

Michigan CON Compliance and Enforcement Issues

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March 28, 2006

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Three Good Reasons to Address CON Compliance

REASON #1: Potential Penalties

- ❖ MDCH may impose any or all of the following for noncompliance with CON:
 - Revoke or suspend a CON
 - Civil fine equal to or less than the billings for the services furnished in violation of CON requirements
 - Action authorized for a violation of Article 17 of the Code, including issuance of a compliance order
 - Injunction
 - Other enforcement action authorized by the Code; and
 - Publicize or report the violation or enforcement action, or both, to any person.

REASON #2: Potential Recoupment

- ❖ Person shall not charge to, collect from another person, or otherwise recover costs for services provided in violation of Part 222 of the Code.
- ❖ *If requested*, a person who furnishes a service in violation of CON requirements shall refund charges for such services either directly or through a credit on a subsequent bill.
- ❖ Under Part 222, refund is by request. However, CON regulations purport to impose mandatory obligation to issue a refund.

REASON #3: Potential Licensure Sanctions

- ❖ Section 20165 grants MDCH the authority to suspend or revoke hospital licensure for failure to comply with Part 222 or a term, condition, or stipulation of a CON issued under Part 222.
- ❖ “Nuclear Option” – but potentially available if egregious circumstances.

**SPECIFIC CON COMPLIANCE
ISSUES**

CON Fundamentals

- ❖ **CON Rule of Thumb.** As a general rule, a CON is required for the initiation, expansion, replacement, relocation, or CHOW of a health facility or a covered clinical service.
 - See attached CON flow-chart as to when CON may be required

- ❖ **CON is Non-transferable.**
 - CON approval is specific to a particular “person,” “place” and “thing”
 - No “bare transfer” of CON approval for project not yet implemented
 - Important to understand timing for CON approvals for a change of ownership (“CHOW”) of a health facility

CON Issues for “Health Facilities”

CON applies to “health facilities” which under Part 222 include hospitals, nursing homes, FSOF/ASCs and applies to:

- Changes involving beds in hospitals and nursing homes (expansion, relocation, replacement, acquisition, including lease)
- Clinical capital expenditures for a “health facility” > \$2,715,000 (effective 1/3/06)

CON Issues for “Health Facilities”

Clinical capital expenditure limits only apply to actual licensed footprint of “health facility” (not HOPD, clinics, or MOBs even if attached to hospital or certified or accredited as part of hospital).

CON capital expenditure thresholds are revised annually.

“Single project” is defined as an activity or group of activities involving a distinct physical area or areas of a health facility or involving the same service(s) or department(s).

CON Issues for “Health Facilities”

If Master Facility Plan, consider whether:

- Phased project
- Single financing
- Whether components of project are properly aggregated for purposes of exceeding capital expenditure threshold
- Whether MDCH likely to aggregate proposed project or require individual CON applications to be filed.

CON Issues for Health Facilities

❖ Changes in Bed Capacity.

- CON approval generally required for a change in bed capacity
- No “conversion” of beds from one type to another, i.e., psych beds to acute-care
- Compliance should include periodic internal assessment of physical plant to confirm that it can accommodate all currently licensed beds – 24 hour rule

CON Issues for Health Facilities

- ❖ **Community Representative Board Requirement.**
 - Applies to nonprofit health facilities
 - Requires governing body composed of majority consumer membership and broadly representative of the population served
 - Option for “advisory board”
 - Potential compliance issue for corporate reorganizations and restructuring activities

CON Compliance Issues Related to Medical Staff

❖ CON Standards Incorporate 16221 By Reference.

Standards require compliance with 16221 with respect to operation and referral of patients to certain CON covered services, including physician volume commitments

- CON Standards subject to this restriction include:
 - MRI
 - CT
 - PET
 - Surgery
 - UESWL (lithotripsy)
 - MRT

CON Compliance Issues Related to Medical Staff

❖ Physician Minimum Volume Requirements.

- Some CON Standards impose annual case load requirements for physicians credentialed for that service
 - Adult Diagnostic Cardiac Cath = minimum of 100 adult procedures/year in the 2nd 12 months after credentialing
 - Adult Therapeutic Cardiac Cath or PCI = minimum of 75 interventions/year in most recent 24 months and annually thereafter
 - Open Heart = Minimum of 50 adult OHS procedures per year
 - CON eligibility requirements should be tied to medical staff documents of hospital to permit hospital to terminate clinical privileges of physician not in compliance

CON Compliance Issues Related to Covered Clinical Services

❖ Replacement.

- Includes relocation of CON-covered physical plant to new “footprint”
- Also includes “replacement” of existing CON-approved covered clinical equipment, e.g., MRI, CT, MRT, PET, etc.
- Distinguish “upgrade” from “replacement”
- If equipment, must be fully depreciated or “clearly poses a threat of safety to the public.”
- As CON application is a public record under FOIA, providers should be cautious about suggesting equipment poses patient safety risks.

CON Compliance Issues Related to Covered Clinical Services

❖ Relocation.

- CON almost always required to change location of covered clinical service
- MDCH uses street address to determine whether a change of location will occur or has occurred

CON Compliance Issues Related to Covered Clinical Services

- ❖ **CON Standards as Proxy for Licensure Standards.**
 - CON “Project Delivery Requirements” include substantive, licensure-type requirements for certain health facilities and covered clinical services
 - With CON Standards being updated more frequently since 2002 PA 619, greater need for annual re-assessment of compliance with Project Delivery Requirements
 - Operations team for CON covered clinical service should be familiar with CON annual minimum volume requirements and periodically assess compliance

CON Compliance Issues Related to Covered Clinical Services

- ❖ **Annual Statistical Questionnaire.** MDCH requires submission of annual statistical questionnaire that includes minimum volumes for covered clinical services
 - Need to ensure accuracy as inaccuracies may affect future CON approvals
 - Important to understand CON definitions and nomenclature when completing
 - Essential to review before submitting to ensure compliance with minimum volumes or to develop plan to achieve compliance

CON Compliance Issues Related to Covered Clinical Services

❖ Special Issues re Joint Ventures.

- Some Standards, e.g., cardiac cath, require CON holder to be hospital
- In joint venture arrangements with physicians, MDCH has advised that CON holder must be entity that bills for technical/facility component of the CON service

CON Compliance Issues re Project Implementation

❖ Implementation of CON Approval.

- CON expires 1 year after effective date unless proposed project is “implemented” i.e., binding agreement for construction or acquisition of equipment
- If substantial progress, may request *one* 6- month extension under CON regulations
- Must begin construction required for the proposed project within 24 months from CON effective date; MDCH has discretion to approve longer period if justified
- Enforceable contract to implement CON for certain covered clinical services must specify installation date of equipment will be within 24 months of effective date of CON (UESWL, MRT, PET, CT, Cardiac Cath, MRI, Air Ambulance)

CON Compliance Issues re Project Implementation

❖ Amendment of CON Approval

- No amendment if completed project
- No amendment for change of applicant or location
- No amendment for change in method and terms of financing, approved capital expenditures, or operating costs unless (i) circumstances beyond CON holder's control; or (ii) amendment offers better alternative as determined by MDCH
- Review period for amendment may not exceed original review period although MDCH usually more prompt

CON Compliance Issues re Project Implementation

❖ Common Compliance Problems Upon Implementation of CON

- Failure to monitor time deadlines
- Changes to project costs that require amendment
- Change in location which is inconsistent with CON approval
- Change in method of financing – watch out for cash projects and equipment leases

Current MDCH Enforcement Issues

- ❖ Currently, MDCH enforcement efforts consist primarily of:
 - “Soft” enforcement
 - Special targeted enforcement initiatives, e.g., open heart surgery, with potential compliance agreement
- ❖ Under Part 222 and MDCH policy, no voluntary disclosure obligation by providers if noncompliance. However, consider whether sanctions may be more lenient if self-reported.

Potential Future Enforcement Strategies?

- ❖ MDCH under increased pressure to enforce CON Standards
- ❖ Potential new enforcement initiatives may include:
 - “Per day” penalties for noncompliance
 - Mandatory notice to third party payers and recoupment
 - Fines related to billings while not in compliance
 - Random provider audits for covered clinical services to verify compliance with project delivery requirements and minimum volumes
 - Other?

MDCH Tips for Avoiding CON Compliance Issues

- ❖ Integrate CON Standards and compliance into substantive departments that furnish CON “covered clinical services”
- ❖ Monitor CON minimum volumes and address any noncompliance promptly
- ❖ Include CON issues in provider’s compliance program
- ❖ Review and verify compliance with CON project delivery requirements annually or upon implementation of revised Standards