

4



The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Determination of Need Program

2 Boylston Street, Boston, MA 02116

(617) 753-7340

FAX (617) 753-7349

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY
SECRETARY

PAUL J. COTE, JR.
COMMISSIONER

MEMORANDUM

TO: Commissioner Paul J. Cote and Members of the Public Health Council

FROM: Paul I. Dreyer, Ph.D., Associate Commissioner
Center for Quality Assurance and Control
Joan Gorga, Acting Director, Determination of Need Program

SUBJECT: Final Adoption of Revisions to the Determination of
Need Guidelines for Megavoltage Radiation Therapy Services

DATE: July 25, 2006 (Issued July 17, 2006)

I. INTRODUCTION

This purpose of this memorandum is to request the Public Health Council's adoption of the attached revisions to the Determination of Need Guidelines for Megavoltage Radiation Therapy Services ("Guidelines") adopted by the Public Health Council on December 29, 1999. The revisions include technical changes.

The technical changes result from more current (2002) cancer incidence data from the Massachusetts Cancer Registry and 2010 census-based population projections, which were not available when the Guidelines were prepared. The technical changes result in a projected need for 68 Radiation Therapy units in the year 2010. After adjusting for existing capacity (including the units approved under 105 CMR 100.308 Special Exemptions but not the units approved as expansion units for existing services under the 1999 revisions to the Guidelines), the Department calculates a statewide need for eight units by the year 2010 as indicated in Exhibit III of the Attachment to this memorandum. New and innovative uses of radiation therapy, which include but are not limited to intraoperative radiation therapy and stereotactic radiosurgery, are not included in the total state capacity since the Guidelines indicate that these units are to be considered outside the need calculations.

The Department has decided to update the need projections to the year 2010 to ensure that patients will continue to receive treatment in a timely and efficacious manner. Approval of the eight additional units will improve geographic access of radiation therapy services to new patients statewide.

The revised guidelines were released for public comment on June 21, 2006. Comments were received from Massachusetts Hospital Association, Caritas Christi Health Care, Jordan Hospital, Cape Cod Hospital, and Southcoast Hospitals Group. The summarized comments with Staff's response are indicated below.

II. Comments

Massachusetts Hospital Association

The Association noted that in several cases units were missing from the chart accompanying the memo. The Association called this to the attention of the Department not to increase the supply of units and reduce the number of units needed but to clarify the need so that providers would not, after going through internal review, planning and consideration find out that there was no need. The Association also suggested that the Department convene a small workgroup of hospitals to review and comment on the revisions.

Staff's Response

Staff has researched the omissions noted by the Associations and is satisfied that the list correctly includes all DoN-approved radiation therapy units. Some hospitals have obtained radiation therapy units through the use of exemption letters pursuant to 100.246 of the Determination of Need Regulations. Since these units are exempt from the Program, they do not form part of the supply for purposes of calculating need and are not included on the list.

The Association's suggestion of a workgroup of hospitals to comment on the proposed changes would be appropriate if policy changes were being proposed, as the Department has often used similar workgroups for that purpose in the past. The changes proposed here however result from the growth of the population and the increase in new cancer cases reported in the state and not from a change in the methodology or the variables of the methodology.

Jordan Hospital and Cape Cod Healthcare

Jordan Hospital and Care Cod Healthcare, while supporting the need for additional radiation therapy units, submitted comments that urge the Department to consider the protection of the existing radiation therapy programs of geographically isolated and sole community hospitals. Both sets of comments ask that the proposed revisions consider language similar to the language in the Guidelines for Freestanding Ambulatory Surgery Center, which would state that the Department will not approve applications for radiation therapy projects located within towns that constitute the primary market area of hospitals that are geographically isolated or sole community providers.

Staff's Response

Staff has considered the argument of Jordan Hospital and Cape Code Healthcare concerning the geographically isolated and sole community provider hospitals. The example of the Freestanding Ambulatory Surgery Center Guidelines ("ASC Guidelines") and the suggested language concerning geographically isolated hospitals and sole community providers is not pertinent to the service under discussion. The Department as a policy matter does not want to create a blanket prohibition for certain geographic areas. Restricting a hospital from applying for a radiation therapy service at its own campus despite a demonstration of need, a situation which could occur if the suggested language were adopted, is not the intention of the Guidelines. Analysis of the submitted application will demonstrate if there is need, if the need is being served by the existing providers or if an existing service with an overlapping service area is underutilized. Information submitted by other parties of interest including potential Ten Taxpayer Groups registered in connection with the application will assist the analyst in developing a staff recommendation on the application during the review process.

Caritas Christi Health Care

Caritas Christi Health Care ("Caritas") has commented seeking clarification on the eligibility of new providers to apply for radiation therapy units under the proposed revisions to the Guidelines since that eligibility has not been explicitly discussed in the proposed revisions. Caritas also has asked for clarification on expansion of radiation therapy units by existing providers and has argued that the expansion criteria currently described in the Guidelines should be allowed to continue. Finally, Caritas has asked that the filing date for radiation therapy be moved from August 1, 2006 to September or October to provide additional time for potential applicants. In addition, via electronic mail, a representative of Caritas noted that the names of Caritas Norwood and Caritas Southwood Hospitals were transposed in the chart that accompanied the informational briefing memo.

Staff's Response

While it is true that the informational briefing memo did not mention new providers or define the eligibility of new or existing providers to apply for the eight additional units, it was stated that approval of the eight units would improve geographic access to new patients statewide. Since the result of the technical revision was a projected need for eight units by 2010, it was the intent of the revisions to improve geographic access by permitting qualified new providers to apply for a radiation therapy service, which has not been permitted since 1999. Existing providers will continue to utilize the expansion criteria introduced into the Guidelines in 1999. Expansion units approved under the expansion criteria will be specifically identified in the list of radiation therapy units in a separate column. Since the expansion units have to some extent been deregulated and approved on the basis of institutional need, they will not be considered as part of the statewide need.

The Department is separately requesting approval of Council to promulgate an emergency amendment to move the filing date for radiation therapy, currently August 1, 2006 to October 1, 2006 in order to permit potential applicants the necessary time to plan and develop an application.

The Department has corrected the mis-labeling of Caritas Norwood and Caritas Southwood Hospitals.

Southcoast Hospitals Group

Southcoast Hospitals Group ("Southcoast") has submitted a letter of support for the technical changes on the Guidelines and urges the Department to focus on underserved areas of the Commonwealth. Southcoast has indicated that its cancer registry data show a 16.6% increase in new cases at a Southcoast hospital from 1999 through 2004.

III. Conclusion

Staff requests that the proposed guidelines, as revised, be approved by the Public Health Council for final adoption.

Exhibit A**REVISIONS TO THE DON GUIDELINES FOR RADIATION THERAPY SERVICES****FACTOR TWO: HEALTH CARE REQUIREMENTS FACTOR**

Standard: The project as proposed shall contribute positively to meeting the health care requirements of the target population, without duplication of services or other adverse service consequences, or with the least such adverse consequences.

Measure 1: A maximum of eight additional megavoltage radiation therapy units for new providers may be approved by the year 2010. These units shall be allocated statewide to ensure reasonable access.

Measure 2: Applicants proposing to establish a new radiation therapy service must be able to demonstrate a projected need of 250 new patients annually and an annual operating capacity of 6,000 treatments per megavoltage unit per year.

Measure 3: Applicants proposing a new radiation therapy service shall demonstrate one or both of the following:

- (a) patients' travel time to the nearest existing radiation therapy services exceeds a minimum of thirty minutes; or
- (b) patients referred in the applicant's region must wait an average of seven days or longer to receive treatment following consultation and the decision to proceed with radiation therapy.

Measure 4: Other data shall be presented to supplement the general need analysis in measures 2 and 3, since these are minimum requirements. These data may describe factors affecting need that are inadequately accounted for or particular institutional characteristics deserving special attention. Examples of such factors appear in the discussion following this standard.

Measure 5: Providers of existing licensed radiation therapy services, either in a hospital or freestanding setting, shall be allowed to expand their services by adding megavoltage radiation therapy units.

Measure 6: Additional megavoltage radiation therapy units shall be located at the site of the existing facility. A new site will be considered if Applicants can demonstrate that the new location will significantly increase access to its current radiation therapy patients without causing any adverse consequences to other existing radiation therapy services.

Measure 7: Applicants proposing expansion of existing licensed radiation therapy services shall demonstrate the following:

- (a) the existing unit or units has or have been operating at 90% capacity for the past year evidenced by the number of treatments performed annually and the hours of operation;
- (b) the existing unit or units operates or operate a minimum of (10) hours or more per day; and
- (c) the radiation therapy service is accredited in radiation oncology by the American College of Radiology.

Measure 8: Applicants proposing to acquire radiation therapy equipment for new and innovative uses such as intraoperative radiation therapy or stereotactic radiosurgery must document need by:

- (a) providing estimates of the type and number of cases to benefit from the new use of the technology; and
- (b) discussing the cost implications of the new use.

Dedicated intraoperative or stereotactic radiosurgery equipment will be considered outside the need discussed in Measure 1.

Measure 9: Pediatric radiation therapy should be undertaken only in those settings which can assure adequate standards of care with particular attention to their special needs. Applicants who wish to treat children below the age of fifteen years in the radiation therapy service shall adequately document the following:

- (a) availability of hospital-based special anesthesia, plaster cast and other methods for pediatric immobilization;
- (b) availability of hospital-based special support staff to serve the particular psycho/social, medical and related needs of children in therapy; and
- (c) periodic peer review of pediatric protocols.

EXHIBIT III

Table 2-2000, 2005 and 2010 Statewide Projected Need
For Megavoltage Radiation Therapy Units

	<u>2000</u>	<u>2005</u>	<u>2010</u>
Projected New Cancer Patients	32,339 ¹	35,756 ¹	38,248 ¹
Estimated Percentage of New Cancer Patients Receiving Radiation therapy	48% ²	48% ²	48% ²
Projected Number of New Cancer Patients Receiving Radiation therapy	15,523	17,163	18,359
Projected Number of New Patients Per Unit	269 ³	269 ³	269 ³
Projected Need for Megavoltage Units	58	64	68
Existing Number of Megavoltage Units	54	63	60
Remaining Net Need (Surplus)	4	1	8

¹Derived from linear regression analysis of 1990-2002 incidence data

²Assumes 1989 rate of new cancer patients receiving radiation therapy

³Based on 1989 statewide rate of new patients per unit

Existing Megavoltage Radiation Therapy Units by HSA (including 308's and other)

<u>HSA</u>	<u>City/Town</u>	<u>Facility</u>	<u>Units</u>	<u>New Since 1999³</u>	<u>Other⁴</u>
I	Springfield	Baystate Medical Center	3		
	Pittsfield	Berkshire Medical Center	1		
	Northampton	Cooley Dickenson Hospital	1		
	Springfield	Mercy Hospital (includes 1 308)	<u>2</u>		
	Subtotal		7		
II	Worcester	St. Vincent's Hospital	2		
	Worcester	UMassMemorial Medical Center	<u>5</u>		
	Subtotal		7		
III	Methuen	Holy Family Hospital	2		
	Lowell	Lowell General Hospital	<u>1</u>	1	
	Subtotal		3		
IV	Boston	Beth Israel Deaconess Medical Center (1 Waltham 308)	5		
	Boston	Boston Medical Center	2		
	Boston	Brigham and Women's Hospital	2		Stereotactic
	Boston	Dana-Farber Cancer Institute (includes 3 308's)	3		
	Norwood	Caritas Norwood Hospital (closed service)	0		
	Southwood	Caritas Southwood Hospital (includes 2 308's)	2		
	Burlington	Lahey Clinic	2	1	
	Boston	Massachusetts General Hospital	6		Proton beam
	Framingham	MetroWest Medical Center	2		
	Cambridge	Mount Auburn Hospital	1		
	Boston	New England Medical Center	3		Gamma knife
	Quincy	South Suburban Oncology Center ¹	1		
	Boston	St. Elizabeth's Medical center	1		
	Waltham	Waltham Hospital (closed)	<u>0</u>		
Subtotal		30			
V	Brockton	Brockton Hospital	2		
	Hyannis	Cape Cod Hospital	2		
	Plymouth	Jordan Hospital	1		
	Taunton	Morton Hospital (DoN expired)	0		
	Fall River	St. Anne's Hospital	2		
	Dartmouth	St. Anne's Hospital/St. Luke's of New Bedford	<u>1</u>		
	Subtotal		8		
VI	Peabody	North Shore Medical Center (Union Hospital)	1		
	Salem	North Shore Medical Center (Salem Hospital)	2	1	
	Stoneham	CHEM ²	<u>2</u>		
	Subtotal		5		
State wide		60	3	3	

¹ Includes Quincy and South Shore Hospitals and Shields Health Care Group

² Includes Whidden Memorial, Lawrence Memorial, Melrose-Wakefield and Malden Hospitals

³ Other indicates approval for a unit of new or innovative radiation therapy which, as indicated in the 1999 Guidelines, is not included for purposes of calculating need.

⁴ New since 1999 indicates that a unit was added by an existing radiation therapy provider under the 1999 revisions to the Guidelines and is not considered as part of the statewide supply.