Frequently Asked Questions about the Certificate of Need Process in South Carolina

Prepared by

STRATEGIC DIRECTIONS
115 Parkwood Rd.
Greenwood, SC 29646

© 2008 Strategic Directions, Inc.
DISCLAIMER
The following questions and responses represent questions that we are frequently asked about South Carolina’s Certificate of Need program. Our answers are based on our twenty-plus years of experience in this area. The answers should not be construed as legal advice. Furthermore, it must be noted that from time to time, changes may occur in the CON process that may not be reflected in these answers. We encourage you to contact us or SC DHEC before making any business decisions that may have CON implications.

FREQUENTLY ASKED QUESTIONS
These questions give a general overview of the CON process. As can be expected, these questions are not comprehensive. If you have more specific questions that you would like to ask, feel free to contact us at sdi@strategicdirectionsinc.com. We look forward to speaking with you.

Do I need to get a Certificate of Need?
Many but not all healthcare services provided in South Carolina must be approved by SC Department of Health and Environmental Control under its “Certification of Need” regulation. The regulation is 61-15 and can be downloaded at LINK. Basically, you must be awarded a CON if the following conditions apply: the purchase of any single piece of medical equipment with a total cost of over $600,000, the capital expenditure by a healthcare facility of over $2,000,000, or a service specified in the SC State Health Plan. Also, a CON is required for a change in majority ownership of a healthcare facility and the regulations provide for some exemptions for certain CON projects, such as, medical office buildings.

What projects are exempt from Certificate of Need review?
Non-medical projects, such as refinancing existing debt, roof replacement, parking garages, computer systems, etc.; the upgrading of facilities which do not involve additional square feet or additional health services; replacements of like equipment with similar capabilities; facilities owned and operated by the federal government; federal facilities operated by the state; educational and penal institutional infirmaries for the exclusive use of their population; and facilities owned and operated by the S.C. Department of Mental Health and the S.C. Department of Disabilities and Special Needs except for the addition of total beds.

What is the SC State Health Plan?
The health plan is prepared and published by SC DHEC bi-annually (and occasionally more frequently). The plan inventories healthcare services and identifies services requiring a CON and the criteria under which a CON might be approved. The Health Plan is only available in hard copy and can be ordered by calling (803) 545-4200. It is also available in most South Carolina Public Libraries.

How do you get a CON?
Securing a CON is a very complex regulatory process. A lengthy application must be prepared and submitted to begin the process. A typical CON application is 100-200
pages, including the required exhibits. The requirements for the application are defined in CON regulation 61-15.

What does a CON cost?
DHEC charges a CON fee for processing the application. The CON fee is on a sliding scale based on the total project cost. The fee maxes at $15,000 for projects in excess of $1.4 million.

How long does it take to get a CON?
The preparation of the application requires 1-2 months if done by someone with experience. Once submitted, the review and decision process at DHEC takes 4-5 months, assuming the application is not opposed.

How is a CON opposed?
Any “affected party” can oppose a CON. “Affected party” is specifically defined in regulation 61-15. Basically, an affected party is any individual or organization within the service area impacted by the proposed project in the CON application. The application can be opposed by requesting a public hearing on the application or by appealing a decision by DHEC to approve the CON.

How can I find out if a CON application has been filed?
Monitoring CON application filings requires diligence. DHEC publishes a monthly “CON Update” that lists all of the CON applications under review. Subscription to this publication costs $120 a year. Recently, DHEC began posting on the internet an abbreviated version of this report; it can be found at ??/ When a CON application has been deemed complete and ready for final review, DHEC is required to place a notification in the SC State Register. Some people engage attorneys or consultants to monitor CON filings on their behalf.

How long is a CON valid?
When a CON is issued, it is valid for 6 months. During that time, you are expected to initiate the project. Under extenuating circumstances, DHEC can give a 6-month extension, and under extreme circumstances the DHEC board can extend a CON another 6 months. You are required to submit monthly reports on your efforts to begin the approved project. Once the project has begun, DHEC requires you to submit specific documentation (such as a signed construction agreement). At that point, you do not need to submit monthly reports. However, when the project is completed DHEC requires a closeout report which must include very specific information.

Can I sell my CON?
No. The regulations are very specific, a CON can not be sold or transferred. Under certain, specific circumstances the change of ownership of a healthcare facility can be exempted from a CON. Otherwise, a new CON must be secured for a change in ownership of an existing CON.
Can I relocate a CON?
A CON is issued for a specific location. Any change in location must be approved by DHEC and typically would require applying for a new CON in the new location.

Do I need a CON to purchase major medical equipment?
Yes, if the total project cost exceeds $600,000. If the total project cost is less than $600,000, you can request a “Non-applicability Determination (NAD)” from DHEC under regulation 61-15. In order for DHEC to approve a NAD, you have to document the total project cost. The cost must include the price of the equipment, sales tax, renovation/installation costs, the value of the space the equipment will occupy, a portion of the common spaces in the building, and other costs related to the project.

Can I get a change of ownership exempted?
The regulations do provide exemption for a change of ownership of a healthcare facility under certain circumstances. The regulations define a healthcare facility as “??.” A new CON will be required for the change of ownership of any service other than a healthcare facility as defined.

Do I need the help of a consultant?
Yes, of course, we think so. However, many larger organizations have internal staff that with CON planning experience. Some smaller organizations, attempt to do their own CON applications and are able to get the job done. The CON process is very complex and time consuming and an experienced consultant can get the work done quicker and more effectively. Our experience is that a CON application for a new client typically requires 100-140 man-hours of work.

CONCLUSION
As demonstrated from the responses to these questions, the CON process, specifically in South Carolina can be a long, arduous, and sometimes expensive process. Mistakes along the way can further exacerbate the timeline and overall project costs. As we previously mentioned, while some organizations, even smaller ones, manage to submit and gain approval for their CON without hiring a professional firm such as ours. However, there are many who do not try that path only to realize the need for experts after much wasted time and money. Furthermore, help from a firm such as Strategic Directions, Inc. can be immensely beneficial not only in terms or expediency or cost but also in the case that a CON is approved but is consequently opposed by an affected party or other medical providers.