WHAT IS THE CON PROGRAM?

Certificate of Need (CON) is a state regulatory program intended to ensure that only needed services are developed in Michigan.

Michigan's CON program was enacted in 1972 and is administered by the Department of Health and Human Services. The CON program is governed by Part 222 of PA 368 of the Public Acts of 1978, as amended.

Go to **www.mi.gov/con** for additional information.

WHAT IS COVERED BY THE CON PRGRAM?

An entity (health facility, physician, group practice, etc.) proposing any of the following types of projects must obtain a CON, regardless of the capital expenditure proposed:

- Increase in the number of licensed beds or the relocation of licensed beds from one site to another.
- ► Acquisition of an existing health facility.
- Operation of a new health facility.
- Initiation, replacement, or expansion of covered clinical services. (See a list of review standards)
- Extended care services program (Swing Beds).

In addition, capital expenditure projects (construction, renovation, etc.) that involve a health facility require a CON. The capital expenditure threshold is indexed

annually by the Department of Treasury based on the Consumer Price Index.

The threshold effective January 1, 2022, is \$3,492,500 for clinical service areas.

For purposes of CON, a health facility is defined as a:

- Hospital
- Psychiatric hospital or unit
- Nursing home
- ► Freestanding surgical outpatient facility
- ► HMO (only for limited projects)

Determinations of whether a project requires CON approval, whether a project complies with applicable requirements, or whether other requirements apply, must be obtained *in writing* from the Department.

REVIEW STANDARDS

The CON Commission, an 11-member independent body appointed by the Governor has approved CON

Review Standards for determining the need and ongoing quality assurance standards for the following:

- Air Ambulances (Helicopters)
- Cardiac Catheterization Services
- Computed Tomography (CT) scanners
- Hospital Beds
- Magnetic Resonance Imaging (MRI) Services
- Megavoltage Radiation Therapy (MRT) Services
- Neonatal Intensive Care Units (NICU)
- ▶ Nursing Home/Hospital Long-Term Care Unit beds
- ► Open Heart Surgery Services
- Positron Emission Tomography (PET) scanners
- Psychiatric Beds and Services
- Surgical Services
- Transplantation Services: Bone Marrow, Including Peripheral Stem Cell; Heart/Lung & liver
- Urinary Lithotripters

The CON Commission is responsible for developing and approving Review Standards used by the Department to regulate covered health facilities and services. The Commission is not involved in making decisions in the review of CON applications.

REVIEW TYPES

Nonsubstantive

Projects not requiring a full review, requiring less information, and are processed more quickly. Examples of projects that may be reviewed on a nonsubstantive basis are equipment replacements and addition of the mobile host sites.

Substantive

Projects requiring a full review, but on an individual basis, such as initiation of an MRI service.

Comparative

Applications competing for project types for which the need is limited: beds, and transplantation services (excluding pancreas). Applications subject to Comparative review must be filed on the first working day of February, June, or October of each year.

HOW DOES THE CON PROCESS WORK?

- An applicant files a Letter of Intent (LOI) with the Department. Based on LOI information, the Department notifies the applicant of required application forms for the project and review type.
- The applicant files a completed application with the Department.
- Within 15 days of receipt of an application, the Department reviews it for completeness and requests any necessary additional information.
- ► The applicant has 15 days to submit the requested information to the Department.
- ► The Department deems the application complete and confirms the review type, decision due date.
- A proposed decision is issued within the deadlines for each review type:

Nonsubstantive - 45 days Substantive -120 days Comparative - 150 days

- If the proposed decision is approved, a final decision is issued by the Department Director within five (5) days.
- If the proposed decision is a disapproval, the applicant has 15 days to request a hearing.
- If a hearing is not requested, a final decision is issued by the Department Director.
- If requested, the hearing must begin within 90 days, unless waived by the applicant.
- ► The final decision is issued by the Department Director following the hearing.
- Letters of Intent, nonsubstantive and substantive applications can be filed online as well as amendments, emergency CONs and swing beds applications. In addition, the application fee can be paid online. Potential comparative applications must be filed by submitting a paper copy only. For more information, visit <u>www.mi.gov/con</u>.

Certificate of Need Activity

During FY 2021, the Department has continued to make process improvements in both the Evaluation Section and Policy Section.

The Evaluation Section promptly put in place a streamlined, electronic process for filing Emergency CON applications to assist health care providers statewide in planning and implementing the bed surge plans to adequately treat patients impacted by COVID-19 pandemic in Michigan, and tirelessly worked to other Governmental agencies and health care organizations to make the processes successful. Due to these efforts, the Department was able to approve numerous Emergency CON applications with an average review period of four (4) days that put in place additional beds at healthcare facilities statewide and continued to assist providers during these challenging times. The CON staff also volunteered to work on the COVID-19 email box and COVID-19 Hotline to help answer questions from Michigan citizens during the COVID-19 pandemic in Michigan. The Department completed statewide compliance review of all facilities providing Cardiac Cath and MRT services. The Section also facilitated webinars to provide up-to-date information on revised CON standards, application processes and Annual Survey reporting requirements.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to better reflect practice, improve quality, and add clarity to the standards; revised the maintenance volume requirements to better reflect current practice for CT Scanner Services; updated NICU Beds and Special Newborn Nursing Services language to better reflect current practice and added language to allow for the use of telemedicine technology for prearranged consultative agreements; developed a new bed need methodology to better reflect the need for Nursing Home and HLTCU Beds; added language that allows for the annualizing of procedure data if the application is utilizing an MRI List where the reporting period is impacted by a public health epidemic for MRI Services; updated the special pool beds for Psychiatric Beds and Services; and updated Cardiac Catheterization Services to better reflect current practice.

These initiatives have greatly increased the availability of CON information and data to improve and streamline the review process, better inform policy makers and enhance community knowledge about Michigan's healthcare system.

| F | CON FEE STRUCTURE Project Costs: | Fee: |
|---|--|-----------|
| 9 | \$0 to \$500,000 | \$ 3,000 |
| 9 | \$500,000 or more but less than \$4,000,000 | \$ 8,000 |
| 9 | \$4,000,000 or more but less than \$10,000,000 | \$ 11,000 |
| 9 | \$10,000,000 or more | \$ 15,000 |
| | Additional Fee: | |
| (| Comparative or Complex Review | \$ 3,000 |
| E | Expedited Review | \$ 1,000 |
| ŀ | Amendment Request or LOI Waiver | \$ 500 |
| ŀ | Annual Survey (per Facility per Covered Service) | \$ 100 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Certificate of Need

CONTACT INFORMATION

CON Evaluation Section 517-241-3344-Phone 517-241-2962-Fax

CON Policy Section (Commission) 517-335-6708-Phone 517-241-1200-Fax

OTHER CON RELATED REGULATORY AGENCIES

Division of Licensing & Regulation (Hospital & Surgical Facilities)-MDLARA 517-335-1980

State Licensing Division-MDLARA 517-241-1970

Health Facilities Engineering Section-MDLARA 517-241-3408

Radiation Safety Section-MIOSHA-MDLEO 517-284-7820

Bureau of Fire Services-MDLARA 517-241-8847

MDLARA=Michigan Department of Licensing & Regulatory Affairs

CON WEB SITE www.michigan.gov/con



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