

CLIENT ADVISORY

MASSACHUSETTS HEALTH OFFICIALS STRENGTHEN RULES GOVERNING HOSPITAL EXPANSION

The Massachusetts Public Health Council (“PHC”) recently approved several amendments to the regulations pertaining to the Determination of Need (“DoN”) program. The amended regulations are intended to strengthen oversight of hospital building projects throughout the Commonwealth and close gaps in the DoN program, which is administered by the Massachusetts Department of Public Health (“DPH”). Among the new amendments is a requirement that hospitals undergo a review by state health officials for the placement of inpatient satellite clinics within the Commonwealth. Prior to the amendments, such expansions by hospitals were not covered by the DoN regulations. The amended regulations also end the use of so-called physician exemption letters to acquire new medical technology for clinical practices. These letters — issued over two decades ago, some of which have never been acted upon — allowed their holders to avoid the DoN review process to determine whether there is a need for additional sites of such technology. The amendments also change the categorization of alterations to previously approved hospital “shell space”, which will now be considered a significant change requiring DoN review. This Client Advisory is meant to provide an overview of these amendments to the DoN regulations.

Satellite Facilities and Inpatient Services

The DoN regulations designate the type of health care facilities that require a DoN under the General Laws of the Commonwealth.¹ The DoN amended regulations add the following to the list of projects requiring a DoN: an off-campus inpatient unit; and placement of inpatient services at a previously-licensed outpatient satellite. The effect of this amendment is that hospitals will now be required to meet the DoN requirements even for the implementation of inpatient services at an already existing, licensed satellite location. This amendment has been met with much debate within the health care industry as it will potentially curtail hospital expansion into rural areas covered by community hospitals.

The DoN regulations set forth nine (9) factors which are assessed in the DoN process.² The ninth factor stated that an applicant *should* demonstrate that the proposed project will not unnecessarily duplicate existing resources in the applicable service area. The DoN amended regulations now read that an applicant *must* evidence this factor.

The intent of these amendments to the DoN process is to institute a more rigorous process for health care system expansions while serving to protect the interest of smaller community providers as well as their patients. The DoN amended regulations also seek to ensure that the services provided are not only non-duplicative, but also focus on the needs of a particular community.

Physician Exemption Letters

The amended regulations also establish a “sunset date” for physician exemption letters (a grandfathering provision which has allowed the acquisition of new technology (e.g. MRI, PET and Radiation Therapy) without DoN review through use of the letters). The amended regulations require substantial and continuing progress on the acquisition of the new technology by September 1, 2008, and full implementation of the project by July 1,

¹ M.G.L. c. 111 §§ 51 to 53.

² 105 CMR 100.533.

2009. This date was selected in consideration of pending projects substantially underway prior to the hearing. The PHC also added a definition for “substantial and continuing progress” to mean either the site has received approval from the DPH’s Plan Review Office or the applicant demonstrates a binding contract for the purchase or lease of the equipment with a party unrelated to the letter holder or ultimate provider of the service or technology.³ The DoN amended regulations establish that persons⁴ who acquired technology that is used to provide an innovative service prior to such an acquisition being subject to DoN (or pursuant to a notice of intent filed prior to December 29, 1993), will be deemed to have acquired the equipment pursuant to a DoN.

Shell Space

The DoN list setting forth the alterations that constitute “significant changes” (and thus require DoN review) was amended to add a project that expands any existing “shell space”.⁵ This measure was imposed to prevent applicants from dividing projects into smaller components in order to avoid a full DoN review. In addition, a new section has been added at 105 CMR 100.758 to require any party that fails to submit an application for a project that is below the expenditure minimum, but which involves the expansion of shell space, to submit a request for an advisory ruling to determine whether the entire project exceeds the expenditure minimum and requires DoN approval.

Community Health Initiatives

The existing special exemptions section allows the DoN Program Director to use his or her discretion to exempt projects from the normal DoN process. The DoN amended regulations allow the Director to stipulate conditions for such exemption which may now include a condition that the project provides community health initiatives.⁶ This amendment further highlights the PHC’s effort to benefit underserved communities and patients through the DoN process.

Conclusion

A complete list of the amendments and the final rules, which will take effect on August 8, 2008, can be found at the DPH website.⁷ If you should have questions regarding the final amendments to 105 CMR 100.000, *et seq.*, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

³ 105 CMR 100.246(F).

⁴ “Person” means an individual or his or her estate upon his or her death, or a corporation, partnership, a trust, an association, or an organized group of persons, whether incorporated or not; or any receiver, trustee, or other liquidating agency of any of the foregoing while acting in such equity. 105 CMR 100.020.

⁵ 105 CMR 100.753.

⁶ “Community health initiatives” are projects that contribute an amount reasonably related to the project toward funding for primary preventive health care for underserved populations, in conjunction with the Office of Health Communities. See Office of Health Communities at: <http://www.mass.gov/dph/ohc/ohc.htm>.

⁷ Found at:

<http://www.mass.gov/?pageID=eohhs2subtopic&L=5&L0=Home&L1=Government&L2=Laws,+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+&+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2>

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