintains a disaster preparedness plan



New Mexico  
Hospital Association

# TIP

Any delegation of governing body responsibility authority should be documented in the minutes of governing body meetings.



New Mexico  
Hospital Association

# CONTRACT SERVICES

Q-0041

- When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe effective manner
- The quality of these contract services are still the responsibility of the governing body



New Mexico  
Hospital Association

# TIP

- Any contractor that provides services related to patient care must be evaluated as part of new QAPI process
- Good time to do evaluation is at renewal of contract or at least once per year
- Set up schedule to do contractor evaluations so they won't be forgotten



# SURVEY PROCESS CONTRACT SERVICES

1. Ask for a complete list of currently contracted services
2. Review personnel files of contract personnel
3. Shared space – contract or formalized agreement
4. How does ASC assess safety & effectiveness of contract services
5. How incorporated into QAPI program
6. ASC management – what process is used to correct deficiencies in contracted services?



# DISASTER PREPAREDNESS PLAN

Q-0043

1. The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.



New Mexico  
Hospital Association

# DISASTER PREPAREDNESS PLAN-CONT.

Q-0043 contd.

2. The ASC coordinates the plan with state and local authorities, as appropriate
3. The ASC conducts drills, **at least annually**, to test the plan's effectiveness
  - The ASC must complete a **written evaluation of each drill and promptly implement any corrections to the plan**



New Mexico  
Hospital Association

# DISASTER PREPAREDNESS PLAN-CONT.

Q-0043 contd.

- Governing body of ASC is responsible for development of plan
- ASC must take all-hazards approach – identifying hazards that are specific to operating environment of ASC as well as hazards that may effect the community



New Mexico  
Hospital Association

# ADMINISTRATION OF ANESTHESIA

## Q-0063

- Anesthetics must be administered by only-
  1. A qualified anesthesiologist or
  2. A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) **or an anesthesiologist's assistant** as defined at 410.69 (b) OR A SUPERVISED TRAINEE IN AN APPROVED EDUCATIONAL PROGRAM.
- The physician qualified to administer anesthesia must be under supervision of operating physician.
- The anesthesiologist's assistant must be under the supervision of an anesthesiologist.
- CRNA's in New Mexico are allowed to practice without supervision of a physician.



# **SUPERVISION of ADMINISTRATION OF ANESTHESIA**

- Anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed; the anesthesiologist must be:
  1. Physically present in the ASC and;
  2. Prepared to immediately conduct hands-on intervention if needed.



# QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

## Q-0080 –CC

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.



New Mexico  
Hospital Association

# QAPI-PROGRAM SCOPE

Q-0081

Ongoing program must:

- Demonstrate **measurable improvement** in patient health outcomes
- Improve patient safety by using quality indicators or performance measures associated with **improved health outcomes**
- **Identify and reduce medical errors**



New Mexico  
Hospital Association

# QAPI-PROGRAM SCOPE- CONT.

The ASC must:

- **Measure**
- **Analyze**
- **Track...**
  - **Quality indicators**
  - **Adverse patient events**
  - **Infection control**
  - **Other aspects of performance**



**New Mexico  
Hospital Association**

# QAPI- PROGRAM ACTIVITIES

The ASC must set priorities for its performance improvement activities that –

- Focus on **high risk, high volume, and problem-prone areas**
- Consider **incidence, prevalence and severity** of problems in those areas
- Affect **health outcomes, patient safety and quality of care**



# QAPI – PROGRAM DATA

Q-0082

The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.



New Mexico  
Hospital Association

# QAPI – PROGRAM ACTIVITIES

## Performance improvement activities

- Track adverse patient events
- Examine their causes
- Implement improvements,
- **Sustain improvements over time**

Note: ASC must implement preventive strategies targeting adverse patient events.



New Mexico  
Hospital Association

# QAPI – PROGRAM ACTIVITIES

QAPI program must have:

- Active data collection
- Data analysis
- Improvement/preventive strategies
- Ability to sustain improvements
- Staff training



New Mexico  
Hospital Association

# QAPI – PROGRAM DATA

The ASC **must** use the data collected to:

- Monitor the effectiveness and safety of its services, and quality of its care
- Identify opportunities that could lead to improvements and changes in its patient care



# QAPI – PERFORMANCE IMPROVEMENT PROJECTS

- The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations
- The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results



# QAPI – GOVERNING BODY RESPONSIBILITIES

The governing body must ensure that the QAPI program-

- Is defined, implemented and maintained by the ASC
- Addresses ASC's priorities and that all improvements are evaluated for effectiveness
- Specifies data collection methods, frequency, and details
- Clearly establishes its expectations for safety
- Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program



# LABORATORY & RADIOLOGIC SERVICES – CONT.

If the ASC uses radiological services as an integral part of the surgical procedure it performs, those radiological services must be provided in a manner that complies with the hospital condition of participation for radiological services found at 42 CFR 482.26.



New Mexico  
Hospital Association

# LABORATORY & RADIOLOGIC SERVICES

Q-0202

## ***New standard***

- The ASC must have procedures for obtaining radiological services from a Medicare approved facility
- Radiological services must meet the hospital conditions of participation for radiologic services specified in 482.26



New Mexico  
Hospital Association

# LABORATORY & RADIOLOGIC SERVICES

If an ASC does not provide these radiological services directly, i.e., utilizing its own staff, then it must obtain them via a contract or other formal arrangement from a Medicare-approved, i.e., a Medicare – participating facility.



New Mexico  
Hospital Association

# LABORATORY & RADIOLOGIC SERVICES-CONT.

- The ASC is responsible for compliance under 482.26, radiological services whether the service is provided directly by the ASC or under arrangement.
- ASC's radiological services, including any contracted services, must be integrated into its QAPI program.



# HOSPITAL COP RADIOLOGICAL SERVICES

The hospital must maintain or have available, diagnostic radiologic services. If therapeutic services are also provided, both services, must meet professionally approved standards for safety and personnel qualifications.



New Mexico  
Hospital Association

# HOSPITAL COP RADIOLOGICAL SERVICES- Contd.

Radiologic services, particularly ionizing procedures, must be free from hazards for patients and personnel.



New Mexico  
Hospital Association

# HOSPITAL COP RADIOLOGICAL SERVICES- Contd.

## Radiation Hazards

- Proper safety precautions
- Adequate shielding for patients, personnel and facilities
  - Radiation Workers
    - periodic checks, by the use of exposure meters or badge tests
- Appropriate storage, use and disposal of radioactive materials
- Periodic inspection of equipment
- Hazards identified and corrected



# PATIENT RIGHTS

Q-0220

New condition of coverage

- The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights.



New Mexico  
Hospital Association

# PATIENT RIGHTS NOTICE OF RIGHTS

Q-0221

Standard

The ASC must provide the patient or patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.



New Mexico  
Hospital Association

# PATIENT RIGHTS NOTICE OF RIGHTS

It is not acceptable for the ASC to provide the required notice for the first time to a patient on the day that the surgical procedure is scheduled to occur, **unless:**

- The referral to the ASC for surgery is made on that same date.
- The referring physician indicates, in writing, that it is medically necessary for the patient to have the surgery on the same day, and that surgery in an ASC setting is suitable for that patient.



# PATIENT RIGHTS NOTICE OF RIGHTS

Q-0222

The ASC must post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives) waiting for treatment.

The ASC's notice of rights must include:

- the state agency to whom patients can report complaints
  - name
  - address
  - telephone number
- as well as the web site for the office of the Medicare beneficiary ombudsman.



New Mexico  
Hospital Association

# PATIENT RIGHTS NOTICE OF RIGHTS

Q-0223

ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of part 420 of this subchapter.

Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.



New Mexico  
Hospital Association

# PATIENT RIGHTS ADVANCE DIRECTIVES

Q-0224

The ASC must comply with the following requirements:

- Provide the patient or patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable state health and safety laws, if requested, official state advance directive forms.



New Mexico  
Hospital Association

# PATIENT RIGHTS ADVANCE DIRECTIVES Contd.

- Inform the patient or, patient's representative of the patient's rights to make informed decisions regarding the patient's care
- Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.



# PATIENT RIGHTS ADVANCE DIRECTIVES

It is not acceptable for the ASC to provide the required information for the first time to a patient on the day that the surgical procedure is scheduled to occur, unless:

- The referral to the ASC for surgery is made on that same day; and
- The referring physician indicates, in writing, that it is medically necessary for the patient to have surgery on the same day and that surgery in an ASC setting is suitable for that patient.



New Mexico  
Hospital Association

# PATIENT RIGHTS SUBMISSION AND INVESTIGATION OF GRIEVANCES

Q-0225

- The ASC must establish a grievance procedure for documenting:
  - Existence
  - Submission
  - Investigation
  - Disposition of a patient's written or verbal grievance



New Mexico  
Hospital Association

# PATIENT RIGHTS SUBMISSION AND INVESTIGATION OF GRIEVANCES-Contd.

The grievance process:

- Must specify timeframes for review of the grievance and the provisions of a response.
- Must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is, or fails to be furnished.



# PATIENT RIGHTS SUBMISSION AND INVESTIGATION OF GRIEVANCES-Contd.

The ASC must:

Provide written notice of its decision which must document:

- How the grievance was addressed
- Steps taken to investigate the grievance
- Results of the grievance process
- Date the grievance process was completed
- The ASC contact



# PATIENT RIGHTS SUBMISSION AND INVESTIGATION OF GRIEVANCES-CONT

Q-0226

Alleged Violations/Grievances:

- Mistreatment, neglect, verbal, mental, sexual or physical abuse, must be fully documented (relating and not limited to).
- Must be immediately reported to a person in authority within the ASC.

Only substantiated allegations must be reported to the state authority or the local authority or both.



New Mexico  
Hospital Association

# PATIENT RIGHTS

## EXERCISE of RIGHTS and RESPECT for PROPERTY and PERSON

The patient has the right to:

Q-0227 Exercise his or her rights without be subjected to discrimination or reprisal.

Q-0228 - Voice grievances regarding treatment or care that is (or fails to be) furnished.

Q-0229 - Be fully informed about a treatment or procedure and the expected outcome before it is performed.

Q-0230 - If a patient is adjudged incompetent under applicable state health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under state law to act on the patient's behalf.

- If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

# PATIENT RIGHTS PRIVACY AND SAFETY

The patient has the right to:

Q-0231- Personal privacy

Q-0232 - Receive care in a safe setting

Q-0233 - Free from all forms of abuse  
or harassment



New Mexico  
Hospital Association

# PATIENT RIGHTS CONFIDENTIALITY OF CLINICAL RECORDS

Q-0234

- The ASC must comply with the department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR 160 and 164
- HIPAA- health Insurance Portability and Accountability Act



New Mexico  
Hospital Association

# INFECTION CONTROL

New condition of coverage

Q-0240

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.



New Mexico  
Hospital Association

# INFECTION CONTROL

CC continued...

The ASC's Infection control program must:

- Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases.
- Be based on nationally recognized infection control guidelines.
- Be directed by a designated health care professional with training in infection control.
- Be integrated to the ASC's QAPI Program.
- Be ongoing.
- Include actions to prevent, identify and manage infections and communicable diseases
- Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.



**New Mexico  
Hospital Association**

# INFECTION CONTROL

Q-0241

Sanitary environment

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.



New Mexico  
Hospital Association

# INFECTION CONTROL

## SANITARY ENVIRONMENT-Contd.

- The ASC must provide and maintain a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases. All areas of the ASC must be clean and sanitary, including:
  - Waiting area(s)
  - Pre-surgical prep area(s)
  - Recovery room(s)
  - Operating or procedure rooms
- The ASC must appropriately monitor housekeeping and maintenance including
  - Repair
  - Renovation
  - Construction activities
  - Other activities to ensure a functional and sanitary environment
- Policies and procedures for a sanitary and functional environment should address the following:
  - Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal and external construction/renovation
  - Maintaining safe air handling systems in areas of special ventilation, such as operating rooms
  - Techniques for food sanitation if employee food storage and eating areas are provided
  - Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture
  - Techniques for disposal of regulated and non-regulated waste
  - Techniques for pest control



# INFECTION CONTROL INFECTION CONTROL PROGRAM

Q-0242

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.



New Mexico  
Hospital Association

# INFECTION CONTROL INFECTION CONTROL PROGRAM

Q-0243

The program is under the direction of a designated and qualified professional who has training in infection control.



New Mexico  
Hospital Association

# INFECTION CONTROL INFECTION CONTROL PROGRAM

Q-0244

The program is an integral part of the ASC's quality assessment and performance improvement program.



New Mexico  
Hospital Association

# INFECTION CONTROL INFECTION CONTROL PROGRAM

Q-0245

The program is responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.



New Mexico  
Hospital Association

# PATIENT ADMISSION, ASSESSMENT AND DISCHARGE

New condition of coverage

Q-0260

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.



New Mexico  
Hospital Association

# PATIENT ADMISSION, ASSESSMENT AND DISCHARGE-Contd.

The core objectives of this condition are to ensure:

- The patient can tolerate a surgical experience
- The patient's anesthesia risk and recovery are properly evaluated
- The patient's post-operative recovery is adequately evaluated
- The patient received effective discharge planning
- The patient is successfully discharged from the ASC



# ADMISSION AND PRE-SURGICAL ASSESSMENT

Q-0261

Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician or other qualified practitioner in accordance with applicable state health and safety laws, standards of practice, and ASC policy.



New Mexico  
Hospital Association

# ADMISSION AND PRE-SURGICAL ASSESSMENT- Contd.

## Q-0262

- Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable state health and safety laws, standards of practice and ASC policy that includes:
  - An updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biological



# ADMISSION AND PRE-SURGICAL ASSESSMENT-CONT

Q-0263

The patient's medical history and physical assessment must be placed in the patient's medical record **prior** to the surgical procedure.



New Mexico  
Hospital Association

# POST-SURGICAL ASSESSMENT

Q-0264

The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable state health and safety laws, standards of practice and ASC policy.



New Mexico  
Hospital Association

# DISCHARGE

## Q-0265

The ASC must provide each patient with written discharge instructions and overnight supplies, when appropriate, make a follow-up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for follow-up care.



New Mexico  
Hospital Association

# DISCHARGE

Q-0266

The ASC must 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.



New Mexico  
Hospital Association

# DISCHARGE

Q-0267

The ASC must ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.



New Mexico  
Hospital Association

### **CNEs**

- **Approved status as providers refers only to continuing education activities and does not imply ANCC Commission on Accreditation or UNA/Lovelace/NMHA endorsement of any commercial products. No off label use of a drug or product is addressed in this presentation.**
- **There are no relevant financial relationships with any commercial interests.**
- **All educational content is designed free from the influence of any commercial supporter; commercial supporters were not a part of the planning committee.**
- **All participants successfully completing activities will receive written verification, which will include the following: name of learner, name and address of provider unit, title and date of activity, an official accreditation statement.**



**New Mexico  
Hospital Association**