



## **CON Basics in Michigan**

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### ***Preamble***

This paper is intended to serve as a preliminary research tool for attorneys dealing with Certificates of Need (CON) in Michigan. The paper should be viewed as a first-tier resource to obtain a perspective on the CON process under Michigan law. It is not intended to be a treatise, nor should it be used as the sole basis for making critical business or legal decisions regarding CONs. The paper does not constitute, and may not be relied upon, as legal advice.

### ***Introduction***

Certificate of Need laws were a significant milestone in Congress's decades-long campaign to federalize health care and reduce public expenditures on it. Michigan's Certificate of Need program imposes state control over the creation and acquisition of many health care services and facilities. Its current authorization is found in Part 222 of the Public Health Code. MCL 333.22201 et seq. This article summarizes the history, structure and operation of the Certificate of Need system in Michigan.

### ***History of Certificate of Need in Michigan***

Michigan owes its Certificate of Need (CON) program to a repealed federal law, the National Health Planning and Resource Development Act of 1974, PL 93-642 (NHPRDA). That

Congressional initiative threatened to withhold federal support for state Medicaid reimbursement to health facilities operating without an appropriate Certificate of Need, and thus drove states and territories, including Michigan, to enact NHPDA-compliant statutes. Stated generally, NHPDA required a state to balance factors of cost, quality and access issues in disposing of an application to incur a capital cost for a new or expanded health facility. States were empowered to tailor those factors to meet their own perceived values, within limits set by the federal law.<sup>1</sup>

NHPDA was a creature of the Medicare and Medicaid “cost-based” provider reimbursement systems that had paid institutional Medicare and Medicaid providers since the programs’ establishment.<sup>2</sup> Less than a decade after their creation, those programs were under political attack as wasteful and inflationary in their administration. Cost-based reimbursement systems paid participating hospitals and nursing homes their audited (“allowable”) capital and operating costs, consisting generally (but not exactly), of all costs attributable to patient care under GAAP.<sup>3</sup> They contained little incentive to provide care efficiently and economically because to a significant degree they insulated providers from the consequences of unregulated capital expansion.<sup>4</sup> A pre-NHPDA federal program limiting Medicare reimbursement to “needed” capital costs, the “Section 1122” program, had had little more effect on federal healthcare costs, and did not apply to Medicaid or the private sector.<sup>5</sup> Congress also had limited

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<sup>1</sup>A few states, notably New York, had adopted Certificate of Need programs before enactment of NHPDA.

<sup>2</sup>Cost-based Medicare payment systems for hospitals and other institutional providers were based on the then-current Blue Cross payment model.

<sup>3</sup>Private payment systems, like Blue Cross, also paid on the cost basis, and private costs were going up as rapidly as costs to the public systems, so payment reform was of interest to the employers paying insurance premiums for their workers.

<sup>4</sup>An illustrative parable in the health planning field recites that a new hospital stayed empty until a doctor moved in next door and filled it to capacity.

<sup>5</sup>Section 1122 of the Social Security Act was codified at 42 U.S.C. 1320a-1.

Medicare and Medicaid cost-based payments to capital costs only, then capped all allowable operating and capital costs.<sup>6</sup>

Eventually, both public and private health insurers gave up trying to rescue the cost-based payment system and moved toward today's payment methods, such as hospital prospective payment (flat fee per admission) and subcontracted managed care, in which private managed care companies contract with the providers. Because the paying agencies thus gained more control over their payment obligations, actual provider costs lost their significance to them. Section 1122 and NHPDA were repealed in 1986. Today, the actual capital and operating costs of only the most unavoidably inefficient services, like small-volume essential rural hospitals, are considered in their reimbursement, and in return for that benefit, they operate under quite restrictive federal requirements.

The repeal of NHPDA withdrew the last federal support for the state Certificate of Need programs that they had created.<sup>7</sup> Some states' Certificate of Need programs have been maintained, however, including Michigan's own.<sup>8</sup> The state Medicaid agency continues to support the legislation, and coalitions of employers and providers continue to seek the protection that the program can give to their disparate interests. Medicaid and the employers believe the program will manage the supply, and therefore indirectly suppress the use and cost, of health

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<sup>6</sup>Major private payors, like Blue Cross, usually followed the federal lead in reimbursing their participating providers.

<sup>7</sup>The National Council of State Legislatures reports that 36 states retain some form of CON regulation. See [www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx](http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx) (last visited July 7, 2014). The scope of covered services varies largely from state to state. In Ohio, for example, only the expansion or inter-county transfer of nursing home beds requires approval; all other investments or transfers that Michigan's program would regulate are unregulated.

<sup>8</sup>In light of the Supreme Court's longstanding recognition that even local health care services can affect interstate commerce, surviving state CON programs have been challenged under the "dormant" Commerce Clause analysis of *Pike v. Bruce Church*, 397 U.S. 137 (1970). The cases, which necessarily are service-specific, have survived motions for summary judgment and judgment on the pleadings. See *Yakima Valley Memorial Hosp. v. Washington State Dept. of Health*, 654 Fed 919 (9th Cir. 2011) and *Colon Health Centers of America, LLC v. Hazel*, 733 F.3d 535 (4th Cir. 2013). There has been no such challenge in Michigan, to our knowledge.

services. Others view it as a barrier to a truly open market place, in which price and service competition would intensify.

### *The Basics*

The CON law requires approval of capital expenditures exceeding \$3,160,000<sup>9</sup> by hospitals, nursing homes, inpatient psychiatric programs, and freestanding surgical outpatient facilities. It also requires approval for initiation, acquisition, expansion or, in some cases, physical movement of the following, regardless of costs:<sup>10</sup>

- Acute Care Hospital Beds
- Inpatient Psychiatric Beds
- Nursing Home and Hospital Long-Term Care Unit beds
- Air Ambulance
- Bone Marrow Transplantation
- Computed Tomography (CT)
- Cardiac Catheterization
- Heart, Lung, and Liver Transplantation
- Magnetic Resonance Imaging (MRI)
- Megavoltage Radiation Therapy (MRT)
- Open Heart Surgery
- Positron Emission Tomography (PET)
- Surgical Services
- Urinary Extracorporeal Shockwave Lithotripsy (UESWL)

The issuance of a CON for any of these services is based on both statutory and administrative criteria. The statutory criteria are very nonspecific, and are generally implemented through administrative enactments with impact similar to administrative rules but identified as Certificate of Need Review Standards. Standards define what constitutes “need” for a project and how a project must be implemented, maintained and operated. Compliance with the Standards, which seldom leave room for interpretation, is largely dispositive of an application. Few applications are disapproved for noncompliance with the statutory criteria.

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<sup>9</sup>Adjusted annually according to the CPI.

<sup>10</sup>See generally MCL 333.22209.

Need criteria in the Standards vary widely with the type of service. For example, the Standards for nursing homes establish county-by-county limits on the number of nursing home beds that may be operated. The limit is based on a fixed number of days of service (bed days) per 1,000 persons in the county who are over sixty-five years of age. On the other hand, surgery services are not area-based, but require an applicant to gather written “commitments” of surgery cases from surgeons. (To guard against duplicative commitments, an elaborate cross check system is in place.) A new surgery service may be established only if nearby surgery services are exceeding a stated minimum number of surgery cases per year. Both methodologies have the effect of protecting existing facilities, usually without regard to their utilization or quality. Frequently, Medicaid program participation is a requirement of CON approval. A robust consultancy industry has arisen to assist project owners in understanding and applying Standards.

### *Certificate of Need Commission and the Standards*

The eleven-member Certificate of Need Commission is responsible for creation and maintenance of the CON Standards. It is appointed by the Governor, and must include two members representing hospitals and one member representing each of several other categories of facilities, professionals, payors, and consumers.<sup>11</sup> The Department of Community Health provides administrative support for the Commission and its subordinate workgroups and committees. It is advised by the Office of Attorney General. It does not participate in the evaluation of any individual CON application.

The Commission may modify the CON Standards and add or remove some types of services from coverage.<sup>12</sup> It reviews each set of Standards at least once every three years. After Commission action, the modified Standard is sent to the Legislature and Governor to review it

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<sup>11</sup>MCL 333.22211.

<sup>12</sup>MCL 333.22211-22215.

and either one may veto it within forty-five days (including nine legislative session days).<sup>13</sup> The Commission may appoint advisory Standards Advisory Committees (SACs) and “workgroups” to review CON Standards and propose changes. SAC composition and function are dictated by the CON statute.<sup>14</sup> Members are appointed by the Chair of the CON Commission, and must include representatives of most stakeholder groups. Although SAC recommendations are only advisory, the CON Commission very rarely deviates from them. Workgroups are less formal. They have no formal membership or voting, and are more commonly used to address a concern or issue where consensus building is more likely to succeed. Workgroups historically have been open for all interested parties to participate. The chair of the workgroup reports the products of the workgroup to the Commission. Because the recommendations typically represent consensus, the Commission rarely deviates from workgroup recommendations.

### ***Program Operation***

The Michigan Department of Community Health administers the Certificate of Need program, applying the statute as well as the Standards that the Commission establishes. It issues the administrative rules for the program (most recently revised effective February 4, 2014), which detail the process for filing and reviewing CON applications, implementing approved projects, amending projects after approval, and appealing denials, but do not set approval criteria for any specific type of project.<sup>15</sup> Two sections within the Department have primary responsibility for the program, CON Policy and CON Evaluation. CON Policy largely staffs the Commission’s activities, while CON Evaluation processes and decides individual applications.

### ***The CON Application Process***

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<sup>13</sup>MCL 333.22215(4).

<sup>14</sup>MCL 333.22215(1)(l).

<sup>15</sup>Michigan Administrative Code R 325.9101 et seq.

The CON application process begins with the filing of a letter of intent (LOI), which is processed by the Department within fifteen-days of receipt.<sup>16</sup> The LOI provides the Department with basic information about what service is being requested, who is requesting it, and where it is proposed to be provided. This information allows the Department to request the appropriate and relevant forms in the application. A letter of intent expires one year after processing if an application has not yet been filed.

### *Application Review*

There are three different types of CON review: non-substantive, substantive, and comparative. Substantial fees are required for all types. Non-substantive reviews are typically for acquisitions, replacements, and/or relocations of existing facilities and/or services, where the project capital costs do not exceed the capital expenditure threshold (currently set at \$3,160,000).<sup>17</sup> A non-substantive application takes forty-five days to review after the application is deemed complete and can be submitted on any day of the month.

Substantive review is applied to initiation or expansion of a covered clinical service, as well as projects exceeding the capital expenditure threshold.<sup>18</sup> These reviews take 120-days after the application is deemed complete (again, thirty days after submission). They are deemed to be submitted on the first business day of each month, regardless of the day they are delivered to MDCH.

Applications for a facility or service which the Standards allow to exist only in limited numbers (hospital beds, inpatient psychiatric beds, nursing home and hospital long-term care unit

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<sup>16</sup>Michigan Administrative Code R 325.9201(1). The LOI is a holdover from NHPDA, where it had a significant role in structuring the review process and notifying the public that a project was open to public comment and hearing. Today, it is the means by which an administrative file is opened, a number is assigned, and forms are designated for submission.

<sup>17</sup>Michigan Administrative Code R 325.9206

<sup>18</sup>Michigan Administrative Code R 325.9207.

beds, transplantation services and others) are subjected to comparative review if the applications filed exceed the allowable limits, which are established by the Standards applicable to each project type.<sup>19</sup> Applications potentially subject to this review are deemed submitted on the first business day of February, June, and October.<sup>20</sup> They take 150-days to review after an initial thirty-day period in which MDCH staff determines whether a comparative review actually is required. If a comparative review is not required (the combined applications do not exceed the applicable limit), the separate applications are reviewed substantively.

An application can be submitted according to the schedules discussed above. During the first thirty-days after submission, the Department may request additional information, and the applicant may respond.<sup>21</sup>

During the initial review of a comparative application for completeness, the Department will accept additional information and may also contact the applicant with questions. To assure fairness, no additional information is accepted after a comparative review has started unless all parties in the comparative group agree to allow the changes.<sup>22</sup>

Within the timeframes delineated for each review, the Department will issue a proposed decision. If it is a proposed approval, the Director has five days to sign it; if signed, it becomes a final agency action, within the meaning of the Administrative Procedure Act and authorizes the action approved. If it is a proposed denial, the applicant may pursue an administrative appeal and, if still unsuccessful, judicial review.

### *Appeals*

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<sup>19</sup>Required by *Huron Hospital v. State Health Facilities Commission*, 110 Mich. App. 236 (1981) and later written into the statute.

<sup>20</sup>Michigan Administrative Code R 325.9208.

<sup>21</sup>If the application is non-substantive the Department will deem it complete and begin its review on the day it receives said response. If it is a substantive or comparative application, it will be deemed complete on the first business day of the following month. Michigan Administrative Code R 325.9201(3).

<sup>22</sup>Michigan Administrative Code R 325.9215(1) (c). One occasion for such a request is a change in Standards that occurs between filing and decision.



A denied applicant has the right to an administrative appeal of its denial.<sup>23</sup> The time for making that request is short – just fifteen-days after the proposed decision is received. The appeal is conducted as a contested case under the Administrative Procedures Act by a hearing officer appointed under authority of MDCH.<sup>24</sup> Where a comparative review has been conducted, appeal by any denied applicant holds in abeyance the approvals of the successful projects. That avoids the possibility of an approved applicant committing funds and creating a facility later deemed in an administrative appeal to have been wrongly approved.<sup>25</sup> Appeals can take several months at the administrative level alone.

The scope of a CON appeal hearing is limited to demonstration that “the application filed by the applicant meets the requirements for approval.” Defects in review procedure or substantive illegality of Standards are not subject to administrative appeal, although cautious appellants raise those issues in order to preserve them for judicial review.<sup>26</sup>

Presiding officers have upheld the administrative “deliberative privilege” in CON hearings, and so pre-hearing deposition of decision makers is restricted, as is access to internal documentation of how a proposed decision was made; the only available decision rationale

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<sup>23</sup>MCL 333.22232.

<sup>24</sup>MDCH has arranged with the State Office of Administrative Hearings and Rules to conduct the hearings. The presiding officers act under authority delegated by the Director under the Public Health Code.

<sup>25</sup>That was the remedy, and the outcome in *Huron Valley*, above.

<sup>26</sup>The burden of proof is seldom addressed directly under the APA in CON hearings, but it lies with the applicant in practice. That view is based on text outside of the administrative appeal provision of MCL 333.22232(1). MDCH has argued in hearings and in court that because the statute requires an initial demonstration “to the satisfaction of the department” that need for the project has been shown (MCL 333.22225[1]), the appellant must also satisfy the hearing officer, thus, establishing a burden of persuasion:

“MCL333.22225(1) makes clear that the applicant only needs to satisfy the Department that their proposed project meets the applicable CON standards to be [approved].” Brief of Appellee Michigan Department of Community Health, *Medilodge of Oxford, et al. v. Michigan Department of Community Health*, Oakland County Circuit Court No. 12-1300-41-AA pp. 2, 12 (October 30, 2012).

The establishment of agency “satisfaction” of compliance, with statutory requirements for approval, perhaps independent of actual compliance, raises an ambiguity about the scope of hearings and burden of proof: it is unlikely that a denial by a “satisfied” review agency will ever produce an appeal. Cases raising the issue have been disposed of on other grounds by the courts, and so the issue has not been answered outside of the administrative hearing process.

available to an appellant is that which the Department chooses to reveal in reports by its pre-decision internal Program and Finance Sections and provides to all applicants. Most cases are disposed of on motion, sometimes supported by MDCH affidavits asserting the Department's factual and legal positions. Proposed decisions are issued by the presiding officers and, after the disappointed party files exceptions, go to the MDCH Director. The Director is empowered to issue the final agency action, and thus position the case for judicial review.

As with other appeals from contested cases, judicial review is available as of right in the Circuit Court of Ingham County or the county of the appealing applicant's principal place of business. Under the APA the time limit for seeking judicial review is sixty-days, but the CON statute limits that period to thirty-days.<sup>27</sup> The judicial review process is otherwise governed by the APA and the Michigan Court Rules.

### ***CON Implementation***

An approved applicant has twelve-months to "implement" an approved project by entering into an enforceable contract for construction or financing.<sup>28</sup> One six-month extension may be granted by MDCH for good cause.<sup>29</sup> Twenty-four months after approval, construction must begin and/or covered clinical equipment installed.<sup>30</sup> The administrative rules include provisions for extensions to that deadline if good cause is shown.

As a CON project is being implemented, the Department tracks progress through the filing of Project Implementation Progress Reports (PIPRs) by the CON holder. These are filed twelve-months after issuance of the CON, once the project has been completely implemented, and periodically in the interim as requested by the Department.

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<sup>27</sup>MCL 333.22231(9).

<sup>28</sup>Michigan Administrative Code R 325.9403(1).

<sup>29</sup>Michigan Administrative Code R 325.9403(2).

<sup>30</sup>Michigan Administrative Code R 325.9417.

If a project has changed significantly since approval, the applicant must file a request to amend the CON.<sup>31</sup> “Significant” changes include an increase in project costs beyond the standard allowance of fifteen-percent of project costs up to \$1 million and 10% of all costs above \$1 million.<sup>32</sup> Other significant changes could be a significant increase in square footage for a construction project, change to the make/model of a piece of covered clinical equipment, or a change in the number of beds being replaced or relocated. Three fundamental things absolutely cannot change during the review of a project or after CON approval – the applicant entity, the location of the project, and the type of covered service.<sup>33</sup>

### *Compliance*

CONs often include ongoing conditions, usually contained in the Standards, aimed at assuring efficient use, open access and quality of service. MDCH’s CON Evaluation Section monitors compliance with approvals through its CON annual survey and compliance reviews. Historically the annual survey has almost exclusively monitored service volumes and facility occupancy, but in very recent years the Department has expanded the survey to address other requirements, notably minimum staffing and Medicaid participation.

Most years the Department chooses a covered clinical service or bed type to review for compliance. Historically, it has chosen services that are relatively few (e.g., open heart surgery, transplantation services, etc.). MDCH will start the focused review by reviewing the annual surveys and will reach out to programs falling below minimum volumes or occupancy, seeking additional information and eventually making a determination of compliance or non-compliance with the conditions of approval of the CON. If a facility is non-compliant with its CON approval

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<sup>31</sup>Michigan Administrative Code R 325.9413.

<sup>32</sup>Michigan Administrative Code R 325.9415.

<sup>33</sup>Michigan Administrative Code R 325.9413(4).

(commonly, by not performing the minimum number of procedures required for approval under the applicable Standards), the Department may offer to enter into a compliance agreement rather than revoke CON approval. The compliance agreements often will include a plan to achieve compliance, as well as civil fine and a charity care undertaking. Because a CON service is held to the standards in effect at the time of its approval, if a standard has been relaxed since approval, the compliance agreement will often bring the program under the new, more relaxed standard. We are not aware of any CON being rescinded after a project has been built, or services have been initiated.

The Department has a great deal of discretion when it comes to enforcement of the CON law. Its powers include revoking the CON, imposing civil fines, and/or requiring notification to all payers allowing them to require a refund of all monies paid for services provided outside of CON compliance.<sup>34</sup>

### *The Future of CON*

The Legislature has taken a great deal of interest in the CON program over the past several years, much of it negative. Last summer, the House Health Policy Committee formed a workgroup of legislators to review the program and make recommendations for changes, including possible repeal. After several meetings and discussions, the workgroup could reach no consensus, and recommended that no changes be made at this time.

A strong case can be made against the effectiveness of CON as a cost control measure. While the CON barrier clearly does deny (or discourage) significant amounts of capital investment in health care each year, the abandonment of cost based reimbursement supports an argument that the original purpose and fundamental function of CON programs have become irrelevant. Improvident capital investment may impose costs on the project owner, but payors are

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<sup>34</sup>MCL 333.22237.

no longer willing to cover those costs beyond their own estimate of reasonable compensation. The Federal Trade Commission has been hostile to CON laws for some time.<sup>35</sup>

Our view is that CON is secure in its place in the health care regulatory system in Michigan for the foreseeable future. It retains strong support from public and private payers, who subscribe to the hospital-in-the-desert parable and believe that oversupply of available services means excessive utilization (perhaps to compensate for loss of cost-based payment). It is also largely supported by existing providers, who, despite the program's potential for dramatic creation of winners and losers, appreciate the protection from new entrants into the market. On the other hand, it generally favors institutional ownership of health services in which physicians might otherwise invest on their own behalf, and so it is significantly opposed by organized medicine.<sup>36</sup> All indications are, however, that Michigan will remain one of those thirty-six states that remain attached to the laws that Congress abandoned more than twenty-years ago.

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<sup>35</sup>See FTC/DOJ September 12, 2008 press release, "Federal Trade Commission, Department of Justice Issue Joint Statement on Certificate-of-Need Laws in Illinois," at [www.ftc.gov/news-events/press-releases/2008/09/federal-trade-commission-department-justice-issue-joint-statement](http://www.ftc.gov/news-events/press-releases/2008/09/federal-trade-commission-department-justice-issue-joint-statement) (last visited July 15, 2014).

<sup>36</sup>The program operates independently of the federal and state laws that prohibit or restrict physician ownership of some health care services. CON relief, if achieved, would not fully clear the way for unlimited physician ownership of non-physician investment in health services.