

# Certificate of Need

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## KEYWORDS

• Certificate of need programs • Health care regulation • Health care legislation • Health care reform

## KEY POINTS

- Certificate of Need (CON) is a method of regulating specific health care services at the state level.
- The covered clinical services vary among the individual states.
- CON can assist in reducing health care costs and maintaining quality of patient care if properly administered.

## INTRODUCTION

Certificate of Need (CON) programs represent a patchwork of state regulatory programs across the United States that regulate the availability of selected health care services. Thirty-six states maintain laws designed to ensure access to health care services, maintain or improve quality, and control capital expenditures on health care services and facilities by limiting unnecessary health facility construction and checking the acquisition of major medical equipment. This article discusses the history of CON and explores controversies surrounding the current state of CON regulations.

CON legislation originally was introduced by the government in an attempt to solve the cost increase and oversupply problems.<sup>1</sup> This legislation required potential acquirers of medical facilities or technology above a certain monetary value to demonstrate the clinical need for acquiring this capability and qualifications for responsibility of ownership.<sup>2</sup>

CON laws primarily focused on hospitals and nursing homes to halt needless duplication of services and excess capacity. CON regulations were seen as a way to control the “medical arms

race” by having organizations demonstrate need for a facility, service, or equipment before investing in them. The term medical arms race implies competition by service expansion and proliferation of new technology. In the 1980s some states expanded their CON regulations to control the proliferation of ambulatory care services as well. Other secondary objectives of CON were to promote access and quality.<sup>3</sup>

Issues surrounding overuse of imaging due to the expansion of availability of imaging centers demonstrate the concept of moral hazard, illustrating supply-driven demand. Moral hazard arises when individuals engage in behaviors under conditions such that their privately taken actions affect the probability distribution of the outcome. By having more scanners in a geographic area, the probability that more studies will be ordered and performed (by virtue of easy access/availability) is increased.

## HISTORY OF CON LEGISLATION

In the mid twentieth century, the nation’s aging medical infrastructure and workforce were poorly prepared to adequately serve the needs of soldiers

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returning from World War II and the subsequent increase in the nation's population.<sup>1</sup> There was an insufficient number of hospitals built during the Great Depression, resulting in inadequate medical care for returning soldiers. Congress responded to the situation by passing 2 laws: The Hill-Burton Act of 1946 and the Health Professions Act of 1963. The Hill-Burton Act was passed with the goal of improving medical supply with focus on facility capacity. This act encouraged community planning and hospital construction using Federal subsidies. The Health Profession Act of 1963 focused on the medical workforce. The federal government also expanded access to health care through the Kerr-Mills Act of 1960 for welfare recipients and the 1965 Social Security Act for the elderly and the poor.<sup>4</sup>

Health care spending was rising significantly by the late 1960s. Health care spending had grown at an annual rate of 3.7% in the 1940s and 1950s, but in the 1960s rose at a rate of 5.8%.<sup>1</sup> As a result, the health care expenditures per capita more than tripled between 1940 and 1970.<sup>5</sup> In particular, hospital expenditures more than tripled, to \$27.6 billion in a little more than the 10 years from 1960 to 1970.<sup>6</sup>

Three main factors contributed to the rising costs of health care: (1) the implementation of Medicare, (2) the widespread adoption of a traditional fee-for-service (FFS) payment system, and (3) the diffusion of new medical technology. The Medicare health insurance program had a great impact on increasing costs of health care. The Social Security Act signed into law by President Lyndon Johnson on July 30, 1965, established the Medicare and Medicaid health insurance programs. The Medicare program provided health insurance for the elderly and the Medicaid program insured the poor. Through Medicare, currently one of the largest health insurance programs in the world, most elderly patients had nearly full-coverage insurance.<sup>7</sup> As a result, the patients generally ignored the price of the services when choosing a facility. With these plans, patients selected the hospitals based on hospital reputation and their perception of the quality of care provided. In turn, this led hospitals to adopt the latest technology and expand offerings to attract more patients.<sup>3</sup>

The FFS system also contributed to the rising costs of health care. Under FFS, hospitals were reimbursed by insurers for all expenses incurred, regardless of the cost, necessity of the service, or quality of the facility.<sup>1</sup> Under FFS, medical services often expanded beyond their actual need.

The technological change that took place during this period is also another primary cause of rapid

increase in health expenditure.<sup>8–10</sup> One of the single most expensive and rapidly diffused medical technologies of that time period was computed tomography (CT) scanning in the mid 1970s.<sup>11</sup> The CT scanner, developed in England by EMI, rapidly changed the diagnostic process for many conditions. Because of its diagnostic capabilities, the CT scanner became rapidly embraced by both patients and clinicians. Sophisticated medical technology is expensive: the unit costs exceed US\$1 million.<sup>2</sup> These factors, among others, led to the establishment of CON legislature.

Several steps preceded the common establishment of CON programs by the US states. In an effort to halt rising costs of health care, the federal government and the states decided to implement a health care regulation model originally initiated in Rochester, New York. The Rochester Patient Care Planning Council, composed of insurers, patients, and providers, evaluated the community's hospital needs and determined what services were needed and not needed.<sup>12</sup>

The Comprehensive Health Planning and Services Act signed by President Johnson in 1966 authorized the states to establish planning processes that would rationally allocate federally granted health-related funding.<sup>4</sup> New York established mandatory CON processes in 1966, followed by Maryland, Rhode Island, and District of Columbia.<sup>12</sup> About half of the states had adopted CON laws by 1974.<sup>13</sup> The National Health Planning and Resources Development Act (NHRPDA) of 1974 required the remaining states to establish CON programs<sup>1</sup> that would review and grant approvals to any facility or equipment projects that would expand health care services by any provider.<sup>14</sup>

Only a few years after the CON programs were federally mandated, they came under increasingly severe criticism and, ultimately, were abandoned prematurely by the federal government. During President Ronald Reagan's first term (1981–1985), CON was dismissed by policy makers as an unjustified federal imposition on states and a barrier to competitive dynamics. Congress let the NHRPDA expire in 1986, and federal funding of state CON programs ended the following year.<sup>15,16</sup> Within 2 years, 10 states eliminated their CON programs.<sup>12</sup> In the 1990s and early 2000s, 5 additional states repealed their CON laws in full.<sup>17</sup> While most states have chosen to keep CON, nearly all of them have modified their CON programs to exempt some medical services.<sup>1</sup>

## CON AND IMAGING SERVICES

Imaging services are covered by CON laws in most states. Commonly covered imaging services are

magnetic resonance (MR) imaging, CT scanning, and positron emission tomography (PET) scanning. However, in some states (eg, Vermont, Maine, District of Columbia, and Hawaii), the basic diagnostic service of ultrasonography requires CON review. The covered services by individual states' CON programs in 2010 are listed in the 2011 American Health Planning Association (AHPA) Directory (available on their Web site, <http://www.ahpanet.org>). CT, MR imaging, and PET coverage for the individual states are provided by the AHPA 2011 Map Book Certificate of Need coverage (Figs. 1–4).

CON regulation of imaging services is controversial. Opponents of CON believe that restricting the development of new imaging services is anticompetitive and impedes patients' access to necessary diagnostic services. In many non-CON states, imaging services are readily available to patients, with little or no waiting time. In CON states where availability of imaging services is restricted, patients may need to schedule their examinations several days in advance and/or during inconvenient hours. Other arguments from the opponents of CON are that CON imposes unnecessary government regulation and that it inhibits the entrepreneurial "spirit."

On the other hand, CON proponents point out that MR imaging, CT, and PET units are costly pieces of equipment and that restricting their numbers ensures optimum use of existing units. Furthermore, many believe that health care

facilities generate their own demand, which can be particularly true of diagnostic services such as imaging. In addition, historically imaging services have been a source of positive financial margin for health care providers. Community hospitals, which provide the full spectrum of health care services, often use the margin from imaging services to offset financial losses resulting from other community services, such as 24-hour emergency care and pediatric departments. CON regulations protect community hospitals from independent imaging providers cherry-picking the patients with good insurance coverage, while allowing patients with insufficient or no insurance to go to the community hospitals for diagnostic imaging.

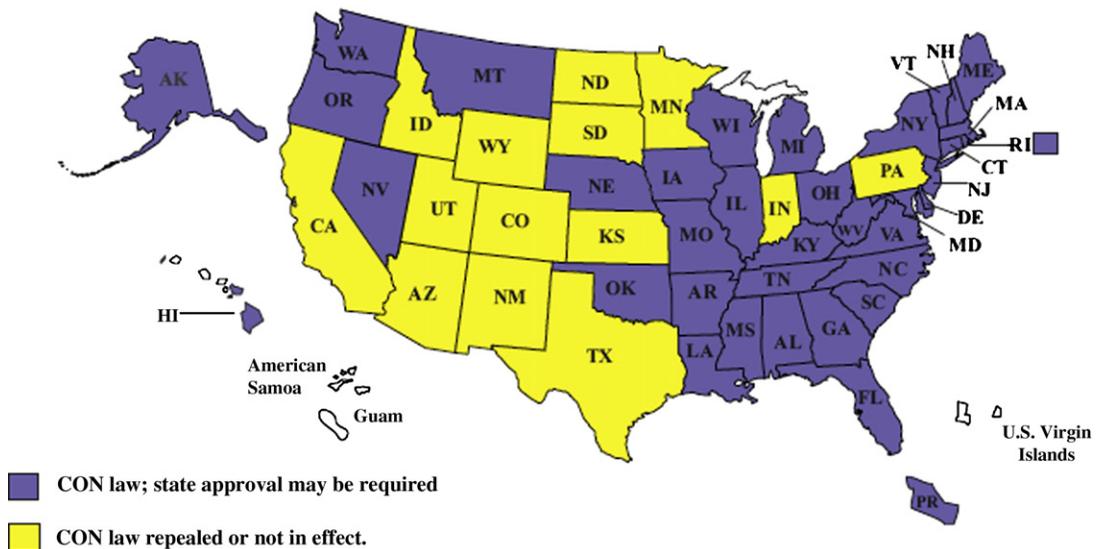
Furthermore, the proponents of CON would say that CON not only limits use and lowers health care costs, as already discussed, it can also discourage nonradiologists from performing complex imaging studies.

## CON CONTROVERSIES

### Proponents

Although the federal law requiring states to have CON regulations expired in 1986, many states retained CON regulations. Policy makers in many states have been reluctant to completely drop CON laws because of concern that with removal, there might be a surge in health care spending, including both capital expenditures and operating expenses. In fact this is what happened in

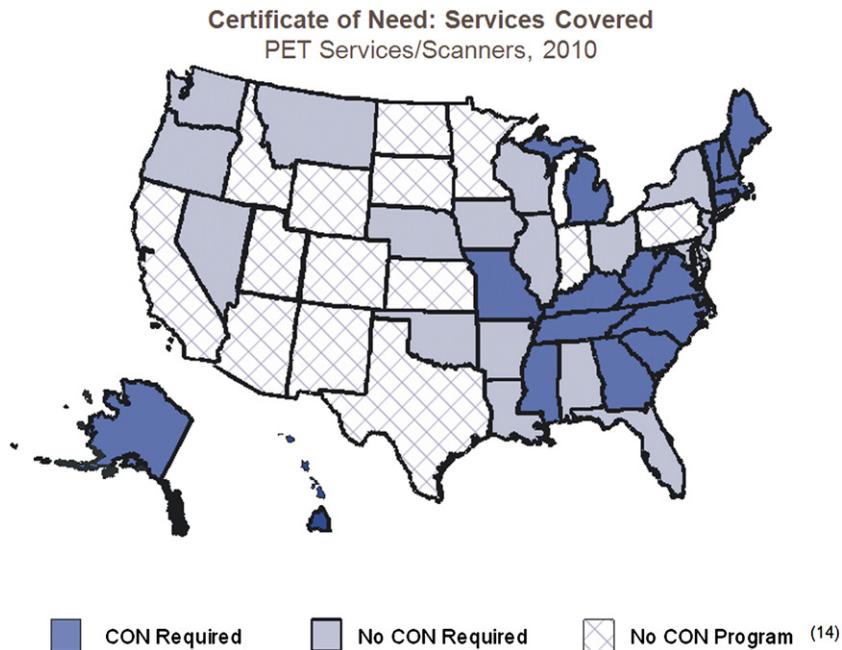
State Certificate of Need (CON) Health Laws, 2010



Compiled by NCSL June 2010; based on data from AHPA

Fig. 1. Certificate of Need coverage: health laws in the United States, 2010. (From American Health Planning Association. Map book: Certificate of Need planning. AHPA; 2011; with permission.)





**Fig. 4.** Certificate of Need coverage for positron emission tomography services. (From American Health Planning Association. Map book: Certificate of Need planning. AHPA; 2011; with permission.)

and 300 additional diagnostic imaging centers. These new facilities are often physician owned. After seeing this expansion of ambulatory surgery centers, free-standing dialysis centers, and radiation therapy centers, Ohio proposed reinstating CON law to protect community hospitals.<sup>18</sup> As already discussed, these services tend to be aimed at high profit for hospitals and are badly needed to offset money-draining operations.

According to its proponents the conceptual purposes of CON include that it: functions as a plan implementation tool; supports community-based health services and health facility planning; supports community-oriented planning by health service programs, facilities, and systems; provides analytical discipline and goal orientation in health service and facility planning at all levels; addresses the “excess supply generating excess demand” phenomenon; and limits unnecessary capital outlays.<sup>12</sup>

CON typically focuses on access and quality more than cost. CON regulations seek to improve economic and social access by requiring providers to accept patients regardless of payment source and assure equitable distribution of health facilities. CON elevates quality by promoting best practices and high standards and by establishing minimum volume requirements. Finally, CON promotes fiscal responsibility by requiring providers to use sound economic and planning principles.

CON proponents point to recent studies that demonstrate the success of CON. Faced with rising health care costs and the possibility of weakening or eliminating Michigan’s CON program, each of the 3 American automakers undertook separate systematic analyses of their health care costs in states where they have large numbers of employees and insured dependents. DaimlerChrysler Corporation showed that their employees in the non-CON regulated states of Wisconsin and Indiana experienced health care costs almost twice as high as those in the CON states of Delaware, Michigan, and New York. General Motors (GM) analyzed health care use and expense data among its employees and dependents in Indiana, Michigan, New York, and Ohio, 4 states where it has large numbers of insured employees, for the period 1996 to 2001. Comparisons show that GM spent nearly a third less in CON states (New York, Michigan) for health care expenses per employee than in non-CON states (Indiana, Ohio). The study by Ford Motor Company included Kentucky, Michigan, and Missouri (CON states), and Indiana and Ohio (non-CON states). In certain respects, the Ford study is broader than the GM study in that it distinguishes inpatient and outpatient hospital costs, as well as service-specific costs for MR imaging and coronary artery bypass graft surgery. When comparing inpatient and outpatient costs, Ford found that health care costs in

CON states were about 20% lower than in non-CON states.<sup>12</sup>

### Opponents

There are several reasons why some states might have chosen to abandon CON laws. During the same time that the desirability of CON was being debated, 2 other types of regulation were developed in an attempt to hold down the costs of health care: The Medicare's Prospective Payment System (PPS) in the 1980s and the Health Maintenance Organization (HMO) Act of 1973. By paying a specified amount for each hospital admission, PPS eliminated hospitals' incentive to inflate costs. In addition to Medicare, more than 30 states adopted rate-setting legislation in the 1980s, which set ceilings on prices that hospitals could charge for certain services.<sup>1</sup> The states followed the lead of the Nixon and Carter administrations, both of which had advocated for increased expenditure controls.<sup>13</sup> The HMO Act of 1973 removed state barriers to managed care. As a result, there was substantial growth of HMOs through the 1980s and managed care in the 1990s.<sup>19</sup> Managed care pressured hospitals to lower costs by negotiating discounted rates. The demand for inpatient hospital care decreased appreciably as a result of growth in managed care planning, as well as implementation of PPS.<sup>3</sup> The lawmakers might have believed that these two regulations (PPS and HMO) along with market pressures would adequately control health care supply and costs without CON regulations.<sup>1</sup> Another big reason could be related to the large amount of empirical evidence accumulated by the early 1980s indicating that CON regulations were ineffective in cost containment.<sup>3</sup>

### CURRENT STATUS OF CON

CON laws remain in effect in 36 states and the District of Columbia.

A recent study conducted by the National Institute for Health Care Reform (HCR) compared the CON programs in 6 states: Connecticut, Georgia, Illinois, Michigan, South Carolina, and Washington. Based on telephone interviews with health care stakeholders in each state, the researchers attempted to assess the effectiveness of the CON programs in these 6 states.<sup>20</sup>

In 5 of the 6 states studied, the CON approval process is perceived to be highly subjective. The process is often influenced heavily by political relationships such as provider's clout, organizational size, or overall wealth and resources, rather than policy objectives. The state of Michigan is an exception to this finding.

Michigan is the only state in the study with a formal advisory role for industry stakeholders, employers, consumers, and other interested parties through a CON Commission of 11 members, appointed by the governor. By law, the members of the CON Commission include the following representation: MD representative, DO representative, MD or DO medical school, hospital representative ( $n = 2$ ), nursing home, nurse, self-insured purchaser, non-self-insured purchaser, labor union, and nonprofit health care organization. The role of the Commission is to establish the rules (called "standards") by which individual CON applications are evaluated.

The Michigan CON Commission relies on issue-specific standards advisory committees (SACs) to recommend changes to the standards for specific CON-covered services (eg, cardiac catheterization, MR imaging, surgical services, and so forth). Membership on the SACs is determined using an open nomination process. By law the composition of a SAC must include a two-thirds majority of subject-matter experts, and representatives of health care provider organizations, health care consumer organizations, health care purchasers, and health care payers. All meetings of the SACs and the Commission are open meetings. Considering recommendations from the SACs and after opportunity for public input, the CON Commission sends proposed CON Review Standards to the State Legislature and the Governor. Either branch of state government can veto the proposed standards. After the specified review period, the new CON Review Standards have the force of law.

The CON Commission does not participate in the review of individual CON applications. Rather, project analysts with the Michigan Department of Community Health evaluate CON applications for compliance with the standards established by the CON Commission. This distribution of responsibility tends to promote greater objectivity and transparency: The appointed commission is responsible for setting CON review standards, and the state Department of Community Health is responsible for the actual review of CON applications.

An overview of the CON application process in the state of Michigan is available at [http://www.michigan.gov/mdch/0,4612,7-132-2945\\_5106-120981-,00.html](http://www.michigan.gov/mdch/0,4612,7-132-2945_5106-120981-,00.html). An applicant must file a Letter of Intent (LOI) with the Michigan Department of Community Health and a regional review agency, if present. Based on the LOI, the Department will notify the applicant of the required application forms for the proposed project. The corresponding CON application can be submitted online through the Department's CON e-Serve system or by

paper to the Lansing Office. Online submission is encouraged to help expedite the application process.

Applications fall into 3 categories: Nonsubstantive, Substantive, and Comparative Review. Nonsubstantive and Substantive applications can be submitted online. Comparative review projects are paper applications. Nonsubstantive reviews involve projects not requiring a full review. Examples include equipment replacements and acquisitions of existing facilities. Substantive reviews involve projects that require a full review on an individual basis, such as a new MR imaging unit or additional units. Comparative reviews involve situations whereby 2 or more applicants are competing for project types for which need is limited.

An applicant must file an application within one of the LOIs as instructed in the Department's notification letter with the required forms and applicable application fee. Within 15 days of receipt of an application, the department reviews it for completeness and requests any additional information as necessary. The applicant has 15 days to submit the requested information.

Once the application is complete, a proposed decision is issued within deadlines for each review type: Nonsubstantive, 45 days; Substantive, 120 days; and Comparative, 150 days. The application is forwarded to the assigned reviewers for an in-depth review of the proposed project. Within the time period the assigned reviewer will prepare a report documenting the analysis and findings of compliance with statutory review criteria and applicable review standards. The reviewer will make a recommendation for approval or disapproval. If the decision is an approval, a final decision is issued by the Department Director within 5 days. If the proposed decision is disapproved, the applicant has 15 days to request a hearing. The hearing must begin within 90 days. Then a final decision is issued by the Department Director following the hearing. If a hearing is not requested, a final decision is issued by the Department Director. There are also opportunities for public input. Any public input received for a particular application will be made part of that application and may be used by the department in its decision. CON application fees are based on total project costs. The fee for projects less than or equal to \$500,000 is \$1500; between \$500,000 and \$4,000,000 is \$5500; and equal to or more than \$4,000,000 is \$8500.

The findings of the HCR study highlight substantial differences among CON programs across the states. In contrast to Michigan, the Illinois Health Facilities and Services Review Board (HFSRB)

issues binding decisions on all CON applications filed in the state. Recently wracked by scandal alleging improprieties by Board members, the HFSRB was reformed by 2007 legislation requiring transparency and accountability in all their deliberations.<sup>21</sup>

Even though the CON requirements are not perfect, many respondents believe that CON programs should remain and could be strengthened by moving away from the political influences and focusing on planning policy based on solid data. The CON process can be strengthened with solid state health planning and by improving the process of evaluation and enforcement of CON requirements.<sup>20</sup> CON might be a way to help plan for the evolving dynamics of the local health care market required by health reform coverage expansions and payment reforms.

## SUMMARY

CON programs have been maintained in a majority of states, despite substantial changes in the health care arena over the last 40 years. Opinions about the effectiveness of CON vary widely, from concerns about undue government interference in the health care market, on the one hand, to belief that CON programs help to rationalize the health care system and restrain health care cost increases, on the other. Although circumstantial, recent evidence provided by American automobile manufacturers supports the latter opinion. However, until there is proof that implementation of the recent federal health care reform legislation results in lower health care costs, it is unlikely that there will be further erosion in the nation's diverse patchwork of state CON programs, as an antiquated but still moderately effective vanguard against runaway health care costs.

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