

Court Holds Certificate of Need Laws May Be Unconstitutional

08.23.11

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The validity of certificate of need laws throughout the western United States is in question as a result of a [decision](#) issued August 22, 2011, by the Ninth Circuit Court of Appeals. In a case initiated by a hospital in Yakima, Washington, the court of appeals ruled state certificate of need regulations will be struck down as unconstitutional if they impose more than an “incidental” burden on interstate commerce.

This ruling is particularly significant for hospitals and other health care providers in Washington, Alaska, Oregon, Montana, Nevada, and Hawai`i. These states fall within the boundaries of the Ninth Circuit Court of Appeals and have CON laws. California, Arizona, Nevada, and Idaho, which also are within the Ninth Circuit, do not enforce CON laws.

The case was sent back to the district court where the hospital will have the burden of proving that the state’s CON regulation of angioplasty (percutaneous coronary interventions or PCI) imposes a burden on interstate commerce that “is clearly excessive in relation to the putative local benefits” of such regulation.

At the same time, the court of appeals affirmed the dismissal of an antitrust challenge to Washington’s CON regulation of PCI procedures.

Background

Since 2008, Washington State’s Department of Health has required health care providers who wish to perform PCI first obtain a CON. Regulatory permission to provide PCI services is granted only if an applicant shows it will perform at least 300 procedures a year and demand in the community proposed to be served outstrips existing capacity by at least another 300 procedures.

Yakima Valley Memorial Hospital is one of two hospitals serving Yakima, Washington. Its rival, Yakima Regional Medical and Cardiac Center, already has a CON to provide PCI. Yakima Valley Memorial, realizing there would be no “need” for an additional provider under the Department’s regulations until at least 2022, sued the Department. The hospital made two arguments. First, the hospital argued the CON requirement unreasonably burdens interstate commerce and so violates the “dormant” Commerce Clause. Second, the hospital claimed the Department’s methodology for determining need is anticompetitive and, as “hybrid” action involving not just the state but private actors, preempted by Section 1 of the Sherman Act.

The Washington State Department of Health filed a motion to dismiss the complaint. The Department argued the hospital lacked standing to challenge the CON regulations and the CON program was immunized from attack by Congress. The Department asserted the antitrust challenge should fail because the action was

“unilateral” action by the state and not preempted by the Sherman Act.

The district court found the plaintiff had standing to pursue a constitutional challenge to the state’s CON regulation, but that Congress immunized that regulation. With respect to the antitrust challenge to the CON regulation of PCI, the court held that the Sherman Act does not preempt state CON regulation. The entire case then was dismissed.

The court of appeals affirmed the dismissal of the antitrust challenge. The court also held—as had the district court before it—that Yakima Valley Memorial had standing to pursue a constitutional challenge to the regulatory scheme. The court of appeals, however, reversed the district court’s finding that Congress had immunized Washington’s CON regulations from attack. Notably, the appellate court found such immunity should not be implied in a context where Congress has not specifically authorized the states to regulate.

The case now returns to the district court for further proceedings in which the hospital must show the state’s regulation of PCI under its CON law imposes more than an incidental burden on interstate commerce.

The Challenge Under the “Dormant Commerce Clause”

The Constitution’s Commerce Clause grants Congress authority to regulate interstate commerce, thereby limiting the ability of states to do so. This implicit limitation is referred to as the “dormant Commerce Clause.”

Yakima Valley Memorial claimed CON regulation of PCI procedures placed an undue burden on interstate commerce and thus violated the dormant Commerce Clause. According to the hospital, but for the CON requirement, it would provide PCI procedures to out-of-state patients, hire out-of-state doctors and obtain supplies from outside Washington. The fact it cannot do so lawfully without a CON, argued the hospital, means the state is impermissibly burdening interstate commerce in violation of the dormant Commerce Clause.

The Ninth Circuit held Memorial had standing to challenge the PCI regulations and found there was insufficient evidence Congress had immunized the state CON regime from challenge under the Commerce Clause. Congress may authorize the states to regulate in areas that otherwise would be fenced off by the Commerce Clause but the state must provide “unmistakably clear” and “unambiguous” evidence that Congress intended to do so.

The Department argued Congress explicitly authorized state CON regulation when it passed the National Health Planning and Resources Development Act of 1974 (NHPDA). That statute was repealed in 1986, however. Washington’s CON regulation of PCI began in 2008. According to the Ninth Circuit, because the repeal of a statute means it must be considered, “except for transactions past and closed, as if it never existed,” the statute, “which Congress snuffed out of existence,” cannot provide the “unmistakably clear” statement of authorization necessary for subsequent CON regulation. The court explicitly refused to address the question of whether the NHPDA could serve as sufficient authorization for CON requirements established before the

Act's repeal in 1986.

It is important to note the fact Congress did not authorize the state's regulation of PCI does not mean all CON regulation is unconstitutional. Under the U.S. Supreme Court's decision in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), incidental burdens on interstate commerce are permitted. More specifically, in subsequent proceedings before the district court, Yakima Valley Memorial must show CON regulation of PCI imposes a burden on interstate commerce that "is clearly excessive in relation to the putative local benefits" of such regulation. Because the case was dismissed on the pleadings, the parties did not develop facts regarding the burden imposed by the state's CON regulation of PCI providers.

Conclusion

Many large states, including California, Texas, and Pennsylvania, have no certificate of need regulation. But many others, including New York, Florida, Michigan, and Illinois, continue to require a CON before a provider may offer certain health care services. Within the states covered by the Ninth Circuit Court of Appeals, Washington, Alaska, Oregon, Montana, Nevada, and Hawai'i all have CON laws.

Whether the Ninth Circuit's opinion represents the beginning of the end of CON laws in those states where they still exist, or whether it simply will be a footnote in CON treatises, will depend in large measure on what happens next. The case was sent back to the lower court for further proceedings during which Yakima Valley Memorial will attempt to show the state's CON program, which prevents the hospital from providing PCI in central Washington, impermissibly burdens interstate commerce. The quality and type of evidence the hospital must present to meet its burden of proof will determine whether this case has significant implications for the viability of other state CON programs.

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