



Client Advisory Certificate of Public Need (“COPN”) Primer for Clients 2009

I. COPN Primer: Introduction

The Certificate of Public Need (“COPN”) program is a state regulatory program intended to balance cost, quality, and access issues, and to ensure that only needed health care services and facilities are developed in Virginia. Virginia’s COPN program was initially enacted in 1973, or at least one year before the federal National Health Planning and Resources Development Act of 1974 required states to operate certificate of need programs as a condition for receiving certain federal funding. Although the federal certificate of need requirements were repealed in 1986, Virginia’s COPN requirements still exist. The COPN program is governed by Va. Code §32.1-102.1 et seq., under which the Board of Health is required to promulgate regulations at 12 VAC 5-220-10 et seq.

The five general principles used in guiding the implementation of the Virginia COPN program follow:

- The COPN program will give preference to medical facility and service development approaches which can document improvement in the cost-effectiveness of health care delivery. Providers should strive to develop new facilities and equipment and use already available facilities and equipment to deliver needed services at the same or higher levels of quality and effectiveness, as demonstrated in patient outcomes, at lower costs.
- The COPN program will seek to achieve a balance between appropriate levels of availability and access to medical care facilities and services for all the citizens of Virginia and the need to constrain excess facility and service capacity.
- The COPN program will seek to achieve economies of scale in development and operation, and optimal quality of care, through establishing limits on the development of specialized medical care facilities and services, on a statewide, regional, or planning district basis.
- The COPN program will give preference to the development and maintenance of needed services which are accessible to every person who can benefit from the services regardless of ability to pay.

- The COPN program will promote the elimination of excess facility and service capacity. The COPN program will promote the conversion of excess facility and service capacity to meet identified needs. The COPN program will not facilitate the survival of medical care facilities and services which have rendered superfluous by changes in health care delivery and financing.

II. When is a COPN required?

The Virginia Code states that “[n]o person shall commence any project without first obtaining a certificate [of public need] issued by the Commissioner.”¹ “Project” is defined as:

- Establishment of a medical care facility,²
- An increase in the total number of beds or operating rooms in an existing medical care facility,
- Relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another in any two-year period,³
- Introduction into an existing medical care facility for any new nursing home service, such as intermediate care facility services, extended care facility services, or skilled nursing facility services, regardless of the type of medical care facility in which those services are provided,
- Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, substance abuse treatment, or such other specialty clinical services as may be designated by the Board of Health by regulation, which the facility has never provided or has not provided in the previous twelve months,
- Conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds,
- The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board

¹ Va. Code §32.1-102.3.

² Medical care facilities include, but are not limited to, general hospitals, sanitariums, nursing homes, intermediate care facilities, extended care facilities, mental hospitals, mental retardation facilities, psychiatric hospitals, rehabilitation hospitals, and certain specialized centers and/or clinics.

³ However, a hospital shall not be required to obtain a certificate for the use of 10% of its beds as nursing home beds.

- of Health by regulation. Replacement of existing equipment shall not require a COPN, and
- Any capital expenditure of five million dollars or more.
- III. Who are the important players in the COPN review process?**

Division of Certificate of Public Need

The Virginia COPN program is administered by the Virginia Department of Health, Center for Quality Health Care and Consumer Protection, Division of Certificate of Public Need (“DCOPN”). In addition to coordinating much of the COPN review process, the DCOPN reviews each COPN application and recommends approval or denial of each application to the Commissioner. The DCOPN’s analysis and recommendations are set forth in its staff report. Attachment A includes a copy of the DCOPN’s website at www.vdh.state.va.us/quality/COPN/default.htm.

Local Health Planning Agency (“HPA”)

The Commonwealth of Virginia is divided into five health planning regions, which are composed of multiple health planning districts. Each health planning region has a HPA, which reviews all COPN applications proposing projects within the HPA’s region. The local HPA issues a staff report, which includes its analysis and recommendations to the Commissioner. Attachment A includes a list of contact information for each health systems agency.

Adjudication Officer

The Commissioner’s Adjudication Officer holds hearings on COPN applications where the DCOPN or HPA recommends against an application.

State Health Commissioner

The State Health Commissioner is the executive officer of the Virginia Department of Health. The Commissioner makes the final decision whether or not to issue a certificate to a COPN applicant. The Commissioner bases his or her decision on the “Twenty Required Considerations” set forth in Attachment B.

IV. What criteria are used by local and state health planners during a COPN review?

A. General Criteria

In reviewing a COPN project, local and state health planners base their recommendations to the Commissioner on the following general criteria.

Accessibility

Accessibility means the ability of a population or set of the population to obtain appropriate, available services. This ability is determined by economic, temporal, locational, architectural, cultural, psychological, organizational and informational factors which may be barriers or facilitators to obtaining services.

Acceptability

Acceptability means to the level of satisfaction expressed by consumers with the availability, accessibility, cost, quality, continuity, and degree of courtesy and consideration afforded them by the health care system.

Availability

Availability means the quantity and types of health services that can be produced in a certain area, given the supply of resources to produce those services.

Continuity of care

Continuity of care means the extent of effective coordination of services provided to individuals and the community over time, within and among health care settings.

Cost

Cost means all expenses incurred in the production and delivery of health services.

Quality of Care

Quality of care means to the degree to which services provided are properly matched to the needs of the population, are technically correct, and achieve beneficial impact. Quality of care can include consideration of appropriateness of physical resources, the process of producing and delivering services, and the outcomes of services on health status, the environment, and/or behavior.

B. State Medical Facilities Plan

The State Medical Facilities Plan (“SMFP”)⁴ is the planning document adopted by the Board of Health, which includes (1) specific methodologies for projecting the need for medical care facility beds and services; (2) statistical information on the availability of medical facility beds and services; and (3) procedures, criteria and standards for the review of each type of COPN application.

V. What are the important steps in the COPN process?

The scope of a particular COPN project will vary depending on the project’s consistency with Virginia’s SMFP and whether opposition against the project exists among other health care providers, the local health planning agency, or the DCOPN. The various steps in Virginia’s COPN process may include, but are not limited to, the following.

- Letter of Intent (“LOI”) Filing
To initiate the COPN process, an applicant must file a LOI with the DCOPN and appropriate HPA according to the schedule set forth in the Batch Calendar listed on the DCOPN’s website. See Attachment A.⁵ The LOI will notify the DCOPN of the applicant’s intent to file a COPN application. The LOI must identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the project.
- COPN Application Preparation and Submission
The DCOPN will forward application forms to the applicant within 7 days of receipt of the LOI. The COPN application must be filed with the appropriate regional HPA and the DCOPN by the date set forth in the Batch Calendar (or 40 days prior to the first day of a scheduled review cycle). Filing a COPN application requires the coordination and collection of a substantial amount of information, data, and documentation necessary to complete the application. Medical care facilities typically hire law firms, such as Mellette, P.C., or other consultants to consolidate the information collected, develop arguments in support of the medical facility’s COPN request, and prepare the application and exhibits before it is filed. At this stage, it may also be necessary to conduct research and develop arguments to contest the projects of any competing applicants. Finally, the applicant is required to pay an application fee in an amount that will vary according to the capital expenditures proposed in the project.
- Responding to Completeness Review Questions

⁴ See 12 VAC 5-230-10 *et seq.*

⁵ The LOI must be filed by the later of (i) 30 days prior to the submission of an application for a project included in a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities which are proposed for the same planning district or medical service area.

- Each type of COPN project has a 120-day review cycle, which is set forth in the Batch Calendar. The review cycle begins once the DCOPN determines that a COPN application is complete. At least 5 days prior to the first day of the review cycle, the applicant must prepare and submit responses to Completeness Review Questions, which are issued by the DCOPN and appropriate HPA approximately 15 days following the filing of the COPN application. Preparation for and Appearance at the Regional HPA's Public Hearing
The regional HPA will schedule a public hearing on a COPN project. At the public hearing, each competing applicant⁶ in the review cycle and the general public will have the opportunity to voice their opinions about pending COPN applications before the staff of the local HPA. The applicant should prepare exhibits and talking points for the various scheduled speakers testifying in support of its COPN application.
- Preparation for and Appearance at Regional HPA's Board Meeting
Following the local HPA public hearing, the local HPA will hold a Board meeting. At the meeting, the applicant will have a final opportunity to respond to any comments made about the applicant's proposed project in the HPA's staff report or at the public hearing. The HPA Board will subsequently vote on whether to recommend approval or denial of the COPN project to the Commissioner.
- Preparation for an Informal Fact Finding Conference (IFFC), if necessary
If the DCOPN schedules an IFFC, the IFFC will be scheduled between the 80th and 90th days of the review cycle. IFFCs are scheduled when (i) determined necessary by the Department of Health or (ii) requested by any person showing good cause.⁷ Most medical care facilities hire a law firm, such as Mellette, PC, to prepare arguments in support of the applicant's COPN application, create exhibits for the IFFC, prepare witnesses, and appear at the IFFC on behalf of the medical care facility.
- Circuit Court COPN appeal, if necessary
If the Commissioner denies the applicant's request for COPN approval, the applicant may appeal the Commissioner's decision to the circuit court.

⁶ Applications for the same or similar services which are proposed for the same planning district or medical service area shall be considered as competing applications by the Commissioner.

⁷ Any person seeking to demonstrate good cause shall file, no later than 4 days after the Department of Health has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the Commissioner, applicant and other competing applicants, and regional HPA stating the grounds for good cause and providing the factual basis therefore under oath. "Good cause" means that (i) there is significant, relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the applications subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the DCOPN's report on the application or on the report submitted by the regional HSA.

VI. How much does it cost to seek COPN approval for a project?

Depending on the scope of the COPN project, an organization can expect to incur substantial costs in seeking COPN approval. A health care organization may incur high capital expenditures, legal fees, a COPN application fee, and additional labor expenses as it moves through the COPN process. An organization should expect to devote a great amount of time and human resources to obtain COPN approval.

VII. What is the future of the Virginia COPN program?

Two important considerations in any proposed COPN project are the likelihood of success and the impact of Senate Bill 337 (2000), whereby the Commonwealth committed itself to phased COPN deregulation. Following the 2000 amendment of the Va. Code §32.1-102.13, the Virginia General Assembly was supposed to provide sufficient funds for indigent care in hospitals as a precondition to deregulation.⁸ The additional funding in subsequent years, along with the adoption of new regulations establishing separate licensing requirements for currently unlicensed services subject to COPN review, was supposed to allow the three-phase deregulation plan to proceed. The additional funding was part of a compromise reached by the 2000 General Assembly that included health care facility associations, such as the Virginia Hospital and Healthcare Association, and physician groups such as the Medical Society of Virginia.

Unfortunately, for deregulation advocates, the state budget challenges have postponed the effective date of deregulation. In the meantime, new proposed regulations implementing the 2000 legislation have been promulgated without the deregulation of services component.

VIII. Conclusion

Peter Mellette has been involved in the planning, preparation, representation, financing and development of well over one hundred fifty (150) COPN projects. His representation has extended throughout Virginia and into eight other states.

This number excludes (1) those proceedings in which the firm's attorneys were retained for the sole purpose of opposing a COPN application; (2) instances in which clients were advised of the method in which to structure to avoid COPN review for what would otherwise be considered a reviewable project under the COPN law; and (3) significant changes to approved projects.

Peter Mellette's COPN activities have included the representation, often more than once, of over twenty (20) Virginia hospitals involving approximately five (5) hospital relocations and over thirty (30) on-site expansion/renovation projects. Peter has sought COPN approval for more than fifty (50) nursing home projects located in more

⁸ While an indigent care funding mechanism currently exists under state law (Va. Code §32.1-332 to -342), the deregulation plan proposal was not approved by the 2001 session.

*Courtesy of:
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than thirty (30) different jurisdictions. It would be very difficult to identify a type of health care project in which Peter has not been involved on more than one occasion.

In a typical COPN project, Peter Mellette will assist the client with the initial analysis of whether a COPN is required for a particular project. If a COPN is required, the firm assists the client in evaluating the project's likelihood of success based on available service utilization, population, and cost data. The firm works as needed with the client in preparation of the COPN application, including the preparation and review of exhibits and the preparation and review of responses to questions concerning the application. Peter works with other consultants, including architects, engineers, and accountants, concerning the design and financial aspects of the application. Peter will appear at public hearings, health planning agency board meetings, informal conferences, and at other meetings with HSA and DCOPN staff. Mellette, PC also stays abreast of legislative developments that may affect the future of COPN in Virginia and will advise the client accordingly.

Should your organization require experienced and professional legal assistance through Virginia's COPN process, please contact Peter Mellette, principal with Mellette, PC at 325 McLaws Circle, Suite 2, Williamsburg, Virginia 23185 or by telephone at (877) 635-5388.