

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 27, 2012
PROJECT ANALYST: Jane Rhoe-Jones
CHIEF: Craig R. Smith
PROJECT I.D. NUMBER: P-8835-12 / CWC HBO, PA dba Comprehensive Wound Care Center / Acquire Hyperbaric Oxygen Chamber / Lenoir County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

The applicant, CWC HBO, PA has submitted a certificate of need application to acquire a multi-place hyperbaric oxygen chamber to be installed in an existing medical office and expand the services currently provided at 204 Airport Road, Kinston, NC. The applicant does not propose to develop beds or services or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). Furthermore, there are no policies in the 2012 SMFP that are applicable to the review of the proposed project. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, CWC HBO, PA has submitted a certificate of need application to acquire a multi-place hyperbaric oxygen chamber to be installed in an existing medical office and expand the

services currently provided, Monday through Friday, 8 a.m. to 5 p.m. and on-call emergency basis to 24 hours per day, seven days per week. The hyperbaric multi-place chamber has the capacity to treat up to seven patients at the same time. CWC HBO currently provides hyperbaric oxygen services to patients with the following diagnoses/conditions: gas gangrene, crush injuries and suturing of severed limbs, osteoradionecrosis, progressive necrotizing fasciitis, compromised skin grafts, chronic refractory osteomyelitis, actinomycosis, acute traumatic peripheral ischemia, acute peripheral arterial insufficiency, diabetic wound lower extremities, acute carbon monoxide intoxication, smoke inhalation, and decompression illness.

Population to Be Served

In Section III.5(a), page 25, the applicant states,

“The geographic service area includes Lenoir County and surrounding and adjacent counties, to include Greene, Craven, Carteret, Duplin, Jones, Wayne, and Onslow. The service area boundaries are reasonable considering there is no other hyperbaric multi-place chamber within this region, and each area is within a reasonable travel distance for standard and emergent care. This area of Eastern North Carolina has a high diabetic population (16%) which can benefit from this most effective treatment.”

In Section III.5(c), page 25 and in clarifying information requested by the Agency, the applicant projects patient origin during the first two operating years for CWC HBO’s hyperbaric oxygen services, as shown in the table below.

Patient Origin CWC Hyperbaric Oxygen Treatment Services	
County	Percent of Total
Lenoir	30.0%
Duplin	14.0%
Onslow	10.0%
Wayne	10.0%
Greene	10.0%
Craven	10.0%
Pitt	2.0%
Jones	10.0%
Carteret	2.0%
Other	2.0%
Total	100.0%

The applicant adequately identifies the population to be served.

Need for the Project

In Section III.1(a) and (b), page 22, the applicant states:

“This is the only hyperbaric multi-place chamber for use by patients in the service area. The availability of the multi-place hyperbaric chamber fulfills an essential need

for wounds resulting from trauma, diabetes, and peripheral vascular disease. Not only does the chamber provide wound care, but also emergency care without which unnecessary and preventable injuries and death would ensue. There is no comparable alternative to the use of the multi-place hyperbaric chamber in the event of diagnoses including smoke inhalation, carbon monoxide poisoning, gas gangrene, or decompression illnesses suffered by our citizens. ...

Our service area is over one million people, of which 66% are obese, 16% are diabetic, 24% are smokers and 21% live below the poverty level. Each of these factors contributes to foot wounds leading to potential amputations, which can be potentially prevented with hyperbaric oxygen therapy. In addition, our service area is home to 8 military bases with varying types of military aircraft, with the potential for pilot altitude sickness, for which hyperbaric oxygen is the only effective treatment. Time is of the essence in these rare but serious emergencies and our pilots currently must be transported by ground to Durham, North Carolina for treatment as they cannot be moved by air. This results in delays which can prove disastrous. Hyperbaric oxygen is also an underused but extremely effective modality for the treatment of smoke inhalation, which is the leading cause of death in residential and commercial fires. ...”

Projected Utilization

In Section IV.1, page 28, the applicant states projected utilization and assumptions. The applicant treats over 100 patients per year with an average of 40 treatments per patient.

Thus, 101 patients x 40 treatments = 4,160 treatments per year (first project year)
And 147 patients x 40 treatments = 5,880 treatments per year (second project year)

Assumption: The applicant states:

“In year 2 and 3, we are assuming a small increase specific to public service use, which is represented in the increased commercial insurance category on the Financial Proformas and in Section VI.”

In Section VI, page 40 and in the Proforma, page 4 and Form E, the applicant projects the commercial insurance utilization to increase from 2% to 5% in the second full fiscal year of the project; 7% increase in Year 3.

In Section IV.2, page 28, the applicant states,

“The projected annual maximum capacity under normal business hours will be approximately 180 patients per year.”

Therefore, 180 x 40 treatments = 7,200 or the maximum number of treatments per year.

Assumptions (page 28):

Each patient will require 40 treatments.

Each treatment is 2.5 hours in the hyperbaric chamber.

Additional patients can be treated after hours on an on-call basis or emergency basis.

The standard use rate for major medical equipment is 80% of capacity. In applying the standard of 80% utilization the following conclusions can be reached: If the maximum number of treatments per year is 7,200 treatments, then 80% of capacity is 5,760 treatments ($7,200 \times .80 = 5,760$). The applicant is projecting 5,880 treatments per year which exceeds the standard 80% utilization rate.

For Section II, page 16: **14C.3104 Need for Services, a. 1**, - in clarifying information requested by the Agency, the applicant provides the projected number of cases classified by diagnosis for CWC HBO within the first two project years.

CWC HBO Projected Cases		
	FY 2013	FY 2014
Gas Gangrene	1	3
Crush injuries & Suturing Severed Limbs	2	1
Osteoradionecrosis	15	38
Progressive Necrotizing Fasciitis	2	3
Compromised Skin Grafts	1	2
Chronic Refractory Osteomyelitis	40	45
Actinomycosis	2	3
Acute traumatic Peripheral Ischemia	1	2
Acute Peripheral Arterial Insufficiency	25	26
Diabetic Wound - Lower Extremities	12	17
Acute Carbon Monoxide Intoxication	0	3
Smoke Inhalation	0	2
Decompression Illness	0	2
Totals	101	147

In summary, there are not any utilization standards known to the Agency for hyperbaric oxygen therapy. Projected utilization is based on reasonable and supported assumptions regarding historical utilization growth trends and current population needs. The applicant adequately demonstrates the need for the proposed equipment. Thus, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

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In Section III, page 23, the applicant states:

“Due to the fact that no other hyperbaric multi-place chamber exists in the service area, the equipment is necessary for treatment of the prevailing diagnoses as listed in the response to 14C3104.a(1) above. The chamber was required to be implemented to most effectively treat wounds and the other designated illnesses. Medically speaking, there is no true alternative for this most effective treatment.”

In additional information required by the Agency, the applicant states,

“In the event of Air Gas Embolism of Decompression Sickness Type II greater than 3 ATA may be necessary for treatment. When treating patients at greater than 3ATA, 100% Oxygen cannot be utilized due to serious side effects such as Oxygen toxicity. A monoplace chamber is only capable of giving 100% Oxygen. A multiplace chamber is capable of administering the safe Oxygen amount that is required to treat such cases.

... our multiplace hyperbaric chamber is available to treat much larger numbers of citizens and ... there is NO emergency hyperbaric programs [sic] in all of Eastern North Carolina. In addition to being appropriate for emergency response another distinguishing factor of the hyperbaric chamber here is that we offer care for non-wound issues. The hyperbaric programs at the wound centers in all of Eastern North Carolina deal only with wound. There are multiple other treatments such as radiation-induced injury, such as colitis and cystitis, but also conditions such as compartment syndrome and idiopathic sudden sensorineural hearing loss. These are conditions, which are not necessarily approved by all third party payers but do have efficacy with hyperbaric oxygen, which we do treat regardless of the patients [sic] inability to pay.”

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative because it is the only multiplace chamber in eastern North Carolina. Furthermore, the application is conforming to the administrative rules for certificate of need 10A NCAC 14C.3100 – Criteria and Standards for Major Medical Equipment and thus, is approvable.

In summary, the applicant adequately demonstrate that the CWC hyperbaric oxygen chamber is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. CWC HBO, PA dba Comprehensive Wound Care Center shall materially comply with all representations made in the certificate of need application and supplemental responses. In those instances where representations conflict,**

Carolina East Home Care & Hospice, Inc. shall materially comply with the last-made representation.

- 2. CWC HBO, PA dba Comprehensive Wound Care Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of this application and which would otherwise require a certificate of need.**
 - 3. CWC HBO, PA dba Comprehensive Wound Care Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, the applicant states that the project costs are actual costs that were previously incurred for the facility construction and capital lease of the hyperbaric chamber equipment. The total project capital cost as listed on page 51 of the application is \$910,386.22 which includes: \$86,460 for total site costs, \$349,411 for construction, \$436,420.20 for equipment, and \$4,450 for water service.

Exhibit BB contains the existing loan documents for the real estate and equipment. The applicant also states that CWC HBO is finalizing loan documents to purchase the hyperbaric chamber upgrade. Proforma Forms A – E are found behind Section XII in the application.

In the projected revenue and expense statements for CWC HBO, (Form B) and (Form C) submitted as clarifying information requested by the Agency, the applicant projects that operating expenses will exceed revenues by Year 2 of the first three project years of operation.

CWC HBO			
Revenue, Expenses & Income			
FY 2013-2015			
	FY 2013	FY 2014	FY 2015
Net Revenue	\$919,296	\$1,019,072	\$1,045,600
Total Expenses	\$919,413	\$954,969	\$976,403
Net Income	-\$117	\$64,103	\$69,197

The assumptions used by the applicant in preparation of the revenue and expense statements are reasonable, including projected utilization. The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and costs, and therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant, CWC HBO, PA proposes to expand the hyperbaric oxygen chamber services currently provided to 24 hours per day, seven days per week. The hyperbaric multi-place chamber has the capacity to treat up to seven patients at the same time. CWC HBO currently provides hyperbaric oxygen services to patients with the following diagnoses/conditions: gas gangrene, crush injuries and suturing of severed limbs, osteoradionecrosis, progressive necrotizing fasciitis, compromised skin grafts, chronic refractory osteomyelitis, actinomycosis, acute traumatic peripheral ischemia, acute peripheral arterial insufficiency, diabetic wound lower extremities, acute carbon monoxide intoxication, smoke inhalation, and decompression illness. The following table shows the availability of other hyperbaric oxygen chamber treatment facilities in the in the state.

Undersea & Hyperbaric Medical Society Accredited HBO Chambers in North Carolina	
Facility	City/County
CWC HBO	Kinston/Lenoir
<u>Other NC</u>	
Vidant Health	Ahoskie/Hertford
Wound Therapy Center	Asheville/Buncombe
UNC Hospitals	Chapel Hill/Orange
Carolinas Medical Center	Charlotte/Mecklenburg
Presbyterian Hospital	Charlotte/Mecklenburg
St. Luke	Columbus/Polk
North East Medical Center	Concord/Cabarrus
Center for Hyperbaric & Environmental Physiology	Durham/Durham
Duke University Medical Center	Durham/Durham
Morehead Memorial Hospital	Eden/Rockingham
Vidant Health	Greenville/Pitt
Park Ridge Health	Hendersonville/Henderson
Scotland Healthcare System	Durham/Durham
Southeast Regional Medical Center	Lumberton/Robeson
BeachCare Urgent Care	Morehead City/Carteret
FirstHealth Moore Regional Hospital	Pinehurst/Moore
Duke Raleigh Hospital	Raleigh/Wake
FirstHealth Richmond Memorial Hospital	Rockingham/Richmond
Johnston Memorial Hospital	Smithfield/Johnston
Davis Regional Medical Center	Statesville/Iredell
Valdese General Hospital	Valdese/Burke

Source: NC Hyperbaric Treatment Center Directory (website)

As shown in the table above, there are 22 HBO chamber treatment facilities in the State. CWC HBO states that it is the only multi-place chamber east of Interstate 95 in North

Carolina. The complement HBOs represents a distribution that covers most geographic regions of the State.

In Section III of the application, CWC HBO adequately demonstrates the need to expand the service hours and upgrade the HBO chamber to treat decompression illness, wounds, injuries, and other emergency treatment situations. CWC HBO states that its methodology is based on historical experience treating a range of illnesses and medical conditions since 2010; and appropriateness of the technology to treat patients. The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing services. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section VII.1(a), pages 41-43, the applicant states current staffing of the Comprehensive Wound Care Hyperbaric Oxygen therapy consists of 4.66 full-time equivalent (FTE) positions. In Section VII.1(b), pages 44-45, the applicant projects to employ 11.00 FTE positions by the second full fiscal year. This includes the addition of 2.00 supervising physicians, 1.00 registered nurse, 1.00 hyperbaric technician, and 2.00 chamber attendants to support the hyperbaric oxygen chamber. In Section VII.8, page 49, the applicant states the Chief Medical officer is Joseph D. Whitlark, M.D.

The applicant demonstrates the availability of adequate of health manpower and management personnel to provide the proposed services, and therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section II.2, page 11 and in clarifying information requested by the Agency, the applicant states, *“Lenoir Memorial Hospital provides the necessary support services for pre and post hyperbaric oxygen treatments such as: Radiology, Lab, Nutritional evaluations, Referring physicians, i.e. ENT, surgery, psychological, primary care, Emergency room availability.”*

Exhibit V contains letters of support for the proposed project from several physicians and health services providers in the CWC HBO service area. Exhibit U contains a copy of a sample inter-facility transport agreement used by Lenoir Memorial Hospital.

The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system, and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

C

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

In Section VI.2 (a-f), page 35, the applicant states:

“Each of the above group types with a health related need will be eligible for hyperbaric oxygen therapy services as a part of their plan of care. See Exhibit W for the Authorization and Consent Form which identifies the policy for nondiscrimination.”

In Section VI.12 and 13, page 39, the applicant provides the current (January 1-December 31, 2011) payor mix for the CWC hyperbaric oxygen therapy services. On page 40, the applicant states that the projected payor mix reflects anticipated increased volume of indigent and charity cases as CWC HBO collaborates with community health centers to serve these patients.

CWC HBO Therapy Services	
Projected Procedures as Percent of Total Revenue Last Full Fiscal Year January 1, 2010-December 31, 2011	
Medicare/ Managed Care	95.0%
Commercial Insurance	2.0%
Self-Pay/Indigent/Charity	2.0%
Medicaid	1.0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Lenoir county and statewide.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Lenoir County	25.0%	11.0%	21.0%
Statewide	17.0%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by CWC HBO.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website

includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the hyperbaric oxygen therapy services provided at CWC HBO. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.10(a), page 38, the applicant states:

“Not applicable, there have been no civil rights equal access complaints filed.”

In Section VI.11, page 38, the applicant states:

“There is no regulatory requirement that uncompensated services be provided to the medically underserved, minorities, or handicapped individuals. The services however will be offered to all patients, including medically underserved, minorities, and handicapped persons, meeting the medically necessity criteria, regardless of ability to pay.”

Therefore, the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

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In Section VI.13, page 39, the applicant provides the future payor mix as depicted in the chart on page 13 of these findings. In Section VI.15, page 40 of the application, the applicant states:

“These percentages were derived in anticipation of a higher patient volume of indigent and charity procedures, and in anticipation of collaboration with local community health centers to serve these patients.”

CWC HBO Therapy Services	
Projected Procedures as Percent of Total Revenue	
Second Full Fiscal Year	
January 1, 2013-December 31, 2014	
Medicare/Managed Care	71.0%
Medicaid	14.0%
Self-Pay/Indigent/Charity	10.0%
Commercial Insurance	5.0%
Total	100.0%

The applicant projects that 85.0% percent of the hyperbaric oxygen therapy patients will have some or all of their services paid for by Medicare or Medicaid; while 5.0% will be paid for by commercial insurance. CWC HBO estimates that another 10.0% of services will be self-pay/indigent/charity. The applicant demonstrates that CWC HBO will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 37, the applicant states,

“All patients meeting medically necessity requirements will be accepted.”

The applicant defines medically necessity in clarifying information required by the Agency. Further, in Section VI.9(b), page 37, the applicant states that historically it has received referrals from hospitals, home health agencies, primary care physicians, podiatrists and other healthcare providers in the service area.

The information the applicant provides is reasonable and credible and supports a finding of conformity to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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In Section V. 1(a-c), page 31, the applicant discusses how CWC HBO meets the clinical needs of health professional training programs in the area. The applicant states in part, “*Since there is no other multi-place hyperbaric chamber unit in the service area, the chamber is integral in providing a complete clinical training process for nursing students and other medical training programs.*” See Exhibit S for letters from Craven Community College, Pitt Community College and Lenoir Community College. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

See Sections II (pages 11-13), III.1(c), (page 23), V, VI (pages 35-40) and VII, Exhibit I (Quality Assurance Program). In particular, see Section V.7, pages 33-34, in which CWC HBO discusses the impact of the project as it relates to promoting cost-effectiveness and access. As the applicant notes in Section I.8, page 7 and other places in the application, CWC HBO center is accredited by the Undersea and Hyperbaric Medical Society, a nationally recognized accreditation entity. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to hyperbaric oxygen therapy services in Lenoir County. This determination is based on the information on the following:

- ◆ The applicant adequately demonstrates the need to provide hyperbaric oxygen treatment services and that it is a cost-effective alternative. It is the only provider of services in Lenoir County and several surrounding counties in eastern NC;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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CWC HBO states that the chamber is accredited by the Undersea and Hyperbaric Medical Society, and received its Clinical Hyperbaric Facility Accreditation in December 2011, and will continue to operate in compliance with those accreditation standards. The applicant also states that the credential procedures include all policies and procedures for medical treatment and quality assurance in operating the chamber. The information provided by the applicant is reasonable and credible. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

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The proposal is conforming as conditioned, with all applicable **Criteria and Standards for Major Medical Equipment as promulgated in 10A NCAC 14C .3100**. The specific criteria are discussed below. See Section II, pages 14-21 and clarifying information requested by the Agency.

10A NCAC 14C .3103 Information Required of Applicant

- (a) *An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.*
- C- The applicant used the Acute Care Facility /Medical Equipment Form for this application.
- (b) *An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services, unless the applicant documents that other*

providers outside of the applicant's existing service area are expected to refer patients to the applicant.

-C- In Section II, page 14, the applicant states that the proposed service area consists of Lenoir, Duplin, Johnston, Greene, Pitt, Wayne, Onslow, Jones, Carteret, Craven counties. In clarifying information requested by the Agency, the applicant included the additional counties of Pamlico, Sampson, Bladen, Columbus, Pender, Brunswick, Wilson, Edgecombe, Halifax, Northhampton, Hyde, Martin, Bertie, Hertford, Gates, Washington, Tyrell and Dare.

(c) *An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.*

-C- In Section II, page 14, the applicant states, “*The owner has obtained necessary certification by the American College of Hyperbaric Medicine, and the equipment has been accredited by the Undersea & Hyperbaric Medical Society. The equipment has been in use by the owner since August 2010.*”

(d) *An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.*

-C- The applicant provides documentation of U.S. Food and Drug Administration approval of the hyperbaric oxygen chamber in Exhibit J.

(e) *An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:*

- (1) *receiving/registering area;*
- (2) *waiting area;*
- (3) *pre-procedure area;*
- (4) *procedure area or rooms;*
- (5) *post-procedure areas, including observation areas; and*
- (6) *administrative and support areas.*

-C- In Exhibit K, the applicant provides copies of floor plans which identify all the areas listed in this rule.

(f) *An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and federal, state, and local manufacture's standards for the type of major medical equipment to be installed.*

-C- The applicant provides manufacturer's certification, medical gas/vacuum systems verification, City building code, and NC Department of Labor inspection and certification documentation in Exhibit L.

10A NCAC 14C .3104 Need for Services

- (a) *An applicant proposing to acquire major medical equipment shall provide the following information:*
- (1) *the number of patients who will use the service, classified by diagnosis;*
- C- In Section II., page 16 and in clarifying information requested by the Agency, the applicant provides projected utilization by diagnosis during the first two project years (11.1.2012-10.31.2013 and 11.1.2013-10.31.2014) the hyperbaric oxygen therapy equipment is operational.

CWC HBO Projected Cases		
	FY 2013	FY 2014
Gas Gangrene	1	3
Crush injuries & Suturing Severed Limbs	2	1
Osteoradionecrosis	15	38
Progressive Necrotizing Fasciitis	2	3
Compromised Skin Grafts	1	2
Chronic Refractory Osteomyelitis	40	45
Actinomycosis	2	3
Acute traumatic Peripheral Ischemia	1	2
Acute Peripheral Arterial Insufficiency	25	26
Diabetic Wound - Lower Extremities	12	17
Acute Carbon Monoxide Intoxication	0	3
Smoke Inhalation	0	2
Decompression Illness	0	2
Totals	101	147

- (2) *the number of patients who will use the service, classified by county of residence;*
- C- In Section II., page 16 and in clarifying information requested by the Agency, the applicant provides the number of patients projected to utilize the equipment by county of residence for each of the first two project years (11.1.2012-10.31.2013 and 11.1.2013-10.31.2014) of operation.

Patient Origin CWC HBO Treatment Services		
County	Year 1	Year 2
Lenoir	30	42
Duplin	15	27
Onslow	10	14
Wayne	10	14
Greene	10	14
Craven	10	14
Pitt	2	3
Jones	10	14
Carteret	2	3
Other	2	2

Total	101	147
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(3) *documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;*

-C- In Section II., page 17, the applicant states that, *“the hyperbaric multi-place chamber is capable of treating up to seven (7) patients simultaneously. ... Each treatment block (dive) of the chamber takes approximately 2.5 hours. In an normal business day, the maximum number of patients which can be treated is 21, ...*

The average treatment plan requires 40 treatments per patient. ... The projected number of patients per month would therefore be calculated as follows:

- *21 patients per day x 20 days per month = 420 treatments per month*
- *420 treatments per month / 40 average treatments per patients = 10.5 patients per month*
- *Patients treated per quarter would therefore be approximately 30 per quarter.”*

In Section IV.2, page 29, the applicant states, *“The projected annual maximum capacity under normal business hours will be approximately 180 patients per year. The number is derived by assuming each patient will receive approximately 40 treatments, and each treatment will consist of a 2.5 hour exposure in the hyperbaric chamber.”*

(4) *quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and*

-C- In Section II, page 17, the applicant provides quarterly projected utilization for the first three fiscal years of operation.

CWC HBO Quarterly Utilization	
Quarter 1	20
Quarter 2	21
Quarter 3	30
Quarter 4	30
Quarter 5	30
Quarter 6	30
Quarter 7	40
Quarter 8	47
Quarter 9	40
Quarter 10	40

Quarter 11	40
Quarter 12	45

- (5) *all the assumptions and data supporting the methodology used for the projections in this Rule.*
- C- In Section II, page 17, Section III, page 26 and Section IV, page 28 the applicant provides the assumptions used to project utilization of the hyperbaric oxygen chamber.
- (b) *An applicant proposing to acquire new major medical technology shall provide the following information:*
- (1) *the number of patients who will use the service, classified by diagnosis;*
- (2) *the number of patients who will use the service, classified by county of residence;*
- (3) *quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;*
- (4) *documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;*
- (5) *documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and*
- (6) *all the assumptions and data supporting the methodology used for the projections in this Rule.*
- NA- The hyperbaric oxygen chamber is not new major medical technology.

10A NCAC 14C .3105 Required Support Services

- (a) *An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.*
- C- In Section II.2, page 19 and in clarifying information requested by the Agency, the applicant provides a list of the ancillary and support services required to support the hyperbaric oxygen chamber.

10A NCAC 14C .3106 Required Staffing and Staff Training

- (a) *An applicant proposing to acquire major medical equipment or new major medical technology shall document that:*
- (1) *trained and qualified clinical staff shall be employed, and*
- C- In Section II, pages 20-21, Section VII, pages 47-49, and in clarifying information requested by the Agency, the applicant provides the proposed staffing, training, competencies and qualifications. See Exhibits D, E, N and Z. See Criterion (7) for discussion regarding staffing.

- (2) *trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.*
- C- In Section VII.2, pages 41-48, the applicant discusses existing plus proposed FTE positions to support the hyperbaric oxygen chamber. See Criterion (7) for discussion regarding staffing.

- (b) *An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.*
- C- See Section II, page 20 for documentation regarding the physicians' training to use the hyperbaric oxygen chamber.

- (c) *An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:*
 - (1) *certification in cardiopulmonary resuscitation and basic cardiac life support; and*
 - C- See Exhibit N and clarifying information requested by the Agency for documentation of certification of cardiopulmonary resuscitation and basic life support certification.

- (2) *an organized program of staff education and training which is integral to the proper training of new personnel.*
- C- See Section II, pages 20- 21, Section VII, page 47 and Exhibit O.