



## Periodic Review / Retain Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-220
<b>Regulation title</b>	Virginia Medical Facilities Certificate of Public Need (COPN) Rules and Regulations
<b>Document preparation date</b>	12/5/2012

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 14 (2010) and 58 (1999).

### Legal basis

*Please identify the state and/or federal legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., agency, board, or person.*

The Medical Care Facilities Certificate of Public Need Rules and Regulations (COPN regulation) is promulgated by the Office of Licensure and Certification of the Virginia Department of Health, for the Board of Health, under the authority of § 32.1-102.2 of the *Code of Virginia* (Code), which mandates that the Board promulgate regulations to “establish concise procedures for the prompt review of applications for certificates” in implementing Virginia’s Medical Care Facilities Certificate of Public Need (COPN) law. Existence of the COPN regulation is, therefore, mandated.

### Alternatives

*Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.*

The department is required to regulate the medical care facility projects defined in § 32.1-102.1 of the Code. The COPN regulation provides applicants and the department with the framework for examining

the need for projects requiring a COPN. The COPN regulation is necessary to carry out the mandate of the COPN law.

**Public comment**

*Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
Lynn Elliot Marshall Mintz, MD Fairfax Radiological Consultants, PC (FRC)	In general, FRC is supportive of the COPN requirements for initiating new services, but we feel that the current COPN regulations should be amended relative to expansion of approved services at existing location...such that approval is granted for service providers wishing to expand already approved services at an existing location when the following criteria are proven via the application process: the applicant's service volumes at the existing location are at capacity; the applicant consistently provides free or markedly reduce are to indigent patients at or above charity care thresholds defined by COPN; the applicant maintains specific quality standards as demonstrated by criteria such as ACR accreditation, patient survey data, referring physician testimonials, etc.  In addition, we feel strongly that service volumes of other organizations should not be factored into expansion of existing services.	There may be some confusion. This periodic review focused on the regulations pertaining the filing and processes of a COPN application; the comments received are directed at making changes to the State Medical Facilities Plan (SMFP) and are beyond the scope of this review.

No informal advisory group was formed for assisting in this periodic review.

**Effectiveness**

*Please indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

The regulation meets the criteria set out in Executive Order 14 (2010) as it is clearly mandated by law; is clearly written and easily understandable.

**Result**

*Please state that the agency is recommending that the regulation should stay in effect without change.*

---

The Department of Health is recommending that the regulation remain in effect without change at this time.

**Small business impact**

*In order to minimize the economic impact of regulations on small business, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency’s determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.*

---

The COPN program is designed to promote comprehensive health planning to meet the health care needs of the public, while avoiding duplication of specified medical care facilities and services. Regulation is the tool used by state agencies to provide the necessary consistency for the both COPN applicant, good cause petitioners, and state officials to measure the need for prescribed medical care facilities and services in Virginia. There are no comparable federal regulations; therefore, the regulation does not overlap, is not duplicative, and does not conflict with federal regulations. The regulation was last evaluated in 2008. Currently, the regulation meets the intent and purpose of the applicable state mandate. Repeal of the regulations can only be achieved through legislative action. The department will continue to monitor its effectiveness and will seek amendment of the regulation in the event such action is deemed warranted. Small businesses are not impacted by the regulation, unless they choose to offer one of the prescribed services or operate a medical care facility defined in the COPN law.

**Family impact**

*Please provide an analysis of the regulation’s impact on the institution of the family and family stability.*

---

There is no direct impact on the family.