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**Ninth Circuit Holds Washington State's Certificate of Need Law
May Place an Undue Burden on Interstate Commerce—Parallel
Antitrust Challenge to Law Fails**

By Douglas Ross and Charles Wright*

State certificate of need (CON) regulations will be struck down as unconstitutional unless they burden interstate commerce only "incidentally," according to a three-judge panel of the ninth circuit. In a ruling issued August 19, 2011, the court [held](#) a Washington state hospital has standing to challenge the state's CON regulation of coronary angioplasty and held Congress did not immunize state CON regulation from attack under the "dormant" Commerce Clause.

The case will return to the district court, where the burden will be on the hospital to persuade the district court the state's CON regulation of angioplasty (more formally known as 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 Department of Health has required healthcare providers who wish to perform PCI to 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, WA. 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 Department of Health filed a motion to dismiss the complaint. The Department argued the hospital lacked standing to challenge the state's regulatory scheme and the scheme was immunized from attack by Congress in any event. 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 held Congress immunized that regulation. The court turned aside the antitrust challenge to the CON regulation of PCI, holding that the Sherman Act does not preempt state CON regulation. The court then dismissed the entire case on the pleadings under Fed. R. Civ. P. 12(c).

The court of appeals affirmed the dismissal of the antitrust challenge. The appellate court also agreed with the lower court that Yakima Valley Memorial had standing to pursue a constitutional challenge to the regulatory scheme, but reversed the ruling that Washington's CON regulations were immune from attack, finding that Congress did not specifically authorize states to regulate in this area.

In consequence, the case now returns to the lower court for further proceedings in which the hospital must show the regulation of PCI providers by the state 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. The grant of authority implicitly limits the states' ability to regulate interstate commerce. This implicit limitation is referred to as the "dormant Commerce Clause."

Yakima Valley Memorial complained 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 means the state is burdening interstate commerce impermissibly and so violating the dormant Commerce Clause.

The ninth circuit held Memorial had standing to challenge the PCI regulations under the dormant Commerce Clause, rebuffing the state's assertion that the hospital could not do so because it operates an in-state hospital only. But the court of appeals disagreed with the lower court's conclusion that 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 burden to show congressional authorization falls on the state, which must satisfy that burden with "unmistakably clear" and "unambiguous" evidence.

Washington's Department of Health argued that Congress explicitly authorized state CON regulation when it passed the National Health Planning and Resources Development Act of 1974 (NHPRDA). Congress repealed that statute in 1986, however. Washington's CON regulation of PCI began in 2008. Because 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 necessary clear statement of authorization for subsequent CON regulations, according to the court of appeals.

The court explicitly refused to address the question of whether the NHPRDA could serve as sufficient authorization for CON requirements established before the Act's repeal in 1986.

But the fact that Congress did not authorize the state's regulation of PCI providers does not mean all such regulation by the state necessarily 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 hospital moved for judgment on the pleadings, the parties did not develop and the court of appeals did not discuss that necessarily fact-intensive analysis.

The Antitrust Challenge

Section 1 of the Sherman Act preempts state regulation only if the regulation creates an irreconcilable conflict with federal antitrust laws *and* the regulation is a hybrid of state and private action, rather than unilateral state action. To show an irreconcilable conflict, the challenged regulation must compel a per se violation of the Sherman Act. To show a hybrid regulation, the plaintiff must demonstrate the state has delegated unsupervised discretion to act to private actors. So-called unilateral

restraints, which involve no further action by a private party after the state acts, are not subject to preemption by the Sherman Act.

The ninth circuit observed Yakima Valley Memorial argued Washington's PCI regulations granted regulatory power to incumbent CON holders because the need for a new CON is calculated based on the number of procedures performed by incumbents. This methodology allows "the incumbent licensees to manipulate the number of PCIs they perform so as to exclude competing hospitals from the elective PCI market." The hospital argued that incumbent providers could constantly expand their capacity to meet growing need, thereby precluding would-be competitors from ever showing a need that outstripped existing capacity by at least 300 additional procedures.

"Memorial mistakes the barrier to entry created by the licensing requirement, and its attendant anticompetitive effects, for a hybrid restraint," the court wrote. A "logical and intended result" of the CON regulation is "the Department will issue a second certificate of need only if the incumbent does not expand its capacity to meet growing demand." While the "PCI regulations create *market power*," that "is different from a hybrid regulation that delegates *regulatory power*." Because the barrier to entry posed by the CON regulatory regime "is complete upon enactment" and does not delegate any aspect of the need calculation to private parties, it is a unilateral—not hybrid—restraint. Because it is unilateral, the court held it is not preempted by the Sherman Act.

Though not necessary to its decision, the court noted as well that an incumbent's discretion to increase supply to meet demand and keep competition at bay "is neither per se illegal nor recognizable as an element of a per se illegal restraint."

Conclusion

Many states, including California, Texas, and Pennsylvania, have no certificate of need regulation. But many others, including the populous states of New York, Florida, Michigan, and Illinois, continue to require issuance of a CON before a provider may offer certain healthcare services. Within the ninth circuit, in addition to Washington, Alaska, Oregon, Montana, Nevada, and Hawaii have CON laws. California, Arizona, and Idaho do not.

Whether the ninth circuit's opinion represents the beginning of the end of CON laws in those states where they still exist, or will simply be a footnote in CON treatises, will depend in large measure on what happens next in this case before the district court. The court of appeals remanded the case to the lower court for further proceedings during which Yakima Valley Memorial will attempt to show that its inability to provide PCI in central Washington impermissibly burdens interstate commerce under *Pike v. Bruce Church*.

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