



Economic Impact Analysis Virginia Department of Planning and Budget

12 VAC 5-220 – Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations

Virginia Department of Health

July 5, 2001

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 9-6.14:7.1.G of the Administrative Process Act and Executive Order Number 25 (98). Section 9-6.14:7.1.G requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

Pursuant to changes in the Code of Virginia (Code) as a result of the 1999 and 2000 sessions of the General Assembly, the Board of Health (board) proposes several changes to the regulations. The proposed changes include: 1) increased fees for Certificate of Public Need (COPN) applications, 2) elimination of the requirement that a COPN be obtained for the replacement of medical equipment, 3) requiring registration for the replacement of medical equipment, 4) elimination of the requirement that nuclear cardiac imaging equipment be subject to the COPN, 5) addition of the needs of rural populations as a factor for consideration in granting a COPN, 6) the Virginia Department of Health's (VDH) review period for COPN applications is increased from 120 days to 190 days, 7) COPN applications are approved by default if VDH does not meet set deadlines, 8) language that allows for informal fact finding conferences to be scheduled earlier, and 9) an increase in the minimum number of liver transplants per year required for program approval. Emergency regulations reflecting these

requirements became effective on January 3, 2000, and expired 12 months later. The board proposes to amend the permanent regulations to reflect the changes in the Code.

Estimated Economic Impact

Pursuant to the Code, application fees for the COPN are set at “one percent of the proposed expenditure for the project, but not less than \$1,000 and no more than \$20,000.” The current regulations have the following COPN application fee schedule:

| For Projects with Capital Expenditures from ... | The Application Fee is ... |
|---|--|
| \$0 up to and including \$1,000,000 | The greater of 1% of the Capital Expenditure or \$1,000 |
| \$1,000,001 up to and including \$2,000,000 | \$10,000 plus 0.25% of the Capital Expenditure above \$1,000,000 |
| \$2,000,001 up to and including \$3,000,000 | \$12,500 plus 0.25% of the Capital Expenditure above \$2,000,000 |
| \$3,000,001 up to and including \$4,000,000 | \$15,000 plus 0.25% of the Capital Expenditure above \$3,000,000 |
| \$4,000,001 up to and including \$5,000,000 | \$17,500 plus 0.25% of the Capital Expenditure above \$4,000,000 |
| \$5,000,001 or more | \$20,000 |

Thus, fees for COPN applicants with projects with capital expenditures greater than \$1,000,000, but less than \$5,000,000, will increase. For example, the application fee for a capital project costing 2,000,000 would be \$20,000 under the proposed regulations, while it is \$12,500 under the current regulations. According to VDH, application fees are used to cover costs in operating the COPN program for both the agency and the five regional health-planning agencies. The costs of the higher fees are clear. The benefits of the higher fees are less clear and are related to the value of requiring a COPN.

There are essentially three arguments in favor of requiring a COPN. First, it is argued that adding medical service capacity creates its own demand for medical services, which drives up medical costs. For example, say patients need to wait days or weeks to get access to a certain

type of medical equipment. If a hospital acquires more of that type of equipment, more of the services associated with that type of equipment could be performed in a given period time, thus driving up costs associated with the services related to that equipment. Thus, limiting the supply of medical services may help in slowing the rise in medical costs. In reality, though, unmet demand already exists in this example; the acquisition of the additional equipment adds supply to meet already existing demand. This argument boils down to the rationing of services to save on costs. The net benefits of rationing medical services and potentially limiting total medical costs through the use of COPNs are unclear. It is not known whether the benefits of potential cost savings associated rationing medical services and potentially limiting total medical costs through the use of COPNs exceed the costs to patients of reduced medical services. Additionally, there may be more efficient methods of rationing. Second, the threat of a disapproved COPN application can be used to get medical facilities to agree to serve a minimum number of charity care patients or money-losing services that are desired by the public. The provision of these services does provide public benefit, but it is not clear whether it is always equitable and efficient to require medical facilities to absorb these costs. Third, according to VDH, some services and patients are inherently net money losers (emergency rooms, ICUs, indigent, etc) and need to be cross-subsidized by profitable services (ambulatory surgery, MRIs, CTs, etc) for hospitals to remain financially viable. If, for example, independent ambulatory surgery centers were permitted to form without restrictions in the vicinity of full-service hospitals, then the full-service hospitals would be put at a competitive disadvantage; unlike hospitals, the independent ambulatory surgery centers could operate without having to pay cross subsidies to maintain money-losing services needed by the public. Restricting the services offered or requiring additional money-losing services for practices such as an independent ambulatory surgery center may seem equitable compared with hospitals, and will likely provide public benefit, but may also discourage the formation of valuable new practices. Thus, the net benefit of requiring a COPN is unclear.

The Code and proposed regulations no longer require that medical facilities obtain a COPN for the replacement of medical equipment. Instead, the replacement equipment would need to be registered. This change represents a significant reduction in fees, time, and labor costs. According to VDH, the registration form has no fee and takes at most half an hour to fill out. The COPN application has a fee as described in the above table, and takes at least 40 hours

to fill out.¹ Prior to the Code change, in practice, VDH did not usually require concessions (increased charitable case load, for example) or altered plans for COPN approval on replacement equipment. This change likely produces a net benefit since the cost savings are significant, while the actions of the medical facilities are not substantially altered.

Eliminating the requirement that nuclear cardiac imaging be subject to a COPN will save medical facilities fees and the time and labor associated with preparing a COPN. The fees saved depend on the project cost as described in the table above. According to VDH, it takes at least 40 hours of labor to file a COPN application. Prior to the change in the Code, VDH did require concessions (increased charitable case load, for example) or altered plans for COPN approval on new nuclear cardiac imaging equipment. Thus, by eliminating the COPN requirement for new nuclear cardiac imaging, the benefits and costs associated with concessions and altered plans made by medical facilities in order to a COPN are eliminated as well.

The regulations include numerous factors for consideration when VDH decides whether or not to grant a COPN to an applicant. The Code and proposed regulations add the needs of rural populations as a factor for consideration in granting a COPN. According to VDH, there is no set formula in determining approval. Thus, the impact of adding the needs of rural populations as a factor will depend on how much the agency chooses to consider it when making their approval decision. To the extent that it is used, it may have a positive impact on the amount of medical services offered in rural areas.

VDH is allotted 190 days to review COPN applications under the proposed regulations, versus 120 days under the current regulations. But, under the current regulations there are no repercussions for not meeting the deadline. According to VDH, it has commonly taken more than 120 days to process COPN applications, and on occasions prior to the implementation of the emergency regulations, taken more than 190 days. Under the proposed regulations, the COPN applications are automatically approved if VDH does not meet their deadline. Thus, in contrast to the previous processing deadline, the proposed 190-day deadline will be effective in practice. This change will be net beneficial in that it will eliminate the small number of occasions where a COPN application takes longer than 190 days to process.

¹ Source: VDH

The proposed regulations also allow informal fact finding conferences to be scheduled earlier in the COPN application process than in the current regulations. This may on some occasions shorten the COPN application process by a matter of days. A shorter application process would allow medical facilities that gain COPN approval to use their capital equipment sooner. Since this proposed change has no apparent costs, it will produce a net benefit.

The Code and proposed regulations also increase the minimum number of liver transplantations performed by a medical facility per year in order for the medical facility to be approved to perform liver transplantations from 12 procedures per year to 20 procedures per year. This change was prompted by research published in the *New England Journal of Medicine*² that found that “as a group, liver-transplantation centers in the United States that perform 20 or fewer transplantations per year have mortality rates that are significantly higher than those at centers that perform more than 20 transplantations per year.” The study did control for attributes other than transplantation volume. This change may prevent some medical facilities from offering liver transplantations that otherwise would have; but, given the finding concerning differences in mortality rates between facilities with less than or greater than 20 procedures per year, it is probable that this change produces a net benefit.

Businesses and Entities Affected

The proposed amendments will affect the 265 licensed nursing facilities, 123 licensed hospitals in Virginia, other medical facilities and practices, rural citizens, indigent patients, and potentially liver transplantation patients.

Localities Particularly Affected

The proposed amendments potentially affect localities throughout the Commonwealth.

Projected Impact on Employment

At least one part position at VDH is no longer necessary due to the elimination of the requirement of a COPN for replacement equipment and nuclear cardiac imaging equipment. Also, fewer labor hours are required by medical facilities in the preparation of COPN

² Edwards, Erick B., Roberts, John P., McBride, Maureen A., Schulak, James A., and Lawrence G. Hunsicker, “The Effect of the Volume of Procedures at Transplantation Centers on Mortality After Liver Transplantation,” *The New England Journal of Medicine*, December 30, 1999 – Vol. 341, No. 27.

applications due to the elimination of the requirement of a COPN for replacement equipment and nuclear cardiac imaging equipment.

Effects on the Use and Value of Private Property

The value of medical facilities acquiring relative large dollar amounts of new non-nuclear cardiac imaging equipment and relative small amounts of replacement and nuclear cardiac imaging equipment will likely decrease in value by a small amount due to the higher COPN application fees on new non-nuclear cardiac imaging equipment. The value of medical facilities acquiring relative small dollar amounts of new non-nuclear cardiac imaging equipment and relative large amounts of replacement and nuclear cardiac imaging equipment will likely increase in value by a small amount due to the elimination of application fees on replacement and nuclear cardiac imaging equipment. Also the value of potential medical facilities that perform fewer than 20 liver transplantations per year may decrease, and the value of medical facilities that perform greater than 20 liver transplantations per year may increase due to the change in minimum number of procedures per year.