Certificate of Need Laws - The Beginning of the End?

Legal Alert
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Garvey Schubert Barer Legal Update, September 14, 2011.

EXECUTIVE SUMMARY

The Ninth Circuit Court of Appeals has ruled that healthcare providers have standing to challenge state Certificate of Need (CON) laws and have those laws declared unconstitutional in certain circumstances. In *Yakima Valley Memorial Hospital v. Washington State Department of Health, D.C.* No. 2:09-cv-03032-EFS (Aug. 19, 2011), the Ninth Circuit Court of Appeals declared, for the first time, that state CON laws are susceptible to challenge and can be invalidated as violating the United States Constitution. This ruling is of particular significance to healthcare providers in Washington, Oregon, and Alaska, as all of those states have a CON regime.

View full ruling here.

The case is now on remand to the federal district trial court that originally heard it. In order to prevail in this case the hospital will have to prove that the Washington State Department of Health's CON regulation of elective percutaneous coronary interventions[1] (PCI) imposes a burden on interstate commerce that is clearly excessive in relation to the presumed local benefits.

OVERVIEW

In 2007, the Washington legislature passed a law directing the Department of Health (DOH) to promulgate regulations requiring a CON for elective PCI. Those regulations were adopted in 2008. The PCI regulations require that a licensed hospital perform at least 300 PCI procedures per year and provide that a CON cannot be issued in an applicant's geographic market unless the applicant can show that demand in that market exceeds current capacity by at least 300 procedures per year. Using the DOH prescribed calculation protocols to establish "need," the Yakima Valley is not expected to show a "need" for an additional hospital to perform PCIs until 2022.

The hospital sued DOH after it promulgated the PCI regulations claiming that the new regulations violated the "Dormant Commerce Clause" by unreasonably burdening interstate commerce. DOH moved to dismiss the case for failure to state a claim and lack of standing[2] . The district court held that the hospital did have standing to bring the action but that it was blocked from making a Commerce Clause argument because CON regimes were expressly

authorized by Congress.

THE DORMANT COMMERCE CLAUSE

The Commerce Clause of the United States Constitution explicitly grants Congress the authority to regulate interstate commerce. As a corollary, the Commerce Clause implicitly limits the regulatory authority of the states over interstate commerce. This inference is commonly referred to as the "dormant Commerce Clause."

The hospital alleged that the PCI regulations violated the dormant Commerce Clause by placing an undue burden on interstate commerce. The hospital stated that it would offer elective PCI to out-of-state patients, as well as hire out-of-state doctors, and import medical supplies from out-of-state to perform the PCI procedures. It claimed that the PCI regulations prevented it from engaging in any of these types of interstate commerce. Where a law only incidentally burdens interstate commerce, it will be upheld unless the burden imposed on interstate commerce is clearly excessive in relation to the supposed local benefits.

Both the federal district court and the court of appeals held that the PCI regulations prevented the hospital from soliciting out-of-state patients and competing in the interstate market for PCI services. However, the district court held that a prior Congressional authorization—the National Health Planning and Resources Development Act of 1974 (NHPRDA)—allowed DOH to engage in the regulation of PCI services even though the Commerce Clause might otherwise forbid it. The district court noted that the NHPRDA conditioned federal funding to states on the enforcement of certificate of need regimes by individual states. States such as Washington, Oregon, and Alaska, enacted CON laws pursuant to this federal Act. Even though the NHPRDA was repealed in 1986, allowing states to abandon their CON programs if they wished, Washington, Oregon, and Alaska, decided to continue their programs.

The Ninth Circuit reversed the district court's decision noting the PCI regulations were not promulgated until 2008, pursuant to a 2007 statute. The Ninth Circuit ruled that DOH had the burden of proving "Congressional authorization" as a defense and that they did not meet their burden because they "failed to show that the NHPRDA, a statute repealed [in 1986], provides the requisite clear statement of authorization for the 2008 PCI regulations." The Ninth Circuit did not address whether the NHPRDA could be used for the Congressional authorization defense for CON regulations promulgated prior to the 1986 repeal of that Act.

APPLICATION OF THIS CASE

Yakima Valley Memorial Hospital is significant in that it represents the first time a federal appeals court has ruled that state CON regulations can be declared unconstitutional as being burden on interstate commerce. However, the full parameters of this ruling are not currently known and will not be known for quite some time.

First, the case is on remand to the district court where the hospital will have to prove all of its allegations and claimed facts. Just the process of getting back to trial could take a year or more. Second, the hospital has the burden of proving that the CON law creates barriers to interstate commerce which are "clearly excessive in relation to the putative local benefits." This creates a balancing test which can be subjective even though it is based on facts. The hospital has to prove that not being allowed to perform one specific procedure created such a burden on interstate commerce that the restriction was clearly excessive when balanced against the alleged benefits claimed by the state in imposing the restriction. For example, the state might claim that imposition of CON restrictions allows it to prevent duplicative services which would help dampen healthcare cost increases. Both sides will be allowed to add weights to their side of the scales and it is impossible to predict which way the court will rule.

Third, the Ninth Circuit limited its decision to CON laws adopted after the repeal of NHPRDA in 1986. This leaves open the question whether CON laws passed before 1986 (when the NHPRDA was repealed) would be immune from challenge since they were adopted when the NHPRDA was still in effect.

This decision might signal the "beginning of the end" to CON laws but it will be a few years before we know whether it is "the end" for CON laws. This case is now remanded for trial which could take 6 months to a year or more. Whoever loses at the trial court will probably appeal the decision so we will most likely see version two of this decision some years from now. That decision will probably still leave open the question of whether CON laws adopted prior to 1986 can survive a dormant Commerce Clause challenge. So, this could be the beginning of the end of CON laws or it might be just a limited exception.

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1 Examples of PCI include stent implantation and laser angioplasty.

2 The district court did not hear any testimony and ruled on this case based on just the pleadings. Thus, the court assumed that all of the facts alleged by the hospital in their complaint were true. On remand, the hospital will now have to prove all of the allegations raised in their pleadings in order to have the court consider them.