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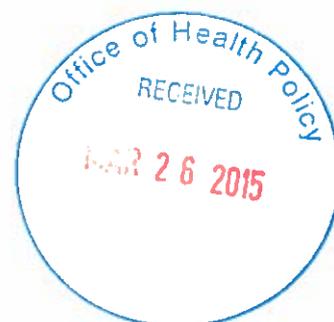
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March 26, 2015

VIA HAND DELIVERY

Ms. Emily Whelan Parento, Executive Director  
Cabinet for Health and Family Services  
Office of Health Policy  
Division of Certificate of Need  
275 East Main Street 4WE  
Frankfort, Kentucky 40621



**Re: Certificate of Need Modernization Program**

Dear Ms. Parento

On behalf of our firm's client, The Christ Hospital Network, enclosed please find supplemental comments addressing the Certificate of Need Modernization Program in the form of a White Paper prepared by Henry Miller, PhD and The Christ Hospital Network.

In addition, we would like to schedule a meeting at the Office of Health Policy sometime the week of April 13, 2015 for Dr. Miller and representatives of The Christ Hospital Network to discuss this White Paper.

We look forward to hearing from you. Thank you.

Sincerely,

  
LISA ENGLISH HINKLE  
MOLLY N. LEWIS

LEH/skw  
Enclosure

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**CERTIFICATE OF NEED MODERNIZATION  
IN KENTUCKY**

**March 19, 2015**

**Prepared by:  
Henry Miller, Ph.D.  
Berkeley Research Group, LLC.  
And  
The Christ Hospital Health Network  
Cincinnati, Ohio**

## **CERTIFICATE OF NEED MODERNIZATION IN KENTUCKY**

### **1. PURPOSE OF THIS PAPER**

In October 2014, the Cabinet for Health and Family Services (the Cabinet) requested stakeholder input regarding the modernization of the Commonwealth's Certificate of Need (CON) program. The Cabinet recognizes that the Kentucky health care system, like systems throughout the U.S., is undergoing substantial changes. CON laws were originally established in the 1970s when cost containment concerns focused on unnecessary duplication of inpatient hospital services. Changes in health care delivery over the past several years slowed the growth of inpatient services while outpatient services grew rapidly. Recently, passage of the Affordable Care Act and other factors further changed the health care systems environment. The need to consider the effects of these changes led the Cabinet to investigate modernization of its CON program.

When it requested stakeholder input, the Cabinet identified Core Principles to guide its consideration of changes in the CON program. These principles, which reflect the environmental changes that the health care system is experiencing, are:

- Supporting the Evolution of Care Delivery,
- Incentivizing the Development of a Full Continuum of Care,
- Incentivizing Quality,
- Improving Access to Care,
- Improving Value of Care,
- Promoting Adoption of Efficient Technology, and
- Exempting Services for which CON is no longer necessary.

This paper has been prepared to provide feedback to the Cabinet. It includes additional descriptions of the Core Principles and identifies the key issues that will underlie the future of Kentucky's CON program. In addition, it recommends changes to the Commonwealth's CON program that will be needed to meet the Cabinet's modernization goal.

### **2. THE NEED FOR MODERNIZATION**

At one time, all 50 states had Certificate of Need laws aimed at containing health care costs and improving access to care by regulating changes in state health systems. Although some states repealed their CON laws, Kentucky is one of 36 states that retained CON requirements, although these requirements vary substantially from state to state.<sup>1</sup>

For example, all states with CON programs regulate changes in nursing home and other long-term care beds. However, eight of the 36 states with CON programs have discontinued regulation of acute care beds; nine of these states do not regulate ambulatory surgery centers; ten do not regulate cardiac catheterization programs; 18 do not regulate home health and hospice care; 21 do not regulate Mobile Technology (CT/MRI/PET); 18 do not regulate magnetic resonance imaging scanners; 13 do not regulate

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<sup>1</sup> National Conference of State Legislatures, "CON – Certificate of Need Laws" at <http://www.ncsl.org/research/health/con-certifictate-of-need-state-laws.aspx>.

radiation therapy and 17 do not regulate substance/Drug Abuse programs. Kentucky includes all of these services in its CON program.<sup>2</sup>

The debate about the effectiveness of CON programs began when the programs were first initiated in the 1970s. Proponents argued that regulation was the best approach for containing rising health care costs and assuring access. Opponents argued that competition more effectively met these goals. As proponents and opponents of CON programs continued to advocate their positions, changes in the U.S. health care system occurred. Utilization of inpatient acute care services declined substantially when the Medicare program introduced case-based prospective payment. At the same time, outpatient service volumes increased dramatically, which led to increased attention paid to these services by state CON programs.

Other important health care system changes also occurred. Hospitals concerned about their financial survival or seeking to gain leverage in private sector payer rate negotiations began to join together to create hospital systems. The growth in outpatient service volumes also led these systems to purchase or create outpatient programs including ambulatory surgery centers, freestanding diagnostic centers and home health agencies. These systems often sought to provide services through the entire continuum of care.

Outpatient care growth in hospital-based and other health care systems has accelerated since the Affordable Care Act (ACA) was enacted in 2010. The ACA's focus on the Triple Aim defined by the Institute for Health Improvement<sup>3</sup> provided new opportunities for health care systems to assume risk for the populations they serve through organizational changes (e.g., Affordable Care Organizations) and new payment methods aimed at promoting quality.

The emerging health care system provides promise for improvements. As providers assume more risk for the health of the populations they serve, they will be incentivized to improve the quality of their services. As providers assume more financial risk through innovative payment methods, they will be incentivized to contain cost and increase the value of the services that they provide.

### 3. ISSUE

The Core Principles recognize the changes in the health care system that have occurred and are continuing to occur. The Cabinet must decide whether the Core Principles can be best achieved through continued regulation or through competition among providers. This decision requires the Cabinet to answer several questions, including:

- Can insights be gained from prior studies of the effectiveness of CON regulation?
- Is there a market that allows competition to be effective?
- Will changes in methods for paying providers be sufficient to achieve the Core Principles?
- Is regulation needed to protect quality of care and sole community providers?

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<sup>2</sup> Id.

<sup>3</sup> Institute for Health Care Improvement, "IHI Triple Aim Initiative" defines the Triple Aim as improving the patient experience of care (including quality and satisfaction, improving the health of populations and reducing the per capita cost of health care. See: <http://www.ihl.org/Engage/Initiatives/TripleAim/pages/default.aspx>.

#### **4. PRIOR STUDIES OF THE EFFECTIVENESS OF CON REGULATION ARE NO LONGER RELEVANT**

Studies of the effectiveness of CON regulation have not been conclusive. Some studies found that CON regulation is effective in controlling cost while others found that competition is more effective.<sup>4</sup> These studies are no longer relevant. For the most part, they were completed between ten and twenty years ago and evaluated a different health care system than the one that exists today and will exist in the future.

Moreover, it is not surprising that studies of the effectiveness of CON have been inconclusive. Substantial excess acute care capacity was created across the U.S. when the Medicare program introduced case-based prospective payment. Hospitals responded rapidly to prospective payment by dramatically reducing patients' average length of stay. The reduction in average length of stay from 1980 to 1990 varied by region but was as great as 40 percent.<sup>5</sup> These reductions created large numbers of unused beds in all states, regardless of whether or not they had CON regulations.

The Cabinet must make its decisions in light of today's health care system and not based on past issues and concerns.

#### **5. THERE IS A MARKET THAT ALLOWS COMPETITION TO BE EFFECTIVE**

In its submission to the Cabinet, the Kentucky Hospital Association argued that there is no real market for health care services.<sup>6</sup> It may have been true that an effective health care market didn't exist when CON regulations were developed, but health care markets are rapidly evolving. A functioning health care market requires patients to have sufficient information to make choices when they seek care. It is especially important for patients to have information on physicians, since physicians frequently determine which hospitals or outpatient facilities a patient will use. Patient satisfaction, patient perceptions of quality and price of care all affect a patient's choice of physician. The Internet has led to rapid growth in the availability of information on these factors. For example, the widely used Healthgrades® web site offers information on patient satisfaction and quality of care indicators such as education, board certification and incidents of malpractice. The site also offers grades on hospital care. A growing number of health plans are offering information on physician and other provider costs on their web sites. As this information is increasingly used, the opportunity for market based decisions grows.

In addition, when the CON program was initiated, the focus of health care system growth was on building costly new acute care beds which meant that competition among providers for these beds had substantial risk and often, it wasn't clear that their construction sufficiently improved access to care to justify their need. Today, the trade-off between access and costs has changed. Health care system growth now focuses on expansion of less costly outpatient services. Competition among providers to develop outpatient services has lower risks for the Cabinet's efforts to contain costs.

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<sup>4</sup> Add FTC/DOJ and auto manufacturers studies.

<sup>5</sup> See Mark R. Chassin, "Variations in Hospital Length of Stay: Their Relationship to Health Outcomes," Health Technology Case Study No. 24, Office of Technology Assessment, Washington, DC, 1983 and "Inpatient Hospital Stays and Length of Stay", HCUP Facts and Figures, Agency for Healthcare Research and Quality, 2009.

<sup>6</sup> Daniel J. Sullivan and Kentucky Hospital Association, "Certificate of Need: Stabilizing Force for Health Care Transformation", December 2014.

The Cabinet must make its decisions with the understanding that the market for health services exists and it will allow competition to be effective in controlling costs and improving access.

**6. CHANGES IN METHODS USED TO PAY PROVIDERS WILL NOT BE SUFFICIENT TO ACHIEVE THE CORE PRINCIPLES**

In its submission to the Cabinet, the Kentucky Hospital Association also argued that changes in methods used to pay providers will be sufficient for the Core Principle of improved value to be achieved.<sup>7</sup> Methods by which providers are rewarded for improved quality, increased attention to accountable care and population based payment were noted. Medicare is leading the way on these approaches, but Medicare will not be effective in today's environment unless its efforts are complemented by similar efforts by health plans. When Medicare introduced prospective payment in 1983, its focus on inpatient acute care was especially effective because Medicare beneficiaries accounted for the greatest number of inpatient acute care patients. As noted, acute care volumes have declined proportionally and outpatient volumes have grown. Medicare beneficiaries make up a relatively small portion of outpatients which means that health plan involvement is needed to assure new payment changes are effective.

In some parts of the U.S., health plans are seeking similar opportunities to change payment methods. Health plans, however, cannot implement payment system changes without competition. Unless health plans have opportunities to select among providers who seek to contract using the new approaches, providers will be able to obtain high rates, regardless of the payment approach that is used. Moreover, there will be no incentive for health plans to contract at these high rates and existing payment systems will remain in effect.

The Cabinet must make its decisions with the understanding that new payment methods will only be effective if health plans can seek contracts with competing providers.

**7. REGULATION IS NOT NEEDED TO PROTECT QUALITY OF CARE AND SOLE COMMUNITY PROVIDERS**

In its submission, the Kentucky Hospital Association concluded that quality of care will be protected by continued CON regulation.<sup>8</sup> Continuing CON regulation will provide protection, but not protection of the quality of care. Instead, Kentucky's existing hospitals and hospital systems will be protected. Regulated entities seek to maintain regulation when they seek protection from potential competitors. This concept of regulatory capture is well documented in the economics literature.<sup>9</sup> The Hospital Association is asking the Cabinet to use CON regulation to keep competitors from challenging the "franchises" they have built.

If CON regulation is used to protect the franchises of existing hospitals and health systems, there is potential for Kentucky's health care system to stagnate. Changes in Medicare payment methods may encourage innovation in the development of a broader continuum of care, but without competition,

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<sup>7</sup> Id.

<sup>8</sup> Id.

<sup>9</sup> See, for example, <http://online.wsj.com/articles/regulatory-capture-101-1412544509>.

innovations will take whatever form existing hospitals and health systems decide to implement. They will have little incentive to innovate beyond the easiest and simplest approaches.

There is also little potential for improvements in quality without competition. The Hospital Association argues that higher quality services are provided in high volume facilities. They conclude that therefore, services should be provided in as few places as possible, to protect volumes. Places however, do not perform services, physicians and other professionals provide services. The relationship between quantity and quality cited by the Hospital Association is misused. There is evidence that the more frequently a surgeon performs a procedure, the better he or she gets at that procedure. This finding, however, is derived from the competitive environment present in most states. Surgeons that are especially effective in performing a procedure attract additional patients and their familiarity with the procedure grows until they are exceptionally good at performing the procedure. The number of times a procedure is performed in a hospital is not relevant since surgeons who perform procedures frequently and those that perform them infrequently may all use the same hospital.

There is evidence that quality may, in fact, suffer when services are concentrated in a single facility. For example, King's Daughters Medical Center in Ashland is the only local hospital that has a CON approved and operational for a comprehensive cardiac catheterization service. In 2013, the Federal government began an investigation of unnecessary percutaneous coronary intervention (PCI) procedures at King's Daughters. The government found that unnecessary procedures had been performed on Medicare patients between 2006 and 2011. King's Daughters paid a substantial civil penalty. Due to King's Daughters Medical Center's strong opposition to competition in the market, another hospital in the market was unsuccessful in obtaining a CON to provide the same service until 2014. In this case, CON regulation did not result in improved quality even though a high volume of services were provided in a single hospital.

The Hospital Association also describes the need to protect sole community hospitals from competitors who will capture their patients who have commercial coverage and leave only the poorly paying Medicare and Medicaid patients for the sole community providers who cannot survive financially unless they have these better paying patients.<sup>10</sup> Unfortunately, sole community providers struggle to survive financially and have been doing so for many years. It is unlikely, however, that competitors will enter their region to compete with them. Kentucky's sole community hospitals do not provide surgical services so if a new ambulatory surgical center was opened in their region, it would not compete. The only service that sole community hospitals provide that could be subject to competition would be Emergency services. The very low volumes of emergency services provided by most of the Commonwealth's sole community hospitals, however, would not be sufficient to attract competitors.

## **8. SUCCESSFULLY ACHIEVING THE CORE PRINCIPLES REQUIRES COMPETITION**

As noted, the Cabinet identified seven Core Principles for the modernization of CON:

- Supporting the Evolution of Care Delivery,
- Incentivizing the Development of a Full Continuum of Care,
- Incentivizing Quality,
- Improving Access to Care,
- Improving Value of Care,

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<sup>10</sup> Sullivan and Kentucky Hospital Association, op. cit.

- Promoting Adoption of Efficient Technology, and
- Exempting Services for which CON is no longer necessary.

The evolution of care delivery has led to the reductions in inpatient services and the growth of outpatient services that have been described. There are continuing needs to encourage the growth of outpatient services. Continuation of CON requirements for outpatient services such as ambulatory surgery centers and freestanding diagnostic centers will limit their growth and constrain efforts to contain costs and improve quality. Competition, not regulation, is needed to support the evolution of care delivery.

If CON regulation is used to limit the introduction of new competitors in the Commonwealth's health care system, incentives to develop a full continuum of care will affect only existing providers. Hospitals and health systems may elect to develop a full continuum of care, but if they do, they will not have incentives to assure the value and quality of the services they provide. Instead, they will be incentivized to increase the size of the continuum of care they offer without having to be concerned about value and quality.

The importance of using competition to incentivize quality has been stressed in earlier discussions in this paper. Continuation of CON regulation will give existing providers the opportunity to establish quality standards that will, at best, be at a lower level than the standards that would be developed through competition.

Competition improves access to care. New competitors seek environments where there are sufficient patient populations that they need to succeed. Access in these environments can only be improved.

Continued CON regulation will limit entry into Kentucky's health markets and will support monopoly and monopsony opportunities for providers. Improvements in the value of care will depend on the willingness of hospitals and health systems to make investments in care although there will be few penalties if they fail to do so. If hospitals and health systems are required to assume responsibility for the health of the populations they serve, they will be incentivized to provide increased value. Although population health is receiving increased attention, it will be many years, at best, before hospitals and health systems suffer penalties for not maintaining the health of their populations. Competition, on the other hand, offers immediate opportunities for improvements in value.

It is difficult to use CON regulation to promote the use of efficient technology. CON regulators can identify efficient technologies and inform providers that they will approve its use, but they cannot require such technology to be developed and used. When a competitor offers newer and more efficient technology, it provides a strong incentive for other competitors to follow suit. Competition, rather than regulation, promotes the use of efficient technology.

Kentucky's health care system will be best served by discontinuing CON regulation and letting competition foster achievement of the Core Principles. The opportunity for competition to improve value, promote access and incentivize improved quality of care may not have existed when CON regulations were originally implemented, but the changes that have occurred mean that there are real opportunities to improve the Commonwealth's health care system by encouraging competition.