

## 2010 CON Seminar



- Cardiac Cath
- Open Heart
- PET
- Lithotripsy

Sallie Flanders  
Reviewer Specialist

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## CON Review Standards for Cardiac Catheterization Services

- Section 1 – Applicability
- Section 2 – Definitions
- Section 3 – Requirements for Approval – All
  - ✓ Dedicated emergency equipment
  - ✓ Medicaid
    - ❖ Documentation for applicant
- Section 4 – Initiation for Adult Diagnostic Cardiac Cath (DCC)
  - ✓ Projections per year by 2<sup>nd</sup> year of operation
    - ❖ 300 PEs in the category of DCC (urban and rural)
    - ❖ 500 PEs per room for rural (one room service)
    - ❖ 750 PEs per room for urban (one room service)
    - ❖ 1000 PEs per room for both rural and urban (multi- room service)

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## CON Review Standards for Cardiac Catheterization Services

- Section 5 – Requirements for Primary PCI
  - ✓ 400 diagnostic cardiac cath for most recent 12-month period (excludes diagnostic EPs and right-heart cath)
  - ✓ Projected 48 PCIs by 2<sup>nd</sup> year of operation
  - ✓ Specialty services required including staffing
- Section 6 – Initiation of Pediatric Cardiac Cath (PCC)
  - ✓ Projected 600 PCCs by 2<sup>nd</sup> year of operation
  - ✓ On-site pediatric open heart required
- Section 7 – Initiation of Adult Therapeutic Cardiac Cath (TCC)
  - ✓ Projection of 300 PEs in the category of TCC by 2<sup>nd</sup> year of operation
  - ✓ On-site adult diagnostic cardiac cath
  - ✓ On-site adult open heart required

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## CON Review Standards for Cardiac Catheterization Services

- Section 8 – Replace/Upgrade Cardiac Cath Labs
  - ✓ For facilities with one room (actual utilization and projected)
  - ✓ Peripheral procedures can't be used to meet volume requirements

	Rural (PEs per room)	Urban (PEs per room)
Adult	500	750
Pediatric	500	500

[Form 716](#)

[CON Homepage](#)

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## CON Review Standards for Cardiac Catheterization Services

- Section 8 – Replace/Upgrade Cardiac Cath Labs (contd.)
  - ✓ For facilities with multi-room (actual utilization and projected)
  - ✓ Peripheral procedures can't be used to meet volume requirements

	Rural (PE per room)	Urban (PE per room)
Adult	1000	1000
Pediatric	500	500
Mobile	500	500

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## CON Review Standards for Cardiac Catheterization Services

- Section 9 – Requirements for Expansion
  - ✓ 1500 PE per room over last 12-month period
  - ✓ Projected 1000 PE per room by 2<sup>nd</sup> year of operation (existing & proposed)
  - ✓ Peripheral procedures can't be used to meet volume requirements
- Section 10 – Mobile Cardiac Cath Service
  - ✓ No increase in mobile cardiac cath networks
  - ✓ No net increase in host sites
  - ✓ Procedures must be performed in hospitals
- Section 11 – Methodology for Cardiac Cath Equivalents
  - ✓ Excludes use of peripheral procedures for expansion and replacement
  - ✓ Department uses form 716 for most recent utilization data
  - ✓ Annual hospital survey

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## CON Review Standards for Cardiac Catheterization Services

- Section 12 – Project Delivery Requirements
  - ✓ Minimum procedure requirements for physicians
- Section 13 – Additional Project Delivery Requirements for PCI
- Section 14 – Documentation of Projections
- Section 15 - Prior CON Review Standards; Comparative Reviews
  - ✓ Not subject to comparative review

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## CON Review Standards for Open Heart Surgery Services

- Section 1 – Applicability
- Section 2 – Definitions
- Section 3 – Initiation – Adult and Pediatric
  - ✓ Must have adult or pediatric diagnostic/therapeutic cardiac cath service
  - ✓ Written agreement with existing open heart provider (min. 400 OH cases)
  - ✓ Demonstrate 300 adult OH cases and 100 pediatric OH cases based on methodology (sections 8 and 9 respectively-MIDB)
- Section 4 – Acquisition
  - ✓ Volume waived for 1<sup>st</sup> acquisition
- Section 5 – Medicaid
  - ✓ Documentation for applicant

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## CON Review Standards for Open Heart Surgery Services

- Section 6 – Requirements for MIDB Data Commitment
  - ✓ 7-year commitment (adult and pediatric)
  - ✓ After 7 years, only additional data can be committed
  - ✓ Data from with in same planning area
  - ✓ Not an Open Heart service provider (operational or approved)
- Section 7- Project Delivery Requirements – All
  - ✓ 300 adult OH surgeries by 3<sup>rd</sup> year of operation
  - ✓ 100 pediatric OH surgeries by 3<sup>rd</sup> year of operation
- Section 8 – Methodology for Adult OH Cases
  - ✓ Department updates OH Utilization weights every 3 years beginning 2007

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## CON Review Standards for Open Heart Surgery Services

- Section 9 – Methodology for Pediatric OH Cases
  - ✓ Department updates OH Utilization weights every 3 years beginning 2007
- Section 10 – Planning Areas
- Section 11 - Prior CON Review Standards; Comparative Reviews
  - ✓ Not subject to comparative review

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## CON Review Standards for PET Scanner Services

- Section 1 – Applicability
- Section 2 – Definitions
- Section 3 – Requirements for Approval – Fixed or Mobile
- Section 4 – Initiation
  - ✓ Fixed – 2600 PET Data Units
  - ✓ Mobile – 2100 PET Data Units
    - ❖ Urban – 360 PET Data Units within the planning area and 20-mile radius
    - ❖ Rural – 240 PET Date Units within the planning area
    - ❖ No volume requirement to initiate host site on existing route
  - ✓ Conversion of Mobile to Fixed
    - ❖ Urban Host – 4500 PEs
    - ❖ Rural Host – 4000 PEs
    - ❖ Can not become host site for 12 months after operation of fixed PET

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## CON Review Standards for PET Scanner Services

- Section 5 – Expansion
  - ✓ Urban Fixed – 5500 PEs
  - ✓ Rural Fixed – 5000 PEs
  - ✓ Urban Mobile – 5000 PEs (at least one urban host)
  - ✓ Rural Mobile – 4500 PEs (only rural hosts)
  - ✓ Expand Fixed Service to Initiate Mobile Route
    - ❖ Urban Fixed – 5500 PEs
    - ❖ Rural Fixed – 5000 PEs
- Section 6 – Replacement
  - ✓ Fixed – 4500 PEs
  - ✓ Mobile – 3000 PEs
  - ✓ Volume exemption for replacing PET with PET/CT  
(Operational before 1-1-05 and not a PET/CT)

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## CON Review Standards for PET Scanner Services

- Section 7 – Acquisition of an Existing PET Scanner Unit
  - ✓ A la carte – no volume requirements
- Section 8 – Acquisition of an Existing PET Scanner Service
  - ✓ No volume requirements
- Section 9 – Relocation (Fixed Service Only)
  - ✓ Service
    - ❖ Operational 36 months
    - ❖ New site within relocation zone (urban – 10 miles, rural – 25 miles)
  - ✓ A la carte
    - ❖ Operational 36 months
    - ❖ New site within relocation zone (urban – 10 miles, rural – 25 miles)
- Section 10 – Dedicated Research PET Scanner

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## CON Review Standards for PET Scanner Services

- Section 11 – Dedicated Pediatric PET Scanner
- Section 12 – Additional Requirements for Mobile
- Section 13 – Medicaid
  - ✓ Fixed – documentation for applicant
  - ✓ Mobile – documentation for each mobile host site
- Section 14 – Project Delivery Requirements – All
  - ✓ Subsection 1(v)(iii) – minimum average annual utilization (1500 PEs per unit after second 12 months for mobile and fixed)
- Section 15 - Project Delivery Requirements – Mobile
- Section 16 – Determination of PET Equivalents
  - ✓ [Worksheet form 732](#)
- Section 17 – Methodology for Computing PET Data Units
  - ✓ New cancer cases, diagnostic cardiac cath sessions & intractable epilepsy

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## CON Review Standards for PET Scanner Services

- Section 18 – Commitment of New Cancer Cases
  - ✓ Gov. body resolution
  - ✓ 5-year data commitment for new cancer cases
  - ✓ Fixed – Commitments from Planning Area (PA)
  - ✓ Mobile – Commitments from PA of host site or w/i 75 miles of host in rural county/25 miles urban county
  - ✓ Cannot be a current service provider or have approval (fixed or mobile)
  - ✓ Not previously committed data or 5 years elapsed
  - ✓ Withdrawal of data after CON denial, CON-withdrawn or expired (Gov. body resolution)
- Section 19 – Documentation of New Cancer Cases
  - ✓ Letter from State Registrar
  - ✓ Most recent cancer registry pursuant to advisory on CON web site

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## CON Review Standards for PET Scanner Services

- Section 20 – Commitment of Diagnostic Card Cath (DCC)
  - ✓ Gov. body resolution
  - ✓ 5-year data commitment for new cancer cases
  - ✓ Fixed – Commitments from Planning Area (PA)
  - ✓ Mobile – Commitments from PA of host site or w/i 75 miles of host in rural county/25 miles urban county
  - ✓ Cannot be a current service provider or have approval (fixed or mobile)
  - ✓ Not previously committed data or 5 years elapsed
  - ✓ DCC cases from most recent annual hospital survey
  - ✓ Withdrawal of data after CON denial, CON-withdrawn or expired (Gov. body resolution)

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## CON Review Standards for PET Scanner Services

- Section 21 – Commitment of Intractable Epilepsy (IE) Cases
  - ✓ Gov. body resolution
  - ✓ 5-year data commitment for new cancer cases
  - ✓ Fixed – Commitments from Planning Area (PA)
  - ✓ Mobile – Commitments from PA of host site or w/i 75 miles of host in rural county/25 miles urban county
  - ✓ Cannot be a current service provider or have approval (fixed or mobile)
  - ✓ Not previously committed data or 5 years elapsed
  - ✓ IE cases from most recent MIDB data
  - ✓ Withdrawal of data after CON denial, CON-withdrawn or expired (Gov. body resolution)

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## CON Review Standards for PET Scanner Services

- Section 22 – Health Service Areas (HSA)
- Section 23 – Planning Areas
- Section 24 – Department Inventory
- Section 25 – Comparative Reviews/Prior Planning Policies
  - ✓ Not subject to comparative review

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## CON Review Standards for Lithotripsy Services

- Section 1 – Applicability
- Section 2 – Definitions
- Section 3 – Initiation
  - ✓ Project 1000 procedures per methodology in Section 13
  - ✓ MIDB data
  - ✓ Proposed site offers all seven services cited under this section
- Section 4 – Replacement
  - ✓ 1000 procedures per unit (fixed or mobile)
  - ✓ Exception to 4(1) – replace existing fixed unit with a mobile
  - ✓ Upgrade - \$125,000 or less over consecutive 24-month period
- Section 5 – Additional Requirements – Mobile
  - ✓ Add Michigan host site to non-state route
  - ✓ 100 procedures to add host site if the region is not served by that route

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## CON Review Standards for Lithotripsy Services

- Section 6 – Acquisition (Fixed or Mobile)
  - ✓ Service
    - ❖ First acquisition after May 2, 1998 – no volume requirements
    - ❖ Second acquisition – 1000 procedures per unit
  - ✓ A la carte
    - ❖ 1000 procedures per unit
- Section 7 – Relocation (Fixed Only)
  - ✓ Service
    - ❖ Operational for 36 months
    - ❖ New site is within relocation zone (25-mile radius)
    - ❖ 1000 procedures per unit
  - ✓ A la carte
    - ❖ Operational for 36 months
    - ❖ New site is within relocation zone (25-mile radius)
    - ❖ 1000 procedures per unit

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## CON Review Standards for Lithotripsy Services

- Section 8 – Expansion (Fixed or Mobile)
  - ✓ 1800 procedures per unit, existing and approved
  - ✓ 1000 projected procedures per unit, existing and proposed
- Section 9 – Medicaid
  - ✓ Fixed – documentation for applicant
  - ✓ Mobile – documentation for each mobile host site
- Section 10 – Project Delivery Requirements – All
- Section 11 – Project Delivery Requirements – Mobile
  - ✓ Notification to Department 30 days prior to deleting host site
- Section 12 – Health Service Area (HSA)
- Section 13 – Methodology for Projecting UESWL Procedures
  - ✓ MIDB Data
  - ✓ Appendix A Factors

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## CON Review Standards for Lithotripsy Services

- Section 14 – Requirements for MIDB Data Commitments
  - ✓ 5-year commitment
  - ✓ 100% of data for the facility
  - ✓ If current service provider, can't commit data to another service
  - ✓ Fixed site - within same Region as proposed service
  - ✓ Mobile host – at least one proposed host site within same region
- Section 15 - Comparative Reviews/Prior Planning Policies
  - ✓ Not subject to comparative review

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