

# COMPLIANCE

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## Follow Up vs. Compliance

- Follow up: The requirement that the facility provide routine updates to the Department and confirmation that the project was completed as proposed. This process ends when the project is operational and deemed 100% complete.
- Compliance: The statutory responsibility to verify that the CON holder is meeting the commitments and obligations set forth in the standards, under which the applicant was approved, for the life of the CON.

## MCL 333.22247

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- MCL 333.22247 (1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.
- MCL 333.22247 (2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following...

## MCL 333.22247 continued...

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- MCL 333.22247(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

## Administrative Rule 325.9419

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- R 325.9419 (1) Upon a determination by the department and applicant is not in compliance with the terms, conditions, or stipulations of an approved certificate of need, the department shall notify the applicant. The department shall also specify the period of time during which the noncompliance occurred. The applicant shall notify all payers of services provided by the applicant that the approved services are not being provided in compliance with the terms, conditions, or stipulations of an approved certificate of need.

## R 325.9419 continued...

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- R 325.9419 (2) In determining the appropriate action to take in accordance with section 22247(2) of the code, the department shall consider the extent and duration of the noncompliance.
- R 325.9419 (3) The department shall make available, to the public, on request, a list of all certificates of need determined not to be in compliance with the terms, conditions, or stipulations approved in a certificate of need.

## Compliance Program Goals

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- Develop a compliance tool to evaluate the noncompliance to ensure fair and consistent application of the process and the remedies.
- Establish a routine audit process for the annual survey data and each CON Standard.
- Create a process for the Department to receive complaints or allegations of noncompliance.

## Scope Criteria

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- Offering service without appropriate approval.
- Providing false documentation to the Department.
- Failure to appropriately file a PIPR.
- Failure to timely or accurately complete the Annual Survey.
- Failure to meet the CON approved volume requirement.
- Failure to meet the CON approved project delivery requirements.

## Volume Requirements

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- Volume per unit/service is 50% to 75% of the volume requirement, but the facility has met the volume requirement in the last three (3) years or is above 75% of the volume requirement, but the facility has never met the volume requirement.
- Volume per unit/service is 50% to 75% of the volume requirement, but the facility has not met the volume requirement in the last three (3) years.
- Volume per unit/service is more than 50% below the volume requirement.

## Severity Criteria

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- Effect of the noncompliance on the facility's ability to offer the service with quality and in a safe manner.
- Length of time the facility has been noncompliant.
- Number of times the facility has been deemed noncompliant by the Department in the last five (5) years.
- Is the facility already taking action to correct the noncompliance?
- The method utilized to identify the area of noncompliance.

## Compliance Remedies

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- Revoke or suspend the CON [MCL 333.22247(2)(a)]
- Reduction in the CON service level (i.e., from 3 CT Scanners to 2 CT Scanners)
- Pursue an injunction to prevent further violation of the terms of the CON [MCL333.22253]
- Civil fine for the noncompliant time period, not to exceed the total billings. [MCL 333.22247(2)(b)]

## Compliance Remedies continued...

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- Require the applicant to notify all payers that the service was being performed while not compliant with the terms and conditions of the CON. [R325.9419(1)]
- Repay all billed amounts paid by the State of Michigan via Medicaid or other programs for services billed for the noncompliant time period. [MCL 333.22247(3)]
- Report the noncompliance on the Department Compliance Report to the Commission. [MCL 333.22247(2)(f)]
- Other remedies deemed appropriate [MCL 333.22247(2)(g)]

## Compliance Activities/Investigations

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- Open Heart Surgery Services - volume check
- Primary PCI - volume check
- Mobile MRI Services – host site check
- CT scanner replacement without CON approval and misreporting of annual survey data.

Any Questions?