

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 24, 2018

Findings Date: September 24, 2018

Project Analyst: Tanya S. Rupp

Chief: Martha J. Frisone

Project ID #: M-11497-18

Facility: Cape Fear Valley Medical Center

FID #: 943057

County: Cumberland

Applicant: Cumberland County Hospital System, Inc.

Project: Develop one new shared operating room (OR) pursuant to the adjusted need determination in the 2018 SMFP for a total of 21 ORs on the hospital license upon completion of this project and Project ID #M-8689-11 (relocate 2 ORs from Highsmith Rainey Specialty Hospital)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Agency 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.

C

The applicant, Cumberland County Hospital System, Inc., doing business as Cape Fear Valley Health System (CFVHS), is located in Fayetteville. CFVHS operates the following health care facilities:

1. Cape Fear Valley Medical Center (CFVMC), in Cumberland County.
2. Highsmith-Rainey Specialty Hospital (HSR), in Cumberland County
3. Hoke Healthcare, LLC, in Hoke County.
4. Bladen Healthcare, LLC, d/b/a Bladen County Hospital, in Bladen County.

In addition, CFVHS has managed Harnett Health System since 2014, which includes the Central Harnett Hospital and Betsy Johnson Medical Center campuses.

In July 2017, CFVHS petitioned the State Health Coordinating Council (SHCC) for an adjusted need determination in the 2018 SMFP for one OR in Cumberland County for the purpose of training surgical residents in inpatient and outpatient procedures. The applicant stated in the petition that the additional OR is needed because of CFVMC's collaboration with Campbell University's Jerry M. Wallace School of Osteopathic Medicine (Campbell). A copy of the Petition is included in Exhibit C.4. The petition was approved by the SHCC and the adjusted need determination was included in the 2018 SMFP as signed by the Governor. In response, the applicant proposes to develop one hybrid OR by renovating existing space in the existing surgical suite on the second floor of CFVMC. In Section C.1, pages 23-24, the applicant states that the proposed hybrid OR will be equipped with a large fixed imaging system that will provide surgeons with real-time image guidance for interventional imaging and complex surgical procedures while the patient is still in the OR. The applicant states that it will be effective for training surgical residents.

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) includes an adjusted need determination for one additional operating room (OR) in the Cumberland County Operating Room Service Area for the purpose of training surgical residents in inpatient and outpatient procedures. The applicant, Cumberland County Hospital System, Inc., proposes to develop one additional hybrid OR in existing space in the cardiac surgical suite (CSOR) at Cape Fear Valley Medical Center (CFVMC) for the purpose of training surgical residents in inpatient and outpatient procedures. See Section B, page 17 and Section C of the application. Upon completion of this project and Project I.D. #M-8689-11 (relocate 2 ORs from HSR), CFVMC will be licensed for a total of 21 ORs, including the one proposed hybrid OR, 15 other shared ORs, 2 dedicated open heart surgery ORs and 3 dedicated C-Section ORs. The application is consistent with the adjusted need determination for one OR in Cumberland County.

Policies

There are two policies in the 2018 SMFP that are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3, on page 33 of the 2018 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and

demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

In Section B.3, pages 15-21, the applicant explains why it believes its application is conforming to Policy GEN-3. The applicant discusses how the proposal would promote safety and quality on pages 15-16, equitable access on pages 16-19 and maximize healthcare value for resources expended on page 20. On pages 20-21, the applicant explains how projected utilization is based on historical increases in surgical cases and expected increases in the average case times as a result of the addition of a surgical residency program at CFVMC. The information on those pages is reasonable and adequately supported.

The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 because the applicant adequately documents in the application how the project will:

- Promote safety and quality in the delivery of surgical services in Cumberland County.
- Promote equitable access to surgical services in Cumberland County.
- Maximize healthcare value for the resources expended in Cumberland County.
- Incorporate the concepts of Policy GEN-3 in its projected volumes in meeting the need.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33 of the 2018 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.3, pages 21-22, the applicant states that the OR will be developed in a manner consistent with this policy. In Exhibit B-11, the applicant provides a letter dated April 15, 2018 from an architect, which describes the energy efficiency and water conservation methods that will be used in the development of the OR. Furthermore, in Section K.4(c), pages 73-74, the applicant lists energy saving features that will be incorporated into the construction plans. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion because

- The applicant proposes to develop one OR for the purpose of training surgical residents in inpatient and outpatient procedures which is consistent with the adjusted need determination in the 2018 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- The applicant adequately documents that the proposal is consistent with Policy GEN-4.

(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 proposes to develop one hybrid OR by renovating existing space in the existing surgical suite on the second floor of CFVMC. In Section C.1, pages 23-24, the applicant states that the proposed hybrid OR will be equipped with a large fixed imaging system that will provide surgeons with real-time image guidance for interventional imaging and complex surgical procedures while the patient is still in the OR. The applicant states that it will be effective for training surgical residents.

Patient Origin

On page 57, the 2018 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” Figure 6.1 on page 62 of the 2018 SMFP shows Cumberland County as a single-county OR service area. Thus, the service area is Cumberland County. Providers may serve residents of counties not included in their service area.

The following table illustrates current patient origin for surgical services at CFVMC, based on data provided in the 2018 Hospital License Renewal Application:

COUNTY	LAST FULL FISCAL YEAR (10/1/2016 – 9/30/2017)		LAST FULL FISCAL YEAR (10/1/2016 – 9/30/2017)	
	# PATIENTS (IP)	# PATIENTS (OP)	% OF TOTAL (IP)	% OF TOTAL (OP)
Cumberland	5,558	3,707	71.1%	71.5%
Hoke	333	226	4.3%	4.4%
Harnett	504	337	6.4%	6.5%
Robeson	554	380	7.1%	7.3%
Bladen	215	127	2.7%	2.4%
Sampson	329	226	4.2%	4.4%
Other	328	181	4.2%	3.5%
Total	7,821	5,184	100.0%	100.0%

The following table illustrates projected patient origin for inpatient surgical services at CFVMC, based on the facility’s historical payor mix, from page 25 of the application:

COUNTY	1 ST FULL FISCAL YEAR (10/1/19 – 9/30/20)		2 ND FULL FISCAL YEAR (10/1/20 – 9/30/21)		3 RD FULL FISCAL YEAR (10/1/21 – 9/30/22)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
Cumberland	4,821	71.1%	4,848	71.1%	4,877	71.1%
Hoke	292	4.3%	293	4.3%	295	4.3%
Harnett	434	6.4%	436	6.4%	439	6.4%
Robeson	481	7.1%	484	7.1%	487	7.1%
Bladen	183	2.7%	184	2.7%	185	2.7%
Sampson	285	4.2%	286	4.2%	288	4.2%
Other	285	4.2%	286	4.2%	288	4.2%
Total	6,780	100.0%	6,819	100.0%	6,859	100.0%

The following table illustrates projected patient origin for outpatient surgical services at CFVMC, based on the facility’s historical payor mix, from page 26 of the application:

COUNTY	1 ST FULL FISCAL YEAR (10/1/19 – 9/30/20)		2 ND FULL FISCAL YEAR (10/1/20 – 9/30/21)		3 RD FULL FISCAL YEAR (10/1/21 – 9/30/22)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
Cumberland	4,389	71.5%	4,474	71.5%	4,560	71.5%
Hoke	270	4.4%	275	4.4%	281	4.4%

Harnett	399	6.5%	407	6.5%	415	6.5%
Robeson	448	7.3%	457	7.3%	466	7.3%
Bladen	147	2.4%	150	2.4%	153	2.4%
Sampson	270	4.4%	275	4.4%	281	4.4%
Other	215	3.5%	219	3.5%	223	3.5%
Total	6,139	100.0%	6,257	100.0%	6,377	100.0%

In Section C, page 26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 27 - 36, the applicant explains the need CFVMC has for the proposed hybrid OR, including the following:

- Collaboration with Campbell. The applicant describes its residency program and how its collaboration with Campbell should result in more physicians and surgeons remaining in the area following their residency (pages 27-30).
- Need for additional physicians and surgeons. The applicant provides statistics that show a lack of physicians and surgeons in rural parts of North Carolina; including Cumberland and surrounding counties (pages 30-31).
- Continuing physician recruitment at CFVMC. The applicant describes recruitment efforts at CFVMC and how the collaboration with Campbell should help those efforts (pages 31-32).
- Increasing population in the market area. The applicant provides projected population data for the counties in the market area through Federal Fiscal Year (FFY) 2022, the third operating year of the project. The population of Hoke County is projected to increase by a compound annual growth rate (CAGR) of 2.9% and the population of Harnett County is projected to increase at a CAGR of 1.6%. The population of the other counties in the market area are not expected to increase significantly (page 32).
- Current surgical utilization at CFVMC and HSR. The applicant states that, despite capacity constraints at both facilities, outpatient and inpatient surgical cases have increased steadily since 2014. (pages 32-34).
- Increasing average surgical case times at CFVMC. The applicant states the average case times at CFVMC have been increasing since 2016 because the hospital is a teaching hospital and residents' average case times are slightly longer than the average case time when teaching is not a factor. This increase in the average case time results in the need for an additional OR at CFVMC (pages 34-36).

The information is reasonable and adequately supported for the following reasons:

- CFVMC recently added a general surgery residency program in collaboration with Campbell. In Section C, Question 4(a), page 27, the applicant states that it admitted 32 residents in five residency programs in 2017. The applicant expects that number to increase to 155 residents in six residency programs by 2022, the third operating year following completion of the project.
- The adjusted need determination for one OR in the Cumberland County Operating Room Service Area in the 2018 SMFP is expressly for the purpose of training surgical residents in inpatient and outpatient procedures and this is why the applicant states the proposed hybrid OR will be needed.
- Expected increases in the average case time as a result of the surgical residency program document a need for the proposed OR.

Projected Utilization

In Section C, Question 4(a), page 42, and Section Q, page 103, the applicant provides historical and projected surgical utilization at CFVMC and HSR as shown in the following tables.

Cape Fear Valley Medical Center	Last Full FY (2018)	1st Full FY (2020)	2nd Full FY (2021)	3rd Full FY (2022)
Number of ORs (1)	15	16	16	16
Standard Hours per OR per Year (2)	1,755	1,755	1,755	1,755
Inpatient Surgical Cases *	6,701	6,780	6,819	6,859
Final Inpatient Case Time in Minutes (3)	138.0	138.0	138.0	138.0
Inpatient Surgical Hours (4)	15,412.3	15,594.0	15,683.7	15,775.7
Ambulatory Surgical Cases *	5,911	6,139	6,257	6,377
Final Ambulatory Case Time in Minutes (3)	111.0	111.0	111.0	111.0
Ambulatory Surgical Hours (4)	10,935.4	11,357.2	11,575.5	11,797.5
Total Surgical Hours (5)	26,347.7	26,951.2	27,259.2	27,573.2
# of ORs Needed (6)	15	15.4	15.5	15.7

Highsmith-Rainey Specialty Hospital	Last Full FY (2018)	1 st Full FY (2020)	2 nd Full FY (2021)	3 rd Full FY (2022)
Number of ORs (1)	3	3	3	3
Standard Hours per OR per Year (2)	1,500	1,500	1,500	1,500
Inpatient Surgical Cases *	53	54	54	55
Final Inpatient Case Time in Minutes (3)	80.3	80.3	80.3	80.3
Inpatient Surgical Hours (4)	70.9	72.3	72.3	73.6
Ambulatory Surgical Cases *	3,033	3,150	3,210	3,272
Final Ambulatory Case Time in Minutes (3)	93.1	93.1	93.1	93.1
Ambulatory Surgical Hours (4)	4,706.2	4,887.8	4,980.9	5,077.1
Total Surgical Hours (5)	4,777.1	4,960.1	5,053.2	5,150.7
# of ORs Needed (6)	3.2	3.3	3.4	3.4

* FY 2018 surgical cases are annualized based on a 3-year average of the October-January quarter volume as a percent of total volume for the entire year.

- (1) Last Full FY is from Table 6A in the 2018 SMFP. The first three full FYs includes the OR proposed in this application. The two ORs approved to be relocated from Highsmith-Rainey Specialty Hospital to Cape Fear Valley North, a new satellite campus of Cape Fear Valley Medical Center, are reflected in the table for Highsmith-Rainey Specialty Hospital. Cape Fear Valley North is not expected to be complete until after the OR proposed in this application is complete. See Section C, Question 9, page 51.
- (2) From Table 6A in the 2018 SMFP.
- (3) From Table 6B in the 2018 SMFP.
- (4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
- (6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year. Since Cumberland County has more than 10 ORs, fractions of 0.5 or greater are rounded up to the next whole number pursuant to the OR Need Methodology.

Summary	Cape Fear Valley Medical Center	Highsmith-Rainey Specialty Hospital	Combined Health System
Number of Existing ORs	15	3	18
# of ORs Needed by FY 2022	16	3	19
Difference	1	0	1

In Section C and Section Q, the applicant provides the assumptions and methodology used to project utilization. Projected utilization in the tables above is based on Steps 1-3 in Methodology Number 1 and holding the average case time constant from Step 7 in Methodology Number 2.

Methodology Number 1

Step 1: Determine the baseline volume. The applicant utilized internal data that as provided in CFVMC's 2018 Hospital License Renewal Application. (see page 37 and Section Q, Form C.)

Step 2: Determine inpatient and outpatient surgical case growth rates. The applicant reviewed historical surgical volume at both CFVMC and HSR from 2015 to 2018 and

determined that inpatient surgical cases increased by a CAGR of 0.6%¹ and outpatient surgical cases increased by a CAGR of 1.9%. These CAGRS were used to project utilization. (See pages 37-38.)

Step 3: Project surgical cases at CFVMC. The baseline from Step 1 and the CAGRs from Step 2 were used to project surgical cases through the third full fiscal year of operation. The applicant used the following methodology:

- Projected inpatient cases x FFY 2016 average inpatient case time + projected outpatient cases x FFY 2016 average outpatient case time = projected surgical hours.
- Projected surgical hours / Group standard hours per OR = total number of ORs needed.
- Total ORs needed – existing ORs = additional ORs needed at CFVMC.

In Steps 4 and 5, the applicant assumes that the average case times would increase because of the residency program. In Step 6, the applicant states that it needs two ORs if average case times do increase.

Methodology Number 2

In Methodology Number 2, the applicant uses Steps 1-3 from Methodology Number 1 but in Step 7, the applicant holds the average case times constant.

Projected utilization is reasonable and adequately supported for the following reasons:

- There is an adjusted need determination in the 2018 SMFP for one OR in Cumberland County for the purpose of training surgical residents in inpatient and outpatient procedures.
- The collaboration with Campbell and the presence of surgical residents will have an impact on the average case times. Specifically, it is reasonable to assume that the average case times will increase. The applicant provides sufficient documentation to support this assumption.
- Projected surgical cases are based on reasonable and adequately supported assumptions about continued growth.
- Even without increased average case times, the applicant demonstrates a need for one additional OR.

¹ On page 38, the applicant states in the narrative that the CAGR for inpatient cases was 0.9%. However, in the table in Step 3, page 38, and the tables in Exhibit C.4, pages 201, 203-204, the applicant used a CAGR of only 0.6% to project inpatient cases.

Access

In Section C, page 46, the applicant states it will provide services to all patients, regardless of race, sex, income status, ability to pay, disability, age or “*other underserved characteristic.*” In Section L, page 78, the applicant projects the following payor mix during the first three full fiscal years of operation following completion of the project, as illustrated in the following table:

PAYOR SOURCE	ENTIRE FACILITY OR CAMPUS	OPERATING ROOMS
Self-Pay	3.1%	2.2%
Charity Care	3.1%	2.2%
Medicare *	47.2%	41.8%
Medicaid *	20.7%	18.1%
Insurance *	18.1%	28.7%
Workers Compensation	0.6%	0.3%
TRICARE	7.0%	6.5%
Other**	0.2%	0.2%
Total	100.0%	100.0%

Numbers may not sum due to rounding.

*Including any managed care plans.

**On page 78, the applicant states “*other*” is “*undetermined*”.

The projected payor mix is the same as the historical payor mix and is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose to reduce, eliminate or relocate a facility or service; therefore, Criterion (3a) is not applicable to this review.

- (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.

C

The applicant proposes to develop one hybrid OR in Cumberland County pursuant to the adjusted need determination in the 2018 SMFP for the purpose of training surgical residents in inpatient and outpatient procedures.

In Section E, page 57, the applicant states it considered only one other alternative to this proposal, which was to add the additional OR at HSR. The applicant explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need.

On page 57, the applicant states that its proposal is the most effective alternative because of the partnership between CFVMC and Campbell to establish a new general surgery residency program and new OB/GYN residency program at CFVMC, thus establishing the need for additional OR capacity to train surgical residents. The applicant also states HSR provides primarily outpatient surgical services; inpatient surgical services are limited to those patients who are admitted to HSR for other long term care needs and whose need for surgical services are incidental to the reasons for the admission. The applicant provides supporting documentation in Exhibit E.2.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Cumberland County Hospital System, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Cumberland County Hospital System, Inc. shall develop no more than one operating room at Cape Fear Valley Medical Center for the purpose of training surgical residents in inpatient and outpatient procedures pursuant to the adjusted need determination in the 2018 State Medical Facilities Plan.**
- 3. Upon completion of this project and Project I.D. #M-8689-11 (relocate 2 operating rooms from Highsmith Rainey Specialty Hospital to Cape Fear Valley North), the hospital shall be licensed for a total of no more than 21 operating rooms.**
- 4. Cumberland County Hospital System, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Cumberland County Hospital System, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

- 6. Cumberland County Hospital System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing 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.

C

The applicant proposes to develop one hybrid OR in Cumberland County pursuant to the adjusted need determination in the 2018 SMFP for the purpose of training surgical residents in inpatient and outpatient procedures.

Capital and Working Capital Costs

In Exhibit F.1a, page 114, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	N/A
Construction Costs	\$1,541,500
Equipment/Furniture Costs	\$2,839,539
Miscellaneous Costs	\$309,772
Total	\$4,690,811

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 60, the applicant states there will be no start-up costs or initial operating expenses associated with the project.

Availability of Funds

In Section F, page 59, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	CAPE FEAR VALLEY MEDICAL CENTER
Loans	\$ 0
Accumulated reserves or OE *	\$4,690,811
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$4,690,811

* OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer for the applicant stating that the funds are available and committed to the project. Exhibit F.2 also contains audited financial statements for the applicant that document that the funds are available.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

Revenues and Expenses

	1 ST FULL FISCAL YEAR (FY 2020)	2 ND FULL FISCAL YEAR (FY 2021)	3 RD FULL FISCAL YEAR (FY 2022)
Total Surgical Cases	12,919	13,076	13,236
Total Gross Revenues (Charges)	\$218,634,883	\$225,717,713	\$233,049,223
Total Net Revenue	\$57,115,865	\$58,966,173	\$60,551,446
Average Net Revenue per Surgical Case	\$4,329	\$4,450	\$4,569
Total Operating Expenses (Costs)	\$55,920,099	\$58,194,110	\$60,481,067
Average Operating Expense per Surgical Case	\$4,329	\$4,450	\$4,569
Net Income	\$1,195,766	\$772,063	\$70,376

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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 proposes to develop one hybrid OR in Cumberland County pursuant to the adjusted need determination in the 2018 SMFP for the purpose of training surgical residents in inpatient and outpatient procedures.

On page 57, the 2018 SMFP states, *“An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.”* Figure 6.1 on page 62 of the 2018 SMFP shows Cumberland County as a single-county OR service area. Thus, the service area is Cumberland County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved operating rooms located in Cumberland County, as shown in Table 6A, page 64, 2018 SMFP.

**Cumberland County
Existing and Approved ORs**

FACILITY	INPATIENT ORs	C-SECTION ORs	SHARED ORs	AMBULATORY ORs	TOTAL
Cape Fear Valley Medical Center*	2	3	13	0	18
Highsmith Rainey Specialty Hospital*	0	0	3	0	3
CFVHS Total	2	3	16	0	21
Fayetteville Ambulatory Surgery Center	0	0	0	11	11
Valleygate Dental Surgery Center of Fayetteville	0	0	0	2	2
Total ORs	2	3	16	13	34

* The 2 ORs authorized to be relocated from HSR to CFVMC are shown at HSR in this table.

** These ORs were approved as part of a dental demonstration project in the 2016 SMFP.

As the table above indicates, there are a total of 34 existing or approved ORs in Cumberland County. The applicant proposes to develop one additional hybrid OR in existing space in the cardiac surgical suite at CFVMC for the purpose of training surgical residents in inpatient and outpatient procedures. See Section B, page 17 and Section C of the application. Upon

completion of this project and Project I.D. #M-8689-11 (relocate 2 ORs from HSR), CFVMC will be licensed for a total of 21 ORs.

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in Cumberland County. The applicant states:

“The proposed project is being developed to meet surgical needs specific to Cape Fear Valley Medical Center’s new surgical residency program and growing surgical volume. ... [T]he need for one new operating room in Cumberland County was included in the 2018 SMFP in response to a Petition submitted by CFVHS to meet the needs of the new surgical residency program.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved ORs in Cumberland County for the following reasons:

- There is an adjusted need determination in the 2018 SMFP for the proposed operating room.
- The applicant adequately demonstrates that the proposed OR is needed in addition to the existing or approved ORs in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

C

In Section Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	Current 2018	Projected		
		1 st Full FY (2020)	2 nd Full FY (2021)	3 rd Full FY (2022)
Registered Nurse	60.9	62.9	62.9	62.9
Nursing Assistant	17.0	17.0	17.0	17.0
Technician	58.7	60.7	60.7	60.7
Clerical	4.7	4.7	4.7	4.7
CRNA	36.7	37.7	37.7	37.7
Perfusionist	4.2	5.2	5.2	5.2
TOTAL	182.2	188.2	188.2	188.2

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.2, page 118, which is found in Section Q. In Section H, pages 65-66, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 67, the applicant identifies the current Chief of Surgery at CFVMC. In Exhibit H.4.b, the applicant provides a letter from the Chief of Surgery indicating his commitment to remain in that capacity following the addition of the OR. In Section H, page 67, the applicant describes its physician recruitment plans. In Exhibit H.4.a, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

C

In Section I, page 68, the applicant lists 17 ancillary and support services that it states are necessary for the proposed services. On page 68, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

C

In Section K, page 72, the applicant states that the project involves renovating 3,320 square feet of existing space within the surgical suite at the hospital. Line drawings are provided in Exhibit K.1.

On page 73, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit F.1.

On page 73, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibits B.11 and F.1.

On pages 73 - 74, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibits B.11 and F.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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:
- (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;

C

In Section L, page 77, the applicant provides the historical payor mix during its last full fiscal year prior to submission of the application (FY 2017) for the proposed services, as shown in the table below:

PAYOR CATEGORY	% SERVICES AS PERCENT OF TOTAL	
	ENTIRE CAMPUS	OPERATING ROOMS
Self-Pay	3.1%	2.2%
Charity Care	3.1%	2.2%
Medicare	47.2%	41.8%
Medicaid	20.7%	18.1%
Insurance	18.1%	28.7%
Workers Compensation	0.6%	0.3%
TRICARE	7.0%	6.5%
Other	0.2%	0.2%
Total	100.0%	100.0%

In Section L, page 76, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED DURING THE LAST FULL FY	PERCENTAGE OF TOTAL SURGICAL PATIENTS SERVED DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF CUMBERLAND COUNTY
Female	61%	65%	51%
Male	39%	35%	49%
Unknown	0%	0%	0%
64 and Younger	76%	70%	88%
65 and Older	24%	30%	12%
American Indian	2%	2%	2%
Asian	1%	1%	3%
Black or African-American	46%	40%	38%
Native Hawaiian or Pacific Islander	0%	0%	0%
White or Caucasian	42%	48%	52%
Other Race	8%	8%	5%
Declined / Unavailable	1%	1%	0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 77, the applicant states it is under no obligation to provide uncompensated care, community service, or access by minorities or handicapped persons. In Exhibit C.10, the applicant provides copies of its corporate policies with regard to patient care and access by underserved groups.

In Section L, page 77, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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

C

In Section L, page 78, the applicant projects the following payor mix for the proposed services during the second and third full fiscal years of operation following completion of the project, as shown in the table below:

PAYOR CATEGORY	% SERVICES AS PERCENT OF TOTAL	
	ENTIRE CAMPUS	OPERATING ROOMS
Self-Pay	3.1%	2.2%
Charity Care	3.1%	2.2%
Medicare	47.2%	41.8%
Medicaid	20.7%	18.1%
Insurance	18.1%	28.7%
Workers Compensation	0.6%	0.3%
TRICARE	7.0%	6.5%
Other	0.2%	0.2%
Total	100.0%	100.0%

As shown in the table above, during the second and third full fiscal years of operation, the applicant projects that 3.1% of total services will be provided to self-pay patients, 3.1% to charity care patients, 47.2% to Medicare patients and 20.7% to Medicaid patients.

On page 78, the applicant provides the assumptions and methodology used to project payor mix during the second and third full fiscal years of operation following

completion of the project. The projected payor mix is the same as the historical payor mix and is reasonable and adequately supported.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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 L, page 79, the applicant adequately describes the range of means by which patients will have access to the proposed services. The applicant provides supporting documentation in Exhibit H.4.a.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming 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.

C

In Section M, pages 80 - 82, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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

The applicant proposes to develop one hybrid OR in Cumberland County pursuant to the adjusted need determination in the 2018 SMFP for the purpose of training surgical residents in inpatient and outpatient procedures.

On page 57, the 2018 SMFP defines the service area for operating rooms as: *“An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.”* Figure 6.1 on page 62 of the 2018 SMFP shows Cumberland County as a single-county OR service area. Thus, the service area is Cumberland County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved operating rooms located in Cumberland County, as shown in Table 6A, page 64, 2018 SMFP.

**Cumberland County
Existing and Approved ORs**

	INPATIENT ORs	C-SECTION ORs	SHARED ORs	AMBULATORY ORs	TOTAL
Cape Fear Valley Medical Center*	2	3	13	0	18
Highsmith Rainey Specialty Hospital*	0	0	3	0	3
CFVHS Total	2	3	16	0	21
Fayetteville Ambulatory Surgery Center	0	0	0	11	11
Valleygate Dental Surgery Center of Fayetteville	0	0	0	2	2
Total ORs	2	3	16	13	34

* The 2 ORs authorized to be relocated from HSR to CFVMC are shown at HSR in this table.

** These ORs were approved as part of a dental demonstration project in the 2016 SMFP.

As the table above indicates, there are a total of 34 existing or approved ORs in Cumberland County. The applicant proposes to develop one additional hybrid OR in existing space in the cardiac surgical suite at CFVMC for the purpose of training surgical residents in inpatient and outpatient procedures. See Section B, page 17 and Section C of the application. Upon completion of this project and Project I.D. #M-8689-11 (relocate 2 ORs from HSR), CFVMC will be licensed for a total of 21 ORs.

In Section N, page 87, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area would promote the cost-effectiveness, quality and access to the proposed services. On page 87, the applicant states:

“Operating rooms at CFVHS in Cumberland County have been operating at over 75% of capacity for the last several years, limiting the flexibility available for growth in surgical cases and robust competition with other surgical providers in the service area and beyond. Many Cumberland County patients have left the market for elective procedures as a result. Expansion of surgical capacity at CFVHS will allow CFVHS additional opportunity to compete with other surgical providers in the market.

The proposed project will foster competition by continuing to promote cost effectiveness, quality, and access to services in the proposed service area”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

C

In Section O.3, page 90, the applicant identifies six hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. In Section O.3.c, page 91, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at these facilities, the Agency determined that the applicant provided sufficient evidence that quality care has been provided in the past. 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.

C

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to this review. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2103 PERFORMANCE STANDARDS

.2103 (a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

-C- This proposal would increase the number of ORs at CFVMC. The applicant projects sufficient surgical cases and hours to demonstrate the need for one additional OR at CFVMC in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2103 (b) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the third operating year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

-C- This proposal would increase the number of ORs in Cumberland County. The applicant projects sufficient surgical cases and hours to demonstrate the need for one additional OR in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2103 (c) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least

365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved, and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- The applicant does not propose to develop an additional dedicated C-section operating room as part of this proposal.

.2103 (d) *An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program shall:*

(1) *provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,312.5 hours per operating room per year; and*

(2) *demonstrate the need in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

-NA- The applicant does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or add a specialty area to a specialty ambulatory surgical program.

.2103(e) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- The applicant provides the assumptions and data supporting the methodology used for the OR projections in Section C, pages 26-46; Section Q, pages 95-107, and Exhibits C.1, C.4 and C.9.