Adult Cardiac Catheterization Service Level II and Level III Service Standards

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1

Agenda

- Review adult cardiac catheterization rules
- Legal considerations
- Waivers and variances
- Necessary action to be compliant
- Recommended action for best practice

2

Effective Date for New Rules

April 30, 2016

3

ACC Documents

- 2012 ACC Document – 2012 ACCF/SCAI expert consensus document on cc laboratory standards update
- 2013 ACC Document – ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures
- 2014 ACC Document – 2014 SCAI/ACC/AHA Expert Consensus Document Update on PCI without on-site surgical backup

3

How Will Surveyors Determine Consistency With ACC Guidelines?

- No change in survey standard
- Review policies and procedures for consistency
- Guidelines vs. rule
- Should vs. shall

5

General Rules OAC 3701-84-01 to -14

- No changes to general rules
- Review for compliance
  - Attestations
  - Patient care policies
  - Personnel and staffing
  - Infection control policies and procedures
  - Disaster preparedness
  - Quality assessment and performance improvement program
  - Complaint process

6

Final Rule Highlights

- PCI permitted without SOS
- Establish 3 service level classifications
- Require 1 year providing only diagnostic services before notice of transitioning to level II or level III service
- Require enrollment in NCDR for level II and III services
- Annual reporting to ODH
- For PCI, report NCDR metric where service is at or below 25th percentile
- If <150 PCI /year, **may** impose
  - Further review
  - Probationary period

7

Level II CC Service Standards OAC 3701-84-30.2

- Adult cc service without SOS providing diagnostic and authorized therapeutic cc procedures
- Operate 24/7 to perform primary PCI
- 16 prohibited procedures
- At least 1 year performing diagnostic procedures prior to notice of intent to provide level II services
  - May be granted accelerated designation

8

Operate 24/7 to perform primary PCI

  - Physician required to be in-house or on-call?
  - How to address unanticipated gaps in 24/7 coverage?
  - For anticipated gaps in 24/7 coverage, should a waiver be requested?
- Must have 2 physicians credentialed to perform interventional procedures
- If neither available, service must make temporary arrangements through a locum tenens arrangement or cease operation of the service
- If cease operation, promptly notify first responders that service not available
- If interruption >24 hours, contact ODH for discussion on whether termination of the service is required

9

Level II Excluded Procedures

- Transcatheter aortic valve replacement
- Chronic total occlusion
- Rotational coronary artherectomy
- Alcohol septal ablation
- Cardiac biopsy
- Mitral valve clip
- Transcatheter mitral valve repair or replacement
- Laser lead extraction *(Can do non-instrumental)*

10

Level II Excluded Procedures – cont'd

- Atrial septal defect, patient foramen ovale, and ventricular septal defect closure
- Balloon aortic valvuloplasty
- PCI of last remaining coronary artery (non-emergent and/or emergent?)
- Left atrial appendage closure
- Ventricular tachycardia ablation
- Atrial fibrillation ablation
- Lead extractions
- Multivessel PCI in the setting of severe left ventricular dysfunction

11

Level II Off-Site Surgical Backup

- Consistent with 2014 ACC document, table 5
  - Working relationship among cardiologists and surgeons
  - Cardiac surgeons should have privileges at referring hospital
  - Face-to-face meetings
  - Assurance that patients will be accepted at all times based on medical condition, capacity, and availability of resources
  - Both administrations endorse transfer agreement

12

Level II Case Selection

- Consistent with 2014 ACC document, table 5
  - Avoid interventions in patients with . . .
  - Decisions on patients with STEMI resuscitated from sudden cardiac death about need for immediate PCI or transfer should be individualized
  - Emergency transfer for coronary bypass surgery patients with . . .

13

Level II Patient and Lesion Characteristics

- Consistent with 2014 ACC document, table 6
  - Defines high-risk patients and high-risk lesions
  - High-risk patients with high-risk lesions should not undergo **nonemergency** PCI at a facility without SOS *(does not prohibit emergent PCI)*
  - High-risk patients with non-high-risk lesions may undergo PCI at level II with confirmation that surgeon and OR are immediately available
  - Non-high-risk patients with high-risk or non-high-risk lesions may undergo PCI at level II with no additional precautions

14

Level II Staffing Requirements

- Consistent with 2014 ACC document, table 4
  - Experienced nursing and technical lab staff must be comfortable with hemodynamic and electrical instability
  - Coronary care unit nursing staff must be experienced with invasive hemodynamic monitoring, operation of temporary pacemaker, management if IABP, . . .
  - Personnel should be capable of endotracheal intubation and ventilator management

15

Level II Facilities, Equipment and Supplies

- Consistent with 2014 ACC document, table 3
  - High-resolution digital imaging capability
  - Real-time transfer of images and hemodynamic data as well as audio and video images for consultation at the receiving facility
  - Inventory of interventional equipment – guide catheters, balloons and stents in multiple sizes . . .
    - Inventory must be able to meet the needs of the service

16

Level II Transfer Protocol

- With registered hospital that provides open heart surgery which can be reached expeditiously by emergency vehicle within a reasonable amount of time
- Provisions for indications and contraindications for transfer
- Initiation of timely med/surg management
- Surgical back-up available for urgent cases at all hours

17

Level II Transfer Protocol – Con't

- Substantive communication between services, medical directors, and physicians
- Collaborative training programs with staff and physicians
- Recommendations by medical director of receiving service re: credentialing criteria
- Annual drilling activities
  - Actual emergent patient transfer meets requirement

18

Annual Drilling Activities

- Must EMS actually transport a mock patient via ground transportation or helicopter?
  - No
- Must include coordination with the transporter

19

Level II Ground/Air Ambulance Service

- Written agreement with service that can commit to on-site availability within 30 minutes of notification
- Capable of advanced cardiac life support and intra-aortic balloon pump transfer
- Consistent with 2014 ACC document, table 3
  - Agree to accept emergent and non-emergent transfers

20

Level II Quality Assessment

- Review major complications and emergency transfers at least every 90 days *(60 days)*
- Obtain enrollment in NCDR by July 1, 2016
- Notify ODH within 48 hours of incident requiring action outside the scope of service
  - Patient confidentiality
  - Date and time of incident
  - Nature of emergency and actions taken
  - Outcome

21

Level II Informed Consent

- Signed by patient prior to procedure
- Acknowledgment that procedure is being performed without SOS
- May be transferred for med/surg management

22

Informed Consent for Emergent Procedures?

- Follow hospital established policies and procedures
- No different from other hospital life-saving surgical procedures

23

Level II Data Reporting

- First report of 2016 data due to ODH by Feb. 14, 2017
  - Emergent transfers
  - # of diagnostic, elective PCI, primary PCI
  - 6 specified NCDR metrics

24

6 Specified Metrics

- PCI in-hospital risk adjusted rate of bleeding (all patients)
- PCI in-hospital risk adjusted mortality rate (patients with ST segment elevation MI)
- " (ST segment elevation MI pts. excluded)
- Proportion of PCI procedures with post procedure MI
  - Among hosps routinely collecting post-PCI biomarkers; or
  - Among hosps who do not routinely collect post-PCI biomarkers
- Composite proportion of PCI pts with death, emergency coronary artery bypass graft, stroke, or repeat target vessel revascularization
- Median time to immediate PCI for ST segment elevation MI patients

25

Level II Quality Metric Reporting

- Within 30 days of receipt of NCDR report, notify ODH of any of the 6 specified metrics where the service is at or below the 25th percentile for any quarter
- Explain why the metric was not met
- Describe how the service intends to meet the metric in the future

26

Level III CC Service Standards OAC 3701-04-30.3

- Hospital with on-site open heart surgery that provides all levels of cc procedures
- Operates 24/7 to perform primary PCI
- Provide 1 year of diagnostic cc procedures prior to providing notice to ODH of intent to provide level III services
  - Accelerated designation may be granted

27

Level III CC Service Standards – con't

- On-site open heart surgery within same hospital as cc lab and accessible by gurney
- Cardiovascular surgical team available in < 60 minutes 24/7
- Support services consistent with 2012 ACC document, table 2
  - Vascular, nephrology, neurology, hematologic consultative and blood bank, advanced imaging . . .

28

Level III Facilities and Equipment

- One or more surgical suites equipped for thoracic and cardiac surgical procedures
- Equipment consistent with 2014 ACC document, table 3
  - High-resolution digital imaging capability
  - Real-time transfer of images and hemodynamic data as well as audio and video images for consultation with the transferring facility
  - Inventory of interventional equipment – guide catheters, balloons and stents in multiple sizes . . .

29

Level III Quality Assessment and Informed Consent

- Review major complications and emergency transfers at least every 90 days *(60 days)*
- Obtain enrollment in NCDR by July 1, 2016
- Obtain signed informed consent from each patient prior to procedure

30

Informed Consent for Emergent Procedures?

- Follow hospital established policies and procedures
- Cardiac catheterization service is no different from other hospital life-saving surgical procedures

31

Level III Data Reporting

- First report of 2016 data due to ODH by Feb. 14, 2017
  - # of diagnostic, elective PCI, primary PCI
  - 6 specified NCDR metrics

32

Level III Quality Metric Reporting

- Within 30 days of receipt of NCDR report, notify ODH of any of the 6 specified metrics where the service is at or below the 25th percentile for any quarter
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- Describe how the service intends to meet the metric in the future

33

General Adult CC Service Standards OAC 3701-84-30

- Adult = 22 and older
- May serve 18-21 if determined to meet patient's needs by attending physician and medical director
- Designate in writing to ODH
  - Service level classification
  - Scope of services
  - # procedure rooms
  - # control rooms
- Written protocol for emergency transfer and care of patients

34

Access to Services

- Immediate access:
  - Hematology and coagulation disorders
  - Electrocardiography
  - Diagnostic radiology
- Services available within a reasonable amount of time to meet the needs of the service:
  - Clinical pathology
  - Nuclear medicine and nuclear cardiology
  - Doppler-echocardiography
  - Pulmonary function testing
  - Microbiology

35

What is Immediate Access and a Reasonable Amount of Time?

- Immediate access
  - In the facility during scheduled procedures
  - Level II and level III must be available to perform unscheduled procedures
- Reasonable amount of time to meet the needs of the service
  - No fixed time period
  - Standard of care and specific circumstances of each case will dictate whether the service was available within a reasonable amount of time

36

Quality Assessment Review Process

- Review quality of cc procedures performed by each physician:
  - Appropriateness of CC procedures
  - Quality of CC procedures
  - Procedure result
  - Rate of therapeutic success
  - Rate of procedural complications
- Establish data base to support review process
- Random peer reviews of physicians for credentialing

37

Physician Criteria

- Establish criteria for # of times a physician must perform each cc procedure to retain privileges, consistent with professional societies
  - 2014 ACC Document
    - Interventional cardiologist - 50 PCI/year over 2 years
    - Primary PCI – 50 elective PCI/year and, ideally, 11 primary PCI/year
    - If <50, consider experience, quality performance, facility volume
  - 2012 ACC Document
    - Diagnostic - No data to support previous recommendation of 150/year
    - No standard for number of diagnostic procedures
  - Hospital must establish minimum # of procedures for credentialing

38

Quality Assessment

- Review mortality and significant morbidity within 90 days of procedure
- Conduct periodic and random peer review of physicians
- Review major complications and emergency transfers at least every 90 days
- *(General rule -12 requires review of deaths and complications within 60 days)*

39

CC Service Setting

- Permanent building of a registered hospital
- Inpatient med/surg in same building and accessible by gurney from cc lab
- Intensive/critical care unit with 24 hour monitoring in same building and accessible by gurney from cc lab
- Observation area for ambulatory cc patients in same building
- Physician coverage to manage post-procedure complications

40

Major Bleeding Defined

- Bleeding event within 72 hours
- Hemorrhagic stroke
- Tamponade
- Post-PCI transfusion with pre-procedure hemoglobin >8 g/dL
- Absolute hemoglobin decrease from pre-PCI to post-PCI of ≥ 3 /dL and pre-procedure hemoglobin ≤ 16 g/dL

41

General Personnel / Staffing OAC 3701-84-31

- Designate a medical director – must meet all:
  - 5 years cc experience
  - Performed at least 500 cc
  - Active participant in operation of the lab by performing at least 50 cc procedures annually
  - Responsible for quality oversight and active participant in quality assessment review process

42

Medical Director for Level II and Level III

- In addition, the medical director for a level II and level III service must meet one of the following
  - Be board certified in interventional cardiology;
  - Have at least 5 years interventional cardiology experience; **OR**
  - Performed as primary operator at least 500 PCI

43

Attestation of Compliance

- Revise attestation of compliance within 30 days of any change in medical director or authorized representative signing an attestation of compliance previously filed with ODH
- Odh.ohio.gov
  - Health Care Services
  - 17024112016

44

Physician Requirements

- Each provider must have at least 2 physicians credentialed to provide cc services on staff and knowledgeable of the lab's protocols and equipment by providing CC services at the hospital
- Physicians performing cc shall
  - Have training that includes at least 1 year dedicated to cc
  - Be fully-accredited member of staff
  - Participate in labs quality assurance and peer review programs
  - If did not perform PCI prior to March 20, 1997, must have completed fellowship training program in interventional cardiology

45

Physician Requirements – con't

- Consider 2013 ACC document in assessing clinical competency
  - Interventional cardiologist should perform ≥ 50 interventional procedures /year over 2 years and ≥ 11 primary PCI/year
  - Provide alternative pathways for evaluation of low-volume operators – experience, certification, educational credits, courses . . .

46

General Personnel

- Qualified staff who are able to supervise and conduct the service
- Support staff - all skilled in cardiac life support
- Expertise in
  - Digital imaging
  - Systematic quality control testing
  - Patient observation
  - Critical care
  - Monitoring and recording electrocardiographic and hemodynamic data
  - Radiographic and angiographic imaging and safety principles
  - For EP – managing blood samples, performing blood gas measurements, and assisting with indicator dilution studies

47

Clarification for Echosonography for Level III

- Is echosonography required to be on-call 24/7 when not on site?
  - 3701-84-31(G) requires the provider to have a sufficient number of qualified staff who are able to supervise and conduct the service

48

Nursing Personnel Involved in the Provision of CC Services

- Expertise in critical care
- Knowledge of operating room techniques
- Advanced cardiac life support certified
- Experience in cardiovascular medications and ability to administer intravenous solutions

49

Other Personnel

- Respiratory therapists and critical care staff **immediately available at all times**
- Biomedical, electronic and radiation safety experts involved in maintaining equipment
- Staffing requirements may be met by individuals with equivalent or greater qualifications if duties are within their scope of practice

50

What is "Immediately Available"?

- In the facility during scheduled procedures
- Level II and III must be available to perform unscheduled procedures

51

Radiologic Technologist?

- Does a Rad Tech in the CC lab need to be ACIS certified?
- Is a Rad Tech required to be present in the CC lab during all cases?
- Is a Rad Tech required to be present in the CC lab anytime that fluro/x-rays are being used?

- Staffing requirements may be met by individuals with equivalent or greater qualifications if the replacement's scope of practice encompasses the duties of the required staff

52

General Facilities, Equipment and Supplies
OAC 3701-84-32

- Procedure Room
  - Before March 20, 1997 – at least 400 sq. ft.
  - Constructed or renovated after March 20, 1997 – at least 500 sq. ft.
- Control Room
  - Before March 20, 1997 – at least 96 sq. ft.
  - Constructed or renovated after March 20, 1997 – at least 150 sq. ft.
- Clean Utility Room

53

General Equipment

- Equipment listed may be replaced by newer technology that has equivalent or superior capability.
- Equipment list – 13
  - Inventory must be available to meet the needs of the service
- Maintain radiation generating equipment in accordance with state and federal requirements

54

General Safety Standards
OAC 3701-84-33

- Maintain safety policies and practices in accordance with regulations and rules
- Electrical safety policies for wiring, electrical isolation, grounding system, and inspections
- Periodically survey all equipment in accordance with manufacturers' recommendations and document surveillance and maintenance activities

55

Performance Measures
OAC 3701-84-34

- By second year of operation
  - Level I should perform at least 300 procedures
  - Level II or level III should perform at least 300 procedures, including 200 PCI
    - If < 150 PCI/year, may be subject to third party review, at expense of provider, and provide ODH with copy
- Volume goals will be considered in conjunction with other indicators of quality and not as the sole indicator

56

Inspection and Review
OAC 3701-84-34.1

- ODH will inspect approximately every 3 years
- # of procedures considered in conjunction with other indicators of quality
- Failure to perform minimum # of procedures **may** result in
  - Extended review
  - Mandatory peer review of PCI procedures
  - Annual inspections until # met for 2 consecutive years or determined to be no longer required
  - Probationary period

57

Probationary Period

- If imposed, ODH will notify of
  - Time period effective
  - Actions that may be taken by ODH for failure to successfully complete

58

Clarification on Remedial Actions

- What is meant by an "extended review"?
  - More comprehensive than a standard survey
- Who conducts the peer review?
  - Responsibility of the hospital administration and medical staff. Normally occurs internally but often advisable to arrange external peer review where potential conflict of interest may occur

59

Clarification on Remedial Actions – Con't

- What is the nature of a "probationary period"?
  - Identify restrictions, extra precautions, and additional reporting requirements
- Can remedial action under OAC 3701-84-34.1 and penalty under OAC 3701-84-06 be imposed simultaneously?
  - -06 describes general inspections for any hcs
  - -34.1 is specific to CC services and controls if there is any conflict between the 2 provisions

60

Survey Matters

- Surveyor required to show ID
- Announce type of survey
  - Complaint
  - CMS
  - ODH
- If on site conducting state inspection and discover CMS deficiencies, complaint may be filed and that complaint investigated while on site
- Standard state inspections are announced (usually 30 day notice)
- Complaint inspections are un-announced

61

Order to Cease Operations OAC 3701-84-34.2

- May terminate
  - Based on clinical criteria
  - Failure to meet designated metrics
  - Failure to comply with chapter 84 requirements
- ODH will provide written notice of termination
- Termination action may be appealed

62

Necessary Action

- Designate to ODH
  - service level classification
  - scope of services
  - number of procedure rooms
  - number of control rooms
- Can use HCS Notification Survey but include # procedure and control rooms and date of initiation if new service level
  - Odh.ohio.gov
  - Health care services
  - 1700Rev416B

63

Necessary Action – Con't

- Update attestation of compliance if change in personnel signing
- Informed consent
- Level II and level III: Secure enrollment in NCDR by July 1, 2016
- Request necessary waiver or variance

64

Waiver

- Waiver request for any requirement not met
  - Identify requirement
  - How requirement is an undue hardship on the service
  - Why the waiver will not jeopardize health or safety of any patient
- May be granted if determines that strict application of the requirement would cause an undue hardship to the service and that granting the waiver would not jeopardize health and safety of any patient

65

Variance

- Variance request for any requirement met in an alternative manner
  - Identify requirement
  - How the service is meeting the intent of the requirement in an alternative manner
- Variance may be granted if determines that the requirement has been met in an alternative manner

66

Decision on Waiver/Variance

- Decision within 45 days of receipt of request and all information
- Stipulate time period to be effective
- Establish conditions for waiver/variance to be operative
- If denied, may request reconsideration within 30 days
- Present new information not available at the time of the request

67

Recommended Action

- Review transfer protocols
  - provisions for annual drilling activities
- Review quality assessment review process
  - monitor required components [3701-84-30 (E)]
- Include alternate pathways to volume for credentialing

68

Recommended Action – con't

- Review major complications and emergency transfers at least every 60 days
- Monitor annual reportable metrics
- Level I and level II:
  - Scope of service addresses included/excluded procedures
  - Patient screening criteria consistent with ACC tables

69

Recommended Action – con't

- Review policies and procedures
  - Update as necessary
  - Review with staff
  - Follow
- Review 2012, 2013, and 2014 ACC documents and incorporate necessary sections with cc lab's policies and procedures

70

Evaluate Low-Volume Open Heart Programs

- ODH rule provides aspirational volume of 250 OH procedures/year
- New rules provide opportunity to close OH program and transition from Level III CC to Level II CC program

71

Actions for Closure of OH Program

- Notice to ODH 30 days prior to discontinuing OH with projected date of program closure
- Notice to ODH 30 days prior to change in scope of CC service
  - Specify change from Level III to Level II CC service
- Prepare transfer protocols and agreements with hospital for OH and for ground/air transportation

72

Actions for Closure of OH Program – cont'd

- Edit patient consent forms
- Edit policies and procedures on patient screening/selection
- Note prohibited procedures

73

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74