

# Economic Impact Analysis Virginia Department of Planning and Budget

12 VAC 5-230 – State Medical Facilities Plan Virginia Department of Health November 26, 2007

## **Summary of the Proposed Amendments to Regulation**

The proposed changes will make many of the measurable criteria used in assessing the public need for the proposed projects less stringent while making a few criteria more stringent. The proposed changes will also significantly edit and reorganize the State Medical Facilities Plan regulations to improve clarity.

# **Result of Analysis**

The benefits likely exceed the costs for most of the proposed changes. Less stringent volume standards for Computed Tomography, Magnetic Resonance Imaging, and organ transplant services would likely yield the same benefits at lower cost.

# **Estimated Economic Impact**

The proposed regulations contain rules for the State Medical Facilities Plan (SMFP) component of the Certificate of Public Need (COPN) program. Under the COPN program, a certificate is required before expanding certain medical services, or creating a new facility. SMFP is one of the 20 criteria used in evaluating a COPN application, but it has a significant impact on approval/denial decisions. SMFP establishes facility need projection methodologies and project review standards. The medical services subject to SMFP include general acute care services, perinatal services, diagnostic imaging services, cardiac services, general surgical services, organ transplantation services, medical rehabilitation services, lithotripsy services, miscellaneous capital expenditures, and nursing facility services.

Numerous proposed changes will significantly reorganize the regulations by eliminating redundant sections, by combining duplicative sections, by deleting philosophical and irrelevant statements, by removing obsolete or non-related definitions, by adding new sections, and by

adding new definitions. These changes are primarily editorial and are not expected to create any significant economic effects, but are expected to improve the clarity of the regulations. Improved clarity would probably streamline the application process, reduce potential confusions, and produce some economic benefits in terms of administrative cost savings, avoided delays, or communication costs.

A significant proposed change is the proposal to allow providers to apply for additional services based on institutional need. This proposed change will make it possible for providers to get approval for services when data determine there is no need for more services within a planning district or region. This, change is expected to make the current regulations less stringent.

Moreover, another significant proposed change will increase the maximum facility size for mental retardation services from four beds to twelve beds that must obtain a certificate of need making the SMFP less stringent.

The proposed changes also include a methodology for establishing measurable criteria in determining the need for mobile services. Currently, the need for mobile services is determined based on the guiding principles of the regulations. VDH indicated that the proposed methodology is consistent with the practice followed currently. Thus, while the proposed methodology for establishing mobile service measurable criteria is likely to improve the clarity of the regulations, no significant economic effect is expected.

Another change will incorporate a statutory change that increases the limit of capital expenditures projects requiring approval from \$5 million to \$15 million making the regulations less stringent.

More importantly, the proposed changes will revise a significant number of measurable criteria and travel times established in the regulations. These criteria and travel times are used to evaluate the need for a proposed facility, equipment, or project and play a crucial role in approval/denial decisions. With the exception of volume standards for Computed Tomography, Magnetic Resonance Imaging, and organ transplant services, all of the proposed changes to measurable criteria appear to be less stringent. A table is provided on next page to compare the proposed volume and travel time changes to current standards.

# Summary Table for Proposed Volume and Travel Time Changes:

Service	Is the proposed standard more or less stringent than the current standard?	
	Volumes	Travel Times
Computed Tomography (CT)	More Stringent	Less Stringent
Magnetic Resonance Imaging (MRI)	More Stringent	Less Stringent
Positron Emission Tomography (PET)	Less Stringent	Less Stringent
Noncardiac Nuclear Imaging (Formerly SPECT)	Less Stringent	Less Stringent
Radiation Therapy	Less Stringent	Less Stringent
Stereotactic Radiosurgery (SR)	Neutral	Less Stringent
SR – Gamma Knife	Less Stringent	Less Stringent
Cardiac Services -Catheterization	Neutral	Less Stringent
Cardiac Services -Open Heart Surgery	Neutral	Less Stringent
General Surgical	No Change	Less Stringent
Inpatient Beds	Less Stringent	Less Stringent
Nursing Facilities	Less Stringent	Less Stringent
Lithotripsy Services	Less Stringent	Less Stringent
Organ Transplant	More Stringent	Neutral
Medical Rehab	No Change	Less Stringent
MH: Acute Psychiatric/substance Abuse	Less Stringent	No Change
Obstetrics	Less Stringent	Less Stringent
Perinatal Services	No Change	Less Stringent

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Less stringent quantitative criteria are expected to cause a small number of applicants to come forward who would not have under somewhat stricter SMFP criteria. We may see a small increase in applications in service areas where the proposed standards are less restrictive. However, a reliable estimate for the potential increase in applications is not available, as this would require extensive resources to develop.

Since the number of approvable projects in certain service areas is likely to increase, this could be seen as less restrictive entry requirements into regulated service areas. To the extent the proposed changes makes the issuance of a COPN less stringent, the economic effects would be akin to those of COPN discussed below. Based on the available empirical literature, we should expect no significant changes in healthcare costs and charity care. We could also see some negative or positive effects on quality and access varying from one service type to another. However, as restrictions on competition are reduced, we would expect a reduction in the welfare transferred from consumers to producers and a reduction in the economic inefficiencies embedded in the COPN program.

In short, we believe that when all proposed volume and travel time changes taken into account, the resulting SMFP regulation will be somewhat less stringent than the current regulations on net increasing the likelihood of obtaining a favorable COPN decision. Higher likelihood of obtaining a favorable COPN decision has significant economic benefits. These potential benefits are discussed below.

#### **History of the COPN program:**

A brief history of the Virginia's COPN program is provided in a 1997 report of the Virginia Joint Commission on Health Care. According to this report, the Virginia COPN program was established in 1973 primarily as a response to 1972 amendments to the federal Social Security Act, which allowed the federal government to deny reimbursement under Medicare, Medicaid, and Child Health Programs for capital projects that are found to be inconsistent with the plans of designated state planning agencies. In 1974, the National Health Planning and Resources Development Act (NHPRDA) mandated all states to develop a COPN program by 1980. Later, in 1988, the role of federal government was eliminated with the

expiration of NHPRDA. However, 36 states, including Virginia, still maintain their COPN programs.<sup>1</sup>

The Virginia COPN program is administered by the Department of Health in cooperation with five regional planning agencies (Health System Agencies). Projects are first evaluated at the regional level and then considered at the state level. The commissioner of health is in charge of making the final decisions. Adverse decisions could be appealed through the court system. The decisions of the commissioner must be consistent with the SMFP or the commissioner must find the SMFP outdated. Based on the amendments to the COPN law in 1998, the commissioner may condition approvals on the provision of free or reduced rate care to indigents, the acceptance of patients with special needs, or the facilitation of primary care for underserved areas.

In 2000, the General Assembly, through Senate Bill 337, required the Joint Commission on Health Care to develop a plan to eliminate the COPN program by July 2004. The deregulation plan was a "fragile" consensus among the stakeholders and contained several provisions for the support it needed. This fragile consensus was contingent upon provisions requiring the Commonwealth to provide \$135 million funding from the general fund for (i) indigent care at academic health centers, (ii) increased Medicaid access to the adult parents, the aged, and the disabled, (iii) undergraduate medical education, (iv) increased Medicaid reimbursement to hospitals, (v) increased reimbursement to physicians, and (vi) increased state matching dollars for indigent health care trust fund. Probably because of significant fiscal implications, the deregulation plan has not been approved and implemented by the General Assembly.

#### **Economics of the COPN program:**

Issues surrounding the COPN program can be grouped under medical care costs, quality, access, and charity care. Economic analysis of Virginia's COPN on each one of these variables requires extensive resources which are beyond the scope of this analysis. Even if significant resources are devoted for this purpose, we suspect that such an analysis would be unable to produce conclusive evidence on every facet of the COPN program and be of little practical importance due to data limitations. Instead, we rely on the economic theory and readily

<sup>&</sup>lt;sup>1</sup> Between 1989 and 1992 specialty services, non-hospital facilities, specialized medical equipment, and other capital expenditures were deregulated.

available empirical evidence to assess likely costs and benefits of the COPN program in Virginia.<sup>2</sup>

**Costs.** The initial driving force for the COPN programs, in addition to the 1974 federal mandate, appears to be the concern that excess capacity and capital investment contributed to publicly funded medical care costs, as early 1970s health care payments were based on cost-based reimbursement methodologies. Under cost-based reimbursement methodologies, providers were being reimbursed for their capital costs and had incentives to build excess capacity.

Since the inception of COPN programs, many changes occurred in health care financing and delivery rendering most of the fiscal benefits expected from COPN obsolete in today's market place. A significant change is the shift from cost-based reimbursement methodologies toward service-based payment methodologies. Many private health care insurance companies as well as large public programs such as Medicare and Medicaid adopted service based payments methods such as inpatient prospective payment system, diagnostic related groups, resource utilization groups, outpatient prospective system, ambulatory payment classification system, and managed care capitation rates over the last two decades. The trend toward service-based payments reduced provider incentives to build excess capacity or take on unneeded capital investment projects, as they cannot directly recover the cost of their investments. Thus, this concern does not seem to have validity in today's health care market as it did 30 years ago.

Additionally, proponents argue that COPN programs lead to fewer, larger firms to provide services, which in turn reduces cost of care. So, in the absence of COPN programs, we could see an increase in health care costs. This argument suggests that large health care firms produce services at lower average costs due to increased plant size, which is a well-known possibility in economics, termed as "economies of scale." While economies of scale may well exist in production of some health care services over certain plant sizes, generalizing this possibility for all services covered under the COPN programs and for any quantity of production is bound to be wrong.

Even for those services where there are economies of scale, forcefully leading fewer firms to produce more output through the COPN program has certain social costs. These social

<sup>&</sup>lt;sup>2</sup> Empirical findings are primarily obtained from the State of Washington Joint Legislative Audit and Review Committee, 1999, literature review to minimize research costs.

costs should be weighed against the benefits expected from lower average production costs. These social costs stem from restricting entry into an otherwise competitive market. Under the COPN umbrella, incumbents are protected against competition from new entrants. Firms with significant market power are well known to charge prices that maximize their revenues rather than those reflect their average costs. And, prices charged definitely exceed the average cost of production if the firm is to make above normal profit, which is the case in a non-competitive market.

In addition, the revenue-maximizing output level is known to be lower and the revenue-maximizing price is known to be higher than what it would be if entry were not restricted. In other words, if entry is limited through COPN, providers are likely to offer less and charge more. This profit maximizing behavior in the absence of competition takes welfare away from consumers and channels it to the providers and creates significant efficiency losses, known as "deadweight losses," <sup>3</sup> for the whole economy. A recent study by the Federal Trade Commission and the Department of Justice in 2004 goes on to state that these two agencies "...believe that CON programs can pose serious competitive concerns that generally outweigh CON programs' purported benefits. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anticompetitive barriers to entry."

In short, the claim that leading fewer firms to produce more reduces cost of health care is not well founded because (i) lower average production costs does not necessarily mean the prices providers charge will be lower, (ii) quite the contrary, firms shielded from competition charge higher prices and produce less than optimal quantities, and (iii) other costs of COPN such as transferring welfare from consumers to providers and deadweight efficiency losses likely exceed any savings expected from COPN.

Another source of social costs that seems to escape the attention of most is the inefficiencies created by ignoring the economies of scope that may exist in health care production. Economies of scope occur when production of one good creates savings for

<sup>&</sup>lt;sup>3</sup> "Deadweight losses" occur because a distortion to the market mechanism (such as restricting competition through the COPN program) takes welfare away from suppliers and buyers and no one in the economy receives them. In other words, it is the net loss in economic welfare that occurs due to distortions in the market. Thus, everyone could be better off if the distortion is removed.

production of another good. In such cases, production costs are lower when the two goods are produced together than produced separately. Because the COPN review criteria focus on volume and capacity but does not directly take into account the other types of services already provided in conjunction with the service for which approval is sought, it is more than likely that the COPN program forgoes some potential savings that would be realized if entry into the market were not restricted.

Empirical research does not appear to support the claim that COPN reduce health care costs. COPN is not found to be effective in controlling overall per capita health care spending because many factors affecting costs such as labor and physician services are beyond the scope of the COPN programs. Also, COPN is not found to be effective in controlling hospital costs because (i) not all services are regulated under COPN, (ii) COPN is not always effective controlling supply, and (iii) when bed supply was controlled expenditures per bed are found to increase. [Arnold and Mendelson, 1992; Delaware Health Commission, 1996; Conover and Sloan, 1998; Custer, 1997; Lanning et al., 1991; Mendelson and Arnold, 1993; Salkever, 1978].

**Quality.** Proponents argue that COPN programs improve quality of care because (i) COPN causes high utilization of medical equipment or services leading to better outcomes, (ii) it helps filter good providers by screening quality records and by judging their ability to meet conditions associated with quality care, (iii) it helps stabilize health care market by filtering out financially unsound or professionally unprepared providers, and (iv) it restrains growth of for-profit providers that may offer lower quality care.

It is probable that COPN could improve quality of care through these channels with the exception of (iv). However, it is a wasteful way trying to improve quality of care through the COPN program. It is important to note that the primary reason behind the COPN program is not that it would improve quality but rather that it would contain costs in a cost-based payment environment and that it was mandated by federal legislation. Thus, improved quality should be evaluated as a secondary unintended benefit associated with COPN programs. If the object of a regulation were to improve quality of care, it would have never been done the way COPN does it. In this sense, COPN is not a necessary program to assure quality of care. Other approaches directly targeting quality of care as the primary goal would probably be economically more efficient. There are already some quality safeguards in place. For example, dissemination of

health care information to consumers mitigates potential quality of care risks through the market mechanism. Also, there are various government programs to monitor quality of care in the absence of the COPN program. These include facility licensure programs and Medicare and Medicaid certification programs. Perhaps, tailoring these existing mechanisms to bolster quality would be much more cost effective in protecting public health and safety rather than relying on very questionable COPN spillover quality improvements.

Furthermore, COPN could have adverse effects on quality by slowing the diffusion of technology, by protecting low-quality providers, and by preventing innovative providers entering the market. For instance, one can easily argue that if the equipment is outdated or the staff is incompetent, a COPN program may be forcing more consumers to take risks they would not be otherwise willing to take. Thus, limitations COPN places on consumer choice may not be in the best interest of the public.

Empirical findings on the quality aspect of COPN appear to be mixed. Evidence is inconclusive regarding the ability of COPN in improving quality by forcing high utilization of equipment or services even though high utilization is found to improve outcomes. There is some evidence that COPN protects quality in the home health sector by filtering out unprepared or unqualified providers. COPN's effect on keeping out for-profit providers and resulting effects on quality are mixed. Finally, findings indicate that COPN does not provide an ongoing mechanism for monitoring quality. [Arnold and Mendelson, 1992; Brown et al., 1992; Collins and Keane, 1997; Conover and Sloan, 1998; Deemez et al., 1992; Delaware Health Care Commission, 1996; Federal Trade Commission, 1986; Griffiths et al., 1994; Lanning et al., 1991; Lewin/ICF and Alpha Center, 1991; Luft and Garnick, 1990; National Home Care Association Newsletter, 1998; Irvin, 1998; Burling, 1998; U.S. General Accounting Office, 1998].

Access. Proponents of the COPN program argue that the program improves access to health care (i) by limiting entry of new providers who may undermine the ability of incumbents to provide unprofitable services, (ii) by restricting expansion of facilities in overbuilt areas leading providers to expand services in underserved areas, and (iii) by requiring providers to serve all patients needing care in a particular geographic area. Again, it is generally unlikely that the COPN program could be effectively used to improve access to care. COPN is simply a wasteful way of trying to improve access. Based on economic theory, it can be reliably inferred that

economic costs associated with trying to improve access through the COPN would far outweigh any ancillary access benefits.

Preventing entry of new competitors so that incumbents could continue to provide unprofitable services such as trauma or burn units, amounts to financing of such unprofitable operations through above normal profits the incumbents are allowed to make under the COPN umbrella. While many examples could be offered, teaching hospitals' status in Virginia is a particularly interesting case given their ability to shift costs. Teaching hospitals are able to collect revenues from high technology services under the COPN umbrella to make up their losses from providing uncompensated indigent care. If ownership were not restricted, new entrants would offer these lucrative revenue-generating services, thereby acerbating teaching hospitals' losses. Thus, the COPN program shields teaching hospitals from competition and allows them to finance the cost centers by the revenue centers.

In this particular case, while proponents may argue COPN improves access to indigent, this mechanism distorts the prices of high technology revenue generating services upward, causes under consumption of these services by paying consumers, and results in inefficient allocation of resources. Economic theory predicts that such social costs would far outweigh the social benefits that can be expected from improved access. Furthermore, the economic theory suggests that in such cases it is best to address the market failure (i.e. provision of unprofitable services in this example) through direct payments and allow the remaining market forces to operate with no intervention.

In general, similar conclusions apply to other cases where COPN is used as a non-market tool to enhance access to care.

The empirical evidence on the access aspect of COPN appears to be limited and conflicting. In some cases, COPN is found to protect inner city facilities and enhance access while in some other cases COPN may have restricted needed services as the opponents argue would happen. Also, access effects seem to vary from state to state and from service to service. Finally, there appears to be lack of empirical evidence to understand the rural access effects of COPN. [Arnold and Mendelson, 1992; Brown et al, 1992; Delaware Health Care Commission, 1996; Hackey, 1993; Kiel, 1993; Lewin/ICF and Alpha Center, 1991; McGinley, 1995; Mendelson and Arnold, 1993; Rettig, 1992; Sloan, 1988; Weaver, 1995].

**Charity Care.** Proponents argue that COPN enhances provision of charity care (i) by explicitly requiring a certain level of charity care as a condition of approval, (ii) indirectly by improving the profit margins of existing providers, (iii) by preventing new entrants who would "cherry pick" lucrative services, and (iv) by favoring not-for-profit providers who would provide more charity care.

In Virginia, the COPN program is used as a tool to provide incentives to providers to offer services to indigent patients at reduced rates through the conditioning process adopted in 1988. In fact, there are claims made by some researchers that the implicit purpose of the COPN program is to issue licenses and restrict competition to create an incentive to provide care to the indigent rather than to prevent duplication of services and investment in costly excess capacity.

This conditioning process was created as a response to findings that the burden of uncompensated care is shared unevenly among the hospitals and there was no mechanism to correct this inequality. The 1988 General Assembly introduced the conditioning process into the COPN program and at the same time created the Indigent Health Care Trust fund to more evenly distribute the uncompensated care burden. With the conditioning mechanism, the state would be able to ensure provision of services to the indigent and uninsured who may have otherwise experienced difficulties with access to care if the intent of a provider were to prioritize paying patients.

The conditioning of certificates can be characterized as a mechanism that allows entry into an otherwise restricted market in exchange for providing uncompensated care. In economic terms, certificate holders are allowed to make above normal profits in the health care market and then required to use some of these proceeds to finance health care for the indigent and the uninsured. Even though it may be difficult to find out whether these above normal profits are commensurate with the cost of uncompensated care provided, economic theory unambiguously predicts that such mechanism would be less efficient compared to financing of uncompensated care through direct payments. In other words, the society as a whole would be better off (particularly given the transfer of welfare from consumers to providers and the deadweight efficiency losses as discussed earlier) if the conditioning mechanism is abandoned and uncompensated providers are paid directly.

Empirical evidence indicates that COPN programs initially screen for the likelihood of a facility providing charity care, but do not monitor ongoing compliance. There is some evidence showing that some states are more likely to approve providers offering more charity care. While COPN's effect on favoring not-for-profit providers is conflicting, evidence suggests that for-profits tend to provide less charity care, and public and teaching hospitals provide the most charity care. Some evidence shows that COPN improves operating margins of existing providers, which may lead to increased charity care. [Campbell and Ahern, 1993; Campbell and Fournier, 1993; Conover and Sloan, 1998; Hackey, 1993; Lanning et al., 1991; Lewin/ICF and Alpha Center, 1991; Mendelson and Arnold, 1993; Pennsylvania Legislative Budget and Finance Committee, 1996].

Summary. COPN programs emerged during 1970s as a response to a federal mandate introduced by the National Health Planning and Resources Development Act (NHPRDA) and to health care cost containment concerns associated with cost-based reimbursement methodologies. In today's environment, none of these original reasons seem to have validity as they did three decades ago. In 1988, when NHPRDA expired, COPN programs were no longer federally mandated. Also, the trend toward service-based payment methodologies coupled with expansion of managed care significantly mitigated the original cost containment concerns that existed when cost-based payment methodologies were being used. Finally, most empirical research has failed to find support for the claim that COPN programs reduce health care costs.

While these developments were taking place, several ancillary benefits seem to have emerged as primary justifications for the continued existence of these regulatory programs. This view severely suffers from several shortcomings. First, theoretically it is just as easy to conjecture that COPN programs could reduce quality, access, and charity care. In fact, empirical evidence on these matters is mixed showing both negative and positive effects. Second, economic theory unambiguously predicts that the use of COPN as an indirect mechanism to improve quality, access, and charity care is inferior to the use of direct mechanisms addressing the same issues. Finally, while COPN may produce some ancillary benefits, it channels significant welfare from consumers to providers, and creates economic inefficiencies known as deadweight losses. Thus, maintaining the COPN program for highly speculative and unreasonable ancillary benefits that may or may not occur is a waste of society's resources.

The balance of economic theory and empirical findings suggest that the repeal of the COPN program and simultaneous adoption of other regulatory programs directly addressing quality, access, and charity care issues would produce net economic benefits for the Commonwealth. The Federal Trade Commission and the Department of Justice further support this conclusion by urging "states with CON programs to reconsider whether they are best serving their citizen's health care needs by allowing these programs to continue." [Federal Trade Commission and the Department of Justice, 2004].

### **Businesses and Entities Affected**

The proposed regulations apply to nursing facilities, hospitals, and other medical facility providers. Current inventory of regulated facilities/beds/equipment include 51 outpatient surgical hospitals, 273 nursing homes, 68 freestanding diagnostic imaging facilities, 88general hospitals, 8 rehabilitation hospitals, 22 freestanding radiation therapy facilities, 5 long-term acute care hospitals, 28 ICF/MR facilities (only 4 larger than 12 beds), 1 freestanding cardiac catherization center, 5 psychiatric hospitals, 1 freestanding substance abuse treatment facility, 31,415 nursing home beds, 17,606 acute care beds, 1,730 psychiatric beds, 585 ICF/MR beds, 876 operating rooms, 104 cardiac catherization labs, 345 computed tomography scanners, 138 magnetic resonance imaging scanners, 27 positron emission tomography scanners, 79 radiation therapy equipment, 49 lithotripsy equipment, 20 open-heart surgery programs, and 5 organ transplant programs. Approximately, 100 applications for regulated services are reviewed each year. Additionally, these regulations affect five Health System Agencies as well as indigent and non-indigent patients receiving services from regulated providers. Approximately, 100 applications for regulated services are reviewed annually. Additionally, these regulations affect five Health System Agencies as well as indigent and non-indigent patients receiving services from regulated providers.

# **Localities Particularly Affected**

The proposed regulations apply throughout the Commonwealth. However, a locality may be particularly affected if it chooses to own or operate a regulated facility, as the facility would be subject to these regulations.

# **Projected Impact on Employment**

The proposed regulations are expected to slightly increase the number of providers seeking approval. As they start providing services, they would hire new medical and support personnel contributing to the employment in Virginia. Whether these new facilities/services would significantly affect the employment by current providers is not known.

On the other hand, the proposed volume standards may reduce the number of providers seeking approval for CT, MRI, and organ transplant services and equipment. As the certificate applications for these services declines, demand for medical and support personnel involved in CT, MRI, and organ transplant services and equipment would be slightly lower than what it would be without the proposed regulations.

# **Effects on the Use and Value of Private Property**

The proposed regulations are not expected to have an effect on the value of physical private property. However, by allowing more providers to operate services already regulated or by allowing providers to offer new services, the proposed regulations are expected to contribute, on average, to value of medical businesses in the Commonwealth. Whether the increased number of providers in the market would significantly affect the asset value of existing medical businesses is not known.

Also, more stringent requirements to offer new CT, MRI, and organ transplant services or expand existing services may positively affect the asset values of existing certificate owners while negatively affecting the asset values of providers who will no longer be able to obtain a certificate under the revised standards.

#### Small Businesses: Costs and Other Effects

According to VDH, all of the 28 ICF/MR facilities, one cardiac catherization laboratory, one freestanding substance abuse treatment facility, twenty nursing homes, and five outpatient surgical hospitals could be considered as small businesses. Less stringent SMFP regulations may make it less difficult for small businesses to start offering new medical services or expanding existing services. However, more stringent volume standards for CT, MRI, and organ transplant services may make it more difficult for small businesses to start offering new or expanding existing CT, MRI, and organ transplant services.

## **Small Businesses: Alternative Method that Minimizes Adverse Impact**

The alternative method that minimizes the adverse impact would be to remove the proposed more stringent CT, MRI, and organ transplant volume standards from this proposed action.

# **Real Estate Development Costs**

The proposed regulations are not anticipated to have any direct effect on real estate development costs.

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# **Legal Mandate**

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H 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. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other

administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.