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## Certificate of Need Strategy

*Lessons Learned from Recent Washington Court Cases*

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Washington courts have recently issued several significant decisions relating to the state's Certificate of Need (CN) laws. Collectively, these decisions illustrate that a CN applicant must fully understand each step of the CN process, and how each step relates to the others, in order to adopt the correct strategies, avoid procedural pitfalls, and maximize the likelihood that its application will be granted and survive legal challenges. These decisions also illustrate the corollary point that other interested persons, who may oppose issuance of a CN, must also have a thorough understanding of the process in order to participate most effectively at each stage.

### Overview of the CN Process

The CN laws require a healthcare provider to obtain a license from the state, a CN, to establish many types of new facilities and services. This regulatory structure is intended to control costs and ensure that the healthcare system is developed in a planned, orderly manner, by regulating whether, when, and where new facilities and services may be established.

The process begins when a CN applicant files a letter of intent with the Department of Health (the Department), which describes the project. After filing a letter of intent, the applicant will file its CN application. The application is then subjected to a thorough review process by the professional staff of the Department's CN Program. This may include written screening questions and responses, a public hearing, and submission of rebuttal materials by the applicant itself and other parties.

A CN application must satisfy four general criteria to be granted: need; financial feasibility; structure and process of care; and cost containment. Specific statistical methodologies exist for evaluating "need" for some, but not all, types of projects. A CN will be granted or denied by the Department based on whether it satisfies

these criteria.

If its application is denied, a CN applicant often will commence an "adjudicative proceeding," an administrative process conducted by a health law judge, an administrative law judge employed by the Department. The adjudicative proceeding frequently will include an evidentiary hearing, during which the parties will present witness testimony and other evidence. At the end of the adjudicative proceeding, the health law judge will issue the Department's final decision on the application. If the health law judge denies the CN, the applicant may seek "judicial review" of the Department's decision in the courts.

This is a complex and often lengthy process, made more complicated by the fact that interested persons, often competitors of the CN applicant who would prefer that the CN not be granted, may seek to participate. In two of the three cases discussed below, for example, the Department initially granted the applicants' requests, and the subsequent adjudicative proceedings were commenced by interested persons who sought to have the Department's initial decisions reversed.

As these recent court cases illustrate, a CN applicant must employ

correct strategies at each step of the CN process in order to maximize its chances of success. This is particularly true where competitors are involved, who could subject the application to years of legal challenges even if the CN is granted.

**The Application Record: *University of Washington Medical Center v. Washington State Department of Health* (Washington Supreme Court, 2008)**

In *University of Washington Medical Center v. Washington State Department of Health*, the Washington Supreme Court issued its first decision in a CN case in thirteen years. The existing, exclusive provider of liver transplants in Washington appealed the Department's approval of a CN application by another hospital to establish a second liver transplant program in the state.

The existing provider argued that the Department improperly restricted the evidence that it could present during the adjudicative proceeding, following the initial approval of the CN. It argued that the health law judge should have permitted additional, new evidence regarding whether a second liver transplant program was needed.

The Supreme Court held that the health law judge has considerable discretion to determine the scope of admissible evidence in an adjudicative proceeding, and that she did not commit reversible error by limiting the new evidence that the existing provider could present in this case.

A key lesson from this decision is the importance of building a thorough evidentiary record during the application phase. If anything is left out, there may not be an op-

portunity to present it during later proceedings.

**The Adjudicative Hearing: *DaVita, Inc. v. Washington State Department of Health* (Washington Court of Appeals, 2007)**

*DaVita, Inc. v. Washington State Department of Health* involved competing CN applications by DaVita and Olympic Peninsula Kidney Center to open dialysis centers. The Department initially granted DaVita's application and

denied Olympic's application, but this decision was reversed by the health law judge, who awarded the CN to Olympic.

The Department's initial decision in favor of DaVita was based on its findings that this would allow patients choice of providers and create competition, because Olympic already operated dialysis centers in the area. However, the health law judge found that the DaVita center would not allow significant pa-



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tient choice, and that there was no evidence that it would create price competition or lower fees. The health law judge therefore found that Olympic's application was superior based on financial feasibility and cost containment factors. This decision was affirmed on appeal.

In its opinion, the Court of Appeals clarified that the health law judge was not acting as a reviewing officer, but rather was the Department's final decisionmaker, and was not obligated to give any particular deference to the CN Program's evaluation. The Court of Appeals also held that a CN applicant bears the burden of proof with respect to its application in the adjudicative proceeding, even if the Program has already awarded it the CN.

A key lesson from this decision is that even if a CN is awarded by the Department, based on the CN Program's evaluation, the CN applicant is going to have to prove its case again if the decision is appealed to a health law judge. The health law judge becomes the Department's decisionmaker, and owes no particular deference to the CN Program's decision, and the CN applicant will bear the burden of proving to the health law judge that it should be awarded a CN.

**The Appeal:** *MultiCare Health System v. Washington State Department of Health* (Washington

## **Court of Appeals, 2008)**

*MultiCare Health System v. Washington State Department of Health* involved an application for a Determination of Non-Reviewability (DNR), or a determination by the Department that no CN is needed for a particular project. In this case, the applicant asked the Department to determine that a proposed ambulatory surgery center, the use of which would be limited to an employed-physician group, was not subject to CN review. The Department agreed, and issued the DNR.

Another provider then wrote to the Department, objecting to the request for a DNR. After approximately five months of discussions between the applicant, the opponent, and the Department, the opponent commenced an adjudicative proceeding challenging the DNR. In the adjudicative proceeding, the health law judge determined that the proposed ambulatory surgery center was, in fact, subject to CN review, and reversed the Department's initial DNR.

The Washington Court of Appeals found that the opponent's application for an adjudicative proceeding was untimely and therefore the health law judge had no jurisdiction to conduct an adjudicative proceeding. Accordingly, the Court vacated the health law judge's decision and reinstated the

Department's initial DNR. The applicant was thus permitted to open its ambulatory surgery center, without having to obtain a CN.

A key lesson from this decision is that use of the Department's formal procedures and strict compliance with any deadlines to seek review are essential. If a party does not invoke the proper review procedure, and do so within the applicable time limits, it may lose the opportunity to challenge a decision on its merits.

## **Conclusion**

The CN application process, and the administrative and legal proceedings which may follow a CN decision, contain a number of potential pitfalls. CN applicants and other interested parties must recognize the particularities of each step in the process in order to maximize their chances of obtaining a favorable result at the end of the day.

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