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Certificate of Need

Federal Appeals Court Rules State CON Laws May Unlawfully Burden Interstate Commerce

A federal appeals court's Aug. 19 decision holding a state's rationing of health care services may violate the commerce clause of the U.S. Constitution could give hospitals and other providers adversely affected by certificate of need (CON) determinations a new weapon to fight these decisions, according to attorneys who spoke to BNA (*Yakima Valley Memorial Hospital v. Washington Department of Health*, 9th Cir., No. 10-35497, 8/19/11).

While practitioners said it was too soon to tell whether the decision by the U.S. Court of Appeals for the Ninth Circuit will be a ''blip'' or a ''game-changer,'' they said the ruling could provide a recipe for providers in other states with CON laws to argue that limits on their entry or expansion are unconstitutional. The ruling, at the very least, casts a temporary shadow over CON laws in the states covered by the Ninth Circuit, they said.

The Ninth Circuit specifically ruled that the Washington regulations that prevent a hospital in the state from performing elective angioplasty procedures may run afoul of the ''dormant'' commerce clause under the U.S. Constitution. In so ruling, the court found there was no clear expression of congressional intent that would empower the state to impose restrictions on the ability of Washington hospitals, such as appellant Yakima Valley Memorial Hospital, to offer percutaneous coronary intervention (PCI) procedures to out-of-state residents.

The court said Congress may have blessed state CON laws at one time, but that the repeal in 1986 of the National Health Planning and Resource Development Act removed the express authorization cited as a basis for finding congressional authorization of state actions that may more than incidentally burden interstate commerce. ''Whatever the NHPRDA authorized prior to 1986, after Congress repealed the statute there was no NHPRDA left to authorize a regulation promulgated in 2008,'' the court said.

Although the state argued that Congress could not have intended in repealing NHPRDA ''to pull the rug out from under the states after inducing their transition to certificate of need programs,'' the appeals court found that, because there was, at best, congressional silence on the issue of congressional authorization, there was no ''clear statement'' that Congress approved of state initiatives that might unreasonably impede interstate commerce.

Commerce Burden. The ''dormant'' commerce clause stands as, essentially, a mirror to Congress's authority to regulate interstate commerce. The judicially created ''dormant'' construct says states may not impose unreasonable impediments to, or burdens upon, interstate commerce without congressional permission.

In this case, the hospital argued that the state regulations prevented it from offering PCI services to patients from outside the state and precluded it from obtaining PCI doctors and supplies for such a program from out of state as well. Both the trial court and the Ninth Circuit found this claim conferred standing for the hospital to bring its challenge.

The ruling, however, reversed the trial court's NHPRDA-based decision that upheld PCI regulations, issued by the Washington Department of Health, that limit, through the state's CON restrictions, the number of hospitals that can offer PCI services.

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''Had Congress meant to perpetuate its alleged authorization for certificate of need programs, it could have included a savings clause in the [NHPRDA] repeal,'' the court said. ''The savings clause would then itself be an unmistakably clear statement of authorization.''

''Instead, Congress repealed the NHPRDA with terse language that, at best, leaves it ambiguous whether Congress affirmatively contemplated the fate of state certificate of need programs,'' the court ruled.

The appeals court affirmed the trial court's May 2010 decision in all other respects, ruling that the regulations were not preempted under federal antitrust laws (19 HLR 799, 6/10/10).

The court remanded the case on the commerce clause issue, leaving the trial court to determine whether there is another source for finding congressional authority for the state regulations. Otherwise, the trial court will be called on to apply the traditional balancing test that asks whether the regulations ''only incidentally'' burden interstate commerce and, if so, whether ''the burden imposed on interstate commerce

is clearly excessive in relation to the putative local benefits.''

Unilateral Restraint. The appeals court agreed that the state action was immune from antitrust scrutiny under the Sherman Act because it qualified as a licensing requirement that is a ''unilateral restraint of trade.'' The appeals court rejected the hospital's claim that the regulatory scheme was actually a ''hybrid'' restraint—in which the state authorizes or sanctions illegal conduct by market participants.

The hospital specifically claimed that the regulations countenanced an illegal monopoly in the provision of PCI services to a few providers who, under the regulatory scheme, were able to manipulate the market to ensure there were no new entrants. The regulations based the need for new PCI services on data from the competing hospitals that had an incentive to increase their own capacity and thereby prevent new market entry, the hospital claimed.

The Ninth Circuit, however, ruled that the case did not involve a ''hybrid'' restraint because the state was unilaterally imposing a barrier to entry, unilaterally determining when to issue new PCI licenses, and tacitly allowing existing licensees, at least potentially, to obtain and assert monopoly power. ''Any anticompetitive effect from allowing the first licensee the option of holding a monopoly in the planning area is 'part-and-parcel of the state-imposed licensing scheme,' '' the court said.

''There is neither a per se illegal agreement nor its functional equivalent to turn the PCI regulations into a hybrid restraint. Absent a hybrid restraint or other per se violation of the antitrust laws, there is no preemption and the district court properly granted judgment on the pleadings,'' the Ninth Circuit said.

Impact Unclear. Douglas C. Ross, Davis Wright Tremaine LLP, Seattle, said the court's antitrust analysis was ''orthodox'' and came to the expected result: the CON laws are not preempted by the Sherman Act. ''The dormant commerce clause issue, however, involves more difficult concerns which seem to revolve around the question of how likely is it that in subsequent proceedings the court might find a state's CON regulations are a real burden on interstate commerce,'' Ross said.

One of those concerns is how difficult it will be for the plaintiff to show the necessary burden on interstate commerce. ''In this case, Yakima Valley Memorial claims that, but for the CON requirement, it would do angioplasty procedures for out-of-state patients, hire out-of-state cardiologists, and buy supplies for the procedures from out of state,'' Ross said. ''Therefore, the hospital argues, this is more than an incidental burden on interstate commerce and should be struck down as unconstitutional.''

''A second concern is whether the determination of constitutionality will vary from applicant to applicant. Yakima Valley Memorial is in the center of the state so a court might ask whether people would flock from outside the state for the procedure,'' Ross continued. ''But what if the plaintiff were a Washington hospital, located in Seattle or near the Oregon border, that draws significant numbers of patients from a multi-state area?''

''The Ninth Circuit's decision, unfortunately, leaves us with more questions than answers,'' Ross concluded.

Howard L. Sollins, with Ober Kaler, Baltimore, agreed that there are a number of important questions related to this case—some of which involve nuances in the provision of cardiac services, including elective and primary PCI, diagnostic catheterizations, and cardiac surgery—that affect its impact.

Sollins asked whether the effect of the ruling was that a program or service can be established to serve any individuals because hospital services or health care services more generally involve interstate commerce. The ruling also implicates whether a state's ability to regulate or expand the services rendered by a health care facility through a CON program could be based on the state's interests in the quality, cost, or efficiency of providing such care at that facility.

State Quality, Efficiency Interests. ''As a practical matter, the ruling could have an effect on hospital cardiology programs beyond elective PCI cases because, often, an elective PCI case follows a diagnostic cardiac catheterization or the patient may be seen at an emergency room that only provides thrombolytic therapy, i.e. drugs, following a heart attack,'' Sollins said.

''Where the hospital is not authorized to perform elective PCI, this means the second procedure is scheduled for a later time. However, if the hospital provides elective PCI, the angioplasty may be performed immediately after the diagnostic cardiac catheterization, avoiding delay and a second procedure,'' he said.

''Moreover, for some procedures such as PCI and cardiac surgery, there is a link between volumes and outcomes within certain parameters,'' Sollins continued. ''Thus, states may have an interest in hospitals meeting volumes, outcomes, and other metrics in providing such a service and may, in response, look to licensing requirements to more closely regulate the service.''

Michael F. Schaff, a partner at Wilentz Goldman & Spitzer PA, in Woodbridge, N.J., agreed that, if the Ninth Circuit's decision is embraced elsewhere, states nevertheless will be able to marshal arguments to justify an incidental burden on interstate commerce. ''Providers obviously want to keep any monopoly they may have been able to acquire, but the reality is that the acknowledged scarcity in health care funds gives states a legitimate interest in looking at the resources that are available and controlling excess capacity,'' he said.

''In addition to promoting efficient use of health care resources, states also are committed to promoting quality and recognize that, by limiting the number of service providers, you improve the quality and skill level in the provision of those services by those providers,'' Schaff said.

''In the end, resolution of the commerce clause question may turn on a determination of what is the hospital's catchment area,'' Schaff added. ''For nonprofit hospitals, arguing that they need additional capacity or service lines to serve out-of-state patients may conflict with their responsibility to serve their communities and charitable missions.''

According to the American Health Planning Association, 36 states and the District of Columbia currently have CON laws.

The hospital was represented by James L. Phillips, with Miller Nash LLP, Seattle. The state was represented by Richard A. McCartan and Michael Steven Tribble, with the state Attorney General's Office, Olympia, Wash.

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The court's decision is at http://op.bna.com/hl.nsf/r?Open=psts-8kvs7z.