

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 27, 2013

PROJECT ANALYST: Fatimah Wilson

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10157-13 / Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville / Acquire interventional radiology equipment to install in existing space / Mecklenburg 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

Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville [**CMC Pineville**] proposes to acquire fixed interventional radiology equipment and install it in existing space located at the medical center to develop a dedicated interventional radiology room. The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2013 State Medical Facilities Plan. There are no policies in the 2013 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.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, Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville, whose parent company is The Charlotte Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas HealthCare System (CHS), currently provides interventional radiology services, but the medical center does not have a dedicated interventional radiology room. The current arrangement allows only limited time for interventional radiology procedures and often results in interventional radiology cases getting bumped for emergency cardiac and vascular cases. Interventional radiology procedures are currently allotted two half days per week of blocked time (8-hours) in one of the medical center's three licensed cardiac catheterization laboratories and a subset of procedures are performed in a procedure room with a mobile C-arm. The applicant states that in order to meet the demands of population growth in its service area, the medical center recently completed a \$300 million dollar expansion that transformed it into a full-service, tertiary medical center in 2012 (CMC-Pineville Phase II Project I.D. #F-7979-07). Major projects completed at CMC-Pineville include: a 100,000 square foot medical office building, a 335,000 square foot expansion and renovation that provides open-heart surgery and interventional cardiology, a 30-bed intensive care unit (ICU), a Levine Cancer Institute facility, radiation oncology therapy, and inpatient kidney dialysis. According to the most recent progress report filed in April 2013, that project is complete and being utilized as proposed. In this application, the applicant proposes to renovate 900 square feet of vacated space pursuant to Project I.D. #F-7979-07. The vacated space for the proposed project was previously utilized as a cardiac catheterization laboratory and will require only minor renovations necessary to support the proposed equipment.

In Section II.1, page 20, the applicant describes the project as follows:

“The proposed project will allow CMC-Pineville to continue providing state-of-the-art radiology services to its patients on site at the medical center, while obviating the need to block time in one of the medical center’s cardiac catheterization laboratories. As such, the development of a dedicated interventional radiology room will improve patient access and decrease scheduling difficulties.”

Population to be Served

In Section III.5(a), page 58, the applicant states:

“CMC-Pineville’s service area includes five submarkets (South Mecklenburg County, York County (SC), Lancaster County (SC), East Gaston County, and Union County) as shown in the table below. ...”

<i>South Mecklenburg County</i>	<i>York County</i>	<i>Lancaster County</i>	<i>East Gaston County</i>	<i>Union County</i>
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28105	29710	29720	28032	28103
28134	29715		28120	28174
28210	29708		28012	28110
28226	29704			28112
28270	29730			28104
28277	29732			28079
28278	29717			28173
28273	29726			
	29742			
	29743			
	29745			

The following table illustrates the projected patient origin for CMC-Pineville’s dedicated interventional radiology room by patients by county of origin as shown in Section II.8, page 35 and Section III.5, page 60:

County	Year 1: Projected # Patients	Year 1: % of Total Patients	Year 2: Projected # Patients	Year 2: % of Total Patients
Mecklenburg	474	49.8%	480	49.8%
York, SC	260	27.3%	264	27.3%
Lancaster, SC	95	10.0%	96	10.0%
Union	50	5.3%	51	5.3%
Gaston	16	1.7%	16	1.7%
Other*	56	5.9%	57	5.9%
TOTAL	952	100.0%	965	100.0%

*Other includes counties in North Carolina as well as other states: Alexander, Anson, Blair, Burke, Cabarrus, Catawba, Chatham, Cheshire, Chester, Chesterfield, Douglas, Hartford, Maricopa, New Hanover, Passaic, Pinellas, Richmond, Rutherford, Spartanburg, Suffolk, Sullivan, and Wilkes.

Note: Totals may not foot due to computer rounding.

On page 60, the applicant states that the projected patient origin is based on the current patient origin of those obtaining services in its interventional radiology department. The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

In Section II.1, pages 17-20, the applicant states:

“Existing Interventional Radiology Services

Interventional radiology procedures are currently assigned two half days per week of block time in one of the medical center’s three licensed cardiac catheterization laboratories and a subset of procedures are performed in a procedure room with a mobile C-arm. The current arrangement allows only limited time for interventional radiology procedures and

often results in interventional radiology cases getting bumped for emergency cardiac and vascular cases.

...

Proposed Equipment

The proposed equipment will provide greater accuracy in image-guided procedures at a low radiation dose.

...

The proposed system for interventional radiology features a large flat detector and affords easy patient access and full body coverage. In addition, ergonomically designed controls streamline workflow and help staff function more efficiently. ...

Flexibility

The proposed equipment integrates industrial robot technology which makes it easier for the physician to shift the C-arm to virtually any position around the patient. The combination of a C-arm with an industrial robot provides the physician with almost unlimited freedom of movement. Such flexibility enables the physician to visualize internal organs, vessels, and diseases from all sides with unprecedented precision. Moreover, the rotating flat detector and collimator allow an optimum level of patient access and provide superb anatomical coverage.

Imaging Excellence

The proposed equipment features key advances that significantly improve the clarity of live fluoroscopy, roadmap, and acquisition images. Such advances also greatly enhance the visualization of peripheral (non-coronary) stents, their meshes, coils, and guide wires. The system features intelligent noise reduction which enhances the fluoroscopy image during a live procedure without a corresponding increase in dose. The system also uses an intelligent motion detection algorithm to separate moving from non-moving structures in real time. Furthermore, the system uses a flat-panel detector which not only enhances image quality, but also significantly reduces the radiation dose to the patient, staff, and physician.¹ Moreover, the flat-panel detector can be used in both landscape and portrait imaging and can be rotated during the procedure, enabling different examinations to be carried out quickly and easily. The system's advanced imaging capabilities enhance the decision making of clinicians and facilitate faster and more effective procedures. ”

In Section III.1(a), page 40, the applicant states:

¹ Due to improved detective quantum efficiency (DQE).

“... The unmet need that necessitates the development of the proposed project is based on the need for a dedicated interventional radiology room; not only as a result of the increased demand for such services, but also to improve continuity of services and ultimately free up time currently assigned in one of the medical center’s three licensed cardiac catheterization laboratories for interventional radiology procedures.”

Need for a Dedicated Interventional Radiology Room

The applicant states on page 40 that the demand for interventional radiology services has increased dramatically at the medical center as a result of the enhanced tertiary-level service component associated with the development of previously approved CMC-Pineville Phase II (Project I.D. #F-7979-07). As a result, interventional radiology has been organized as a distinct and separate financial department which has enabled the medical center to document strong growth for the service. Currently, interventional radiology procedures are assigned two half days per week (8-hours/week) of block time in one of the medical center’s three licensed cardiac catheterization laboratories and a subset of procedures are performed in a procedure room with a mobile C-arm. The applicant states that the current arrangement allows only limited time for interventional radiology procedures and the current arrangement is no longer feasible. The proposed project will result in the development of CMC-Pineville’s first dedicated interventional radiology room and will increase from eight to 47.5 operating hours per week. The applicant states that a dedicated interventional radiology room will improve access, facilitate continuity of care (by preventing patients from going outside the service area for these services), as well as decrease scheduling difficulties and patient stays. On page 43, the applicant states that the proposed project will address CMC-Pineville’s need to improve service availability as well as increase service offerings to support the higher acuity needs and tertiary-level status of the medical center.

Use of Existing Equipment at CMC-Pineville

The applicant states that while CMC-Pineville has performed interventional radiology procedures since the medical center’s inception, no dedicated equipment room has been developed. The applicant states that the medical center’s three licensed cardiac catheterization laboratories are used to perform a variety of procedures including: cardiac catheterization, electrophysiology, vascular, and interventional radiology procedures. As previously stated by the applicant, the current arrangement is no longer feasible as demand for all of these procedures continues to increase. The applicant states that not only are time constraints an issue in scheduling interventional radiology procedures, but also, interventional radiology cases frequently get bumped for ST-Elevation Myocardial Infarction (STEMI) needs. STEMI refers to an emergent, life-threatening type of heart attack during which one of the heart’s major arteries is blocked. In Section III, page 44, the applicant states that since October, a total of 25 interventional radiology procedures have been delayed to accommodate STEMI cases. CMC-Pineville performed the following number of procedures and diagnostic-equivalent procedures from October 1, 2011 to September 30, 2012:

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<i>Procedure</i>	<i>Volume</i>	<i>Diagnostic-Equivalent Factor</i>	<i>Diagnostic-Equivalent Procedures</i>
<i>Adult Diagnostic Catheterization</i>	865	1.00	865
<i>Adult Interventional Catheterization</i>	325	1.75	569
<i>Adult EP Procedures</i>	473	3.00	1,419
Total (Cath)	1,663		2,853
<i>Interventional Radiology Procedures*</i>	554	1.00/1.75	554/970
Total (including Interventional Radiology Procedures)	2,217		3,407/3/823

Source: 2013 Hospital License Renewal Application (HLRA)

*CMC-Pineville internal data for CY 2012

In Section III.1, pages 44-45, the applicant states:

*“Based on defined capacity of 1,500 diagnostic cardiac catheterization equivalent procedures per catheterization laboratory, CMC-Pineville is currently operating at 76 percent utilization of its three cardiac catheterization laboratories (when interventional radiology procedures are included for a total of 3,407 diagnostic equivalent procedures as shown in the table above and assumed to be equivalent to an adult diagnostic catheterization) $(3,407 / (1,500 * 3) = 75.7$ percent). Moreover, since interventional radiology procedures are more similar to an adult interventional catheterization, CMC-Pineville’s current utilization approximates 85 percent utilization if an interventional radiology procedure is counted at 1.75 diagnostic equivalents $(3,823 / (1,500 * 3) = 84.9$ percent).*

*Given the projected growth in interventional radiology procedures detailed in Section III.1(b), which represents 978 procedures in project year three, the medical center’s cardiac catheterization laboratories will be operating at 85 percent utilization in project year three (assuming 1.0 diagnostic equivalent) with no growth in cardiac catheterization or electrophysiology procedures $(2,853 + 978) / (1,500 * 3) = 85.1$ percent), or 101 percent (assuming an interventional radiology procedure is counted at 1.75 diagnostic equivalents $(2,853 + [978 * 1.75]) / (1,500 * 3) = 101.1$ percent). As discussed in Section III.3, increasing the amount of blocked time for interventional radiology procedures in one of the medical center’s three licensed cardiac catheterization laboratories simply is not feasible given the competing demand for growing cardiac and vascular programs.”*

The applicant states that CMC-Pineville’s existing use of one of its three licensed cardiac catheterization laboratories for interventional radiology procedures has resulted in hardships for patients, physicians and staff and that the development of a dedicated interventional radiology room will improve patient access to appropriate services and continuity of care, while providing much needed capacity with state-of-the-art equipment.

Projected Utilization

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In Section IV.1 page 64, the applicant provides historical and projected interventional radiology procedure utilization, as illustrated in the table below.

Table IV	Last Full CY 1/1/12 – 12/31/12	Interim Full CY 1/1/13 – 12/31/13	Interim Full CY 1/1/14 – 12/31/14	PY 1 1/1/15 – 12/31/15	PY 2 1 1/1/15 – 12/31/15	PY 3 1/1/15 – 12/31/15
# of Procedures	554	926	939	952	965	978

The applicant’s assumptions and methodology used to project utilization are provided in Section III.1 (b), pages 45-50, and are described as follows:

“...Beginning in 2012, interventional radiology was organized as a distinct and separate financial department which has enabled CMC-Pineville to document the strong growth for the service.”²

Historical Interventional Radiology Procedures

<i>Month</i>	<i>CY 2012</i>	<i>YTD CY 2013</i>
<i>January</i>	36	84
<i>February</i>	23	63
<i>March</i>	32	65
<i>April</i>	52	79
<i>May</i>	47	95
<i>June</i>	42	NA
<i>July</i>	35	NA
<i>August</i>	43	NA
<i>September</i>	53	NA
<i>October</i>	59	NA
<i>November</i>	64	NA
<i>December</i>	68	NA
<i>Total</i>	<i>554</i>	<i>386</i>

Source: CMC-Pineville internal data.

Note: YTD 2013 includes January to May data

...

*Moreover, year-to-date 2013 volume indicates that CMC-Pineville will perform 926 interventional radiology procedures [(386 * 2) + (386 / 5 * 2) = 926.4] over the course of the year, or 67 percent growth over 2012 volume.*

...

CMC-Pineville’s service area includes five submarkets (South Mecklenburg County, York County (SC), Lancaster County (SC), East Gaston County, and Union

² Prior to 2012, CMC-Pineville’s interventional radiology data was not captured in a departmental performance report. However, CMC-Pineville estimates that it performed 31 procedures in 2010 and 153 procedures in 2011.

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County). ...The following table demonstrates the expected population of CMC-Pineville's service area.

CMC-Pineville Service Area 2013 to 2018 Population Projections

	2013	2018	Population CAGR*
<i>Total Service Area</i>	825,192	882,780	1.4%

Source: Claritas

*Compound annual growth rate (CAGR)

Based on the 2013 to 2018 population projections, the total service area is projected to have a population of 825,192 persons in 2013 and 882,780 persons in 2018, as shown in the table above. CMC-Pineville conservatively projects future growth in interventional radiology procedures of 1.4 percent annually, which is equivalent to the expected population growth of its total service area.

CMC-Pineville believes this assumption to be conservative given that the historical growth rate of the service from May 1, 2012 to May 1, 2013 is 103 percent. The service has experienced substantial growth and this growth is expected to continue through the project years. Moreover, Charlotte Radiology is actively recruiting a dedicated interventional radiology specialist to join the existing rotation of physicians who perform services at CMC-Pineville. The addition of this new physician in the first quarter of 2014 will allow Charlotte Radiology to staff full time the dedicated interventional radiology room with one of eight rotating physicians.

CMC-Pineville has used YTD 2013 procedures annualized as the base year for its projections.³ The table on the following page demonstrates the projected utilization of the proposed dedicated interventional radiology room.

Projected Interventional Radiology Procedures

CY	Procedures
2013	926
2014	939
2015	952
2016	965
2017	978
CAGR	1.4%

Note: CY 2013 is annualized based on January to May data.

³ While YTD 2013 procedures include only five months of data, CMC-Pineville believes that the annualized YTD 2013 procedures equaling 926 is consistent with recent trends in utilization. Although CMC-Pineville data is demonstrated on a calendar year basis, when December of 2012 is included with YTD 2013 procedures, CMC-Pineville performed 454 procedures over the last six months. Thus, based on the previous six months annualized, CMC-Pineville performed 908 (454 * 2) procedures. Based on the increasing complexity and number of cases, CMC-Pineville believes annualized YTD 2013 data is reasonable.

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The proposed dedicated interventional radiology room will schedule procedures from 7:30 a.m. to 5:00 p.m. Monday through Friday. Assuming 50 weeks per year, the interventional radiology room will be operational 2,375 hours per year (2,375 hours per year = 47.5 hours per week x 50 weeks per year). Based on CMC-Pineville's current experience, interventional radiology procedures take on average 1.5 hours. However, the dedicated room will provide the capability to perform more complex interventional radiology procedures. As a result of the expected complex case mix, CMC-Pineville assumes that average time per procedure will increase to two hours. Thus, the proposed room has a capacity of approximately 1,188 procedures per year $[(47.5 \times 50 = 2,375) 2,375 / 2 = 1,187.5]$. CMC-Pineville expects the project to be complete and operational on October 1, 2014. Thus, CY 2015 is the first full fiscal year, CY 2016 is the second full fiscal year, and CY 2017 is the third full fiscal year. As shown below, the proposed room will be utilized at 82 percent of capacity by the third project year.

	Procedures	Capacity	Percent Utilization
<i>First Full Fiscal Year – CY 2015</i>	952	1,188	80%
<i>Second Full Fiscal Year – CY 2016</i>	965	1,188	81%
<i>Third Full Fiscal Year – CY 2017</i>	978	1,188	82%

The applicant states that the projected level of utilization justifies the proposed project for several reasons:

- The projected population growth rate of the service area;
- The creation of a dedicated room with 47.5 scheduled hours of operation per week rather than the eight hours available;
- A full-time interventional radiology physician that will be present at all scheduled hours due to Charlotte Radiology's planned recruitment; and
- The ability of CMC-Pineville to perform additional procedure types in support of the higher acuity needs and tertiary-level status of the medical center.

Access

The applicant projects 65.9% of its patients will be covered by Medicare (58.1%) and Medicaid (7.8%). The applicant demonstrates access for medically underserved groups to the proposed services.

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and

demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, 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.

CA

In Section III.3, pages 53-55, the applicant describes the alternatives considered, including maintaining the status quo and expanding blocked time in the cardiac catheterization laboratory.

- The applicant states it rejected the status quo alternative because it would not allow CMC-Pineville to improve access to interventional radiology procedures in the service area.
- The applicant considered the alternative of expanding blocked time in the cardiac catheterization laboratory; however, this alternative was not deemed a feasible option given the competing demand from growing cardiac and vascular programs and the potential result in an overnight stay for patients, as well as impact their recovery.

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is its 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. Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville shall materially comply with all representations made in its certificate of need application.**

2. **Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville shall acquire no more than one interventional radiology system to be installed in an existing procedure room.**
 3. **Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville shall not use the interventional radiology procedure room or equipment purchased in this project to provide cardiac catheterization services as defined in N.C.G.S. 131-E176 (2g).**
 4. **Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville 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 the application and which would otherwise require a certificate of need.**
 5. **Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**
- (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

In Section VIII.2, page 95, the applicant projects the total capital cost for the project to be \$1,496,232, including \$1,023,412 for fixed equipment, \$110,820 for movable equipment, \$2,000 for furniture and \$45,000 for architect and engineering fees. In Section VIII.3, page 95, the applicant states that the capital cost will be financed with accumulated reserves of The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas Healthcare System (CHS), which is CMC-Pineville's parent company. In Section IX.1, page 100, the applicant states that there are no start-up expenses or initial operating expenses associated with the proposed project. Exhibit 28 contains a July 15, 2013 letter signed by the Executive Vice-President and Chief Financial Officer for CHS, which states:

"...As the Chief Financial Officer for Carolinas HealthCare System, I am responsible for the financial operations of Mercy Hospital, Inc. As such, I am very familiar with the organization's financial position. The total capital expenditure amount for this project is estimated to be \$1,496,232. There are no start-up costs related to this project.

Carolinas HealthCare System will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the line items

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*‘Cash and cash equivalents’ and ‘Other assets: designated as funded depreciation,’
 in the audited financial statements included with this Certificate of Need application.’*

Exhibit 29 of the application contains the audited financial statements for CHS for the years ending December 31, 2012 and December 31, 2011. As of December 31, 2012, CHS had \$85,603,000 in cash and cash equivalents and \$3,313,001,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposed project.

In pro forma financial statements for CMC-Pineville’s interventional radiology services (Form C), the applicant projects revenues will exceed expenses in the second and third operating years, as shown below:

CMC-Pineville Interventional Radiology Services			
	CY 2015 Year 1	CY 2016 Year 2	CY 2017 Year 3
Total Net Patient Revenue	\$1,381,332	\$1,467,812	\$1,559,468
Total Expenses	\$1,110,286	\$1,194,284	\$1,232,882
Net Income (Loss)	\$271,046	\$273,528	\$326,585

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with 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, Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville currently provides interventional radiology services, but the medical center does not have a dedicated interventional radiology room. The applicant does not propose any new health services, beds, or operating rooms. The current arrangement allows only limited time for interventional radiology procedures and often results in interventional radiology cases getting bumped for emergency cardiac and vascular cases. Interventional radiology procedures are currently allotted two half days per week (8-hours) of blocked time in one of the medical center’s three licensed cardiac catheterization laboratories and a subset of procedures are performed in a procedure room with a mobile C-arm. The applicant states that in order to meet the demands of population growth in its service area, the medical center recently completed a \$300 million dollar expansion that transformed it into a full-service, tertiary medical center in 2012 (CMC-Pineville Phase II Project I.D. #F-7979-07). Major projects completed at CMC-Pineville

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include: a 100,000 square foot medical office building, a 335,000 square foot expansion and renovation that provides open-heart surgery and interventional cardiology, a 30-bed intensive care unit (ICU), a Levine Cancer Institute facility, radiation oncology therapy, and inpatient kidney dialysis. According to the most recent progress report filed in April 2013, that project is complete and being utilized as proposed. In this application, the applicant proposes to renovate 900 square feet of vacated space pursuant to Project I.D. #F-7979-07. The vacated space for the proposed project was previously utilized as a cardiac catheterization laboratory and will require only minor renovations necessary to support the proposed equipment.

In Section IV.1 page 64, the applicant provides historical and projected interventional radiology procedure utilization, as illustrated in the table below.

Table IV	Last Full CY 1/1/12 – 12/31/12	Interim Full CY 1/1/13 – 12/31/13	Interim Full CY 1/1/14 – 12/31/14	PY 1 1/1/15 – 12/31/15	PY 2 1 1/1/15 – 12/31/15	PY 3 1/1/15 – 12/31/15
# of Procedures	554	926	939	952	965	978

CMC-Pineville provided historical utilization for cardiac catheterization and interventional radiology services and projected utilization for the service component. The applicant adequately demonstrated the need to acquire dedicated interventional radiology equipment, given that the current blocked scheduling in one of the three licensed cardiac catheterization laboratories is no longer feasible. In Section III.1(b), page 49, the applicant projects the proposed interventional radiology laboratory will operate at 82% ($978 / 1,188 = 0.8232$ or 82%) of its capacity by the third year of operation (CY 2017). Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant's service area. Therefore, the application is conforming with 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.

C

In Section VII.1, pages 86-87, the applicant provides the current and proposed staffing for CMC-Pineville's interventional radiology services, as shown in the table below.

CMC-Pineville Interventional Radiology Staffing	Current FTEs	Proposed FTEs
Staff IR Technologist	1.70	2.50
Staff RN	0.70	1.00
Administrative Support	0.15	0.20
TOTAL	2.55	3.70

As illustrated in the above table, the applicant projects to add 1.15 full-time equivalent (FTE) positions by the second full fiscal year following completion of the proposed project. The applicant states on page 88 that no new positions will result from this project, however, that

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the additional FTEs are currently employed in each of these positions. In Section VII.3, page 88, the applicant states that it does not expect to have difficulty in recruiting the additional FTE's following completion of the proposed project, as CMC-Pineville is a part of CHS and has numerous resources from which to obtain staff. In Section VII.8, page 91, the applicant identifies Michael Beatty, M.D. as the Medical Director for CMC-Pineville. Exhibit 32 contains physician letters of support including a letter from the Medical Director and several physicians from Charlotte Radiology, CMC-Pineville's radiology group, expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. 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.

C

In Section II.2, page 21, and Exhibit 7, the applicant states that all of the necessary ancillary and support services for the proposed service are currently provided at CMC-Pineville. In Exhibit 23 of the application, the applicant provides a copy of a sample transfer agreement and a list of facilities with which CMC-Pineville has transfer agreements. In Exhibit 32 of the application, the applicant provides letters from Charlotte Radiology, the radiology group for CMC-Pineville, supporting the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with 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:

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- (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:
 - (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 VI.13, page 83, the applicant provides the payor mix during CY 2012 for interventional radiology services at CMC-Pineville, as shown in the table below.

**CY 2012 CMC-Pineville
Interventional Radiology Department**

Current Cases As Percent of Total Utilization	
Medicare / Medicare Managed Care	58.1%
Medicaid	7.8%
Managed Care / Commercial	26.9%

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Self Pay / Other*	7.2%
TOTAL	100.0%

*Other includes workers comp and other govt. payors.

Note: Numbers may not foot due to computer rounding

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

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg County	15.0%	5.1%	20.1%
Union County	11.0%	3.4%	18.0%
Gaston County	20.0%	8.6%	19.0%
Statewide	17.0%	6.7%	19.7%

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 interventional radiology services proposed in this application.

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. However, a direct comparison to the applicant's current payer 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.

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The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 82, the applicant states:

“CMC-Pineville has had no obligations to provide uncompensated care during the last three years. As stated earlier, the medical center provides without obligation, a considerable amount of bad debt and charity care and in CY 2012 provided approximately \$80,796,000 in bad debt and charity care.”

In Section VI.10(a), page 81, the applicant states that no complaints have been filed against any affiliated entity of CHS regarding civil rights equal access in the last five years. 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

C

In Section VI.15, page 84, the applicant provides the projected payor mix for the second full fiscal year following completion of the proposed project (CY 2016) for interventional radiology services at CMC-Pineville, as shown in the table below.

**CY 2016 CMC-Pineville
Interventional Radiology Department**

Projected Cases As Percent of Total Utilization	
Medicare / Medicare Managed Care	58.1%
Medicaid	7.8%
Managed Care / Commercial	26.9%
Self Pay / Other*	7.2%
TOTAL	100.0%

*Other includes workers comp and other govt. payors.

Note: Numbers may not foot due to computer rounding

On page 84, the applicant states that CMC-Pineville assumes payor mix for the interventional radiology department would remain consistent with the historical payor

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mix. The applicant demonstrated that medically underserved populations will have adequate access to the proposed services. 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 80, the applicant states:

“Persons have access to services at CMC-Pineville through referrals from physicians who have admitting privileges at the medical center. Patients of CMC-Pineville are also admitted through the emergency department.”

The applicant adequately identified the range of means by which patients will have access to the proposed services. Therefore, 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 V.1(a), page 66, the applicant states that CMC-Pineville, through its relationship with CHS has extensive, existing relationships with health professional training programs, including Central Piedmont Community College, Queens University of Charlotte, The University of North Carolina at Charlotte, Gardner-Webb University and Presbyterian School of Nursing. Exhibit 22 contains a copy of CMC-Pineville’s sample education affiliation agreement. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity with 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

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applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant, Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville currently provides interventional radiology services, but the medical center does not have a dedicated interventional radiology room. The current arrangement allows only limited time for interventional radiology procedures and often results in interventional radiology cases getting bumped for emergency cardiac and vascular cases. Interventional radiology procedures are currently allotted two half days per week (8-hours) of blocked time in one of the medical center's three licensed cardiac catheterization laboratories and a subset of procedures are performed in a procedure room with a mobile C-arm. The applicant states that in order to meet the demands of population growth in its service area, the medical center recently completed a \$300 million dollar expansion that transformed it into a full-service, tertiary medical center in 2012 (CMC-Pineville Phase II Project I.D. #F-7979-07). Major projects completed at CMC-Pineville include: a 100,000 square foot medical office building, a 335,000 square foot expansion and renovation that provides open-heart surgery and interventional cardiology, a 30-bed intensive care unit (ICU), a Levine Cancer Institute facility, radiation oncology therapy, and inpatient kidney dialysis. According to the most recent progress report filed in April 2013, that project is complete and being utilized as proposed. In this application, the applicant proposes to renovate 900 square feet of vacated space pursuant to Project I.D. #F-7979-07. The vacated space for the proposed project was previously utilized as a cardiac catheterization laboratory and will require only minor renovations necessary to support the proposed equipment.

In Section V.7, pages 71-73, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access.

The applicant states:

"The proposed project is indicative of CMC-Pineville's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. ... CMC-Pineville has reduced expenses by utilizing existing space and avoiding new construction and has thus proposed the most value-conscious alternative for the installation of the new proposed equipment.

...

CMC-Pineville has made a long term commitment to providing quality care to its patients as demonstrated by its Quality Assessment and Performance Improvement, Utilization and Risk Management Plans. ... CMC-Pineville maintains the importance of continuous quality monitoring.

...

CMC-Pineville has historically provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.

...

By enhancing access to state-of-the-art interventional radiology services, the proposed project will naturally enhance competition in Mecklenburg County and surrounding areas.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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 in the service area include a position impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant proposes to acquire interventional radiology equipment and to develop a dedicated interventional radiology room by renovating existing space in the medical center to house the proposed equipment and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

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.

C

Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. 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

CMC-Pineville proposes to acquire interventional radiology equipment and to develop a dedicated interventional radiology room by renovating existing space in the medical center to house the proposed equipment. In Section II.8, page 29, the applicant states, “*There are no specific criteria and standards that have been promulgated for this equipment.*” In Section II.1, page 17, the applicant states, “*The proposed project does not involve cardiac catheterization equipment and will not be used to perform cardiac catheterization procedures.*” Therefore, the Criteria and Standards for Cardiac Catheterization Equipment promulgated in 10A NCAC 14C .1600, are not applicable to this review. However, the Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100, are applicable to this review. The application is conforming to all applicable criteria and standards. The specific criteria are discussed below.

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

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 application form.
- (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.*

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- C- In Section II.8, pages 30-31, the applicant defined the service area as South Mecklenburg County, York County (SC), Lancaster County (SC), East Gaston County, and Union County, which is the same service area identified for the applicant's existing services in Section III.4(a), page 56.
- (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 I.12(e), pages 14-16, the applicant provides documentation of its current experience in providing interventional radiology services
- (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- In Exhibit 14, the applicant provides documentation that the proposed interventional radiology equipment has been approved for use by the U.S. Food and Drug Administration.
- (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 5, the applicant provides a floor plan of the proposed interventional radiology services department which identifies 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- In Section II.8, page 32 and Exhibit 15, the applicant provides documentation that the facility meets or exceeds the appropriate building codes and federal,

state, and local manufacture’s standards for the proposed interventional radiology room.

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.8, pages 33-34, the applicant provides documentation of the number patients who will use the service classified by diagnosis.
- (2) *the number of patients who will use the service, classified by county of residence;*
- C- In Section II.8, page 35, the applicant provides the following table showing the number of patients who will use the service by county of residence:

County	Historical Distribution	Projected Patients		
		CY 2015	CY 2016	CY 2017
Mecklenburg	49.8%	474	480	487
York, SC	27.3%	260	264	267
Lancaster, SC	10.0%	95	96	97
Union	5.3%	50	51	52
Gaston	1.7%	16	16	17
Other*	5.9%	56	57	58
TOTAL	100.0%	952	965	978

*Other includes counties in North Carolina as well as other states: Alexander, Anson, Blair, Burke, Cabarrus, Catawba, Chatham, Cheshire, Chester, Chesterfield, Douglas, Hartford, Maricopa, New Hanover, Passaic, Pinellas, Richmond, Rutherford, Spartanburg, Suffolk, Sullivan, and Wilkes.

Note: Totals may not foot due to computer rounding.

Source: CMC-Pineville internal data

- (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.8, page 35, the applicant states,

“CMC-Pineville is currently scheduling interventional radiology procedures in one of the medical center’s three licensed cardiac catheterization laboratories from 1:00 p.m. to 5:00 p.m. on Tuesdays and Thursdays. These hours of operation yield a capacity equaling approximately 400 interventional radiology procedure hours per year

[8weel x 50 weeks/year = 400]. *This capacity is based on the assumption of 50 weeks per year with no interventional procedures getting bumped for emergency cases. ...*”

- (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.8, page 36, the applicant provides a table showing the quarterly projected utilization of CMC-Pineville’s proposed interventional radiology room for the first three years following completion of the project.
- (5) *all the assumptions and data supporting the methodology used for the projections in this Rule.*
- C- The applicant provides the assumptions and data supporting the methodology used for the projections in Section III.1(b), pages 45-50.
- (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- In Section II.8, page 37, the applicant states, “*CMC-Pineville is not proposing to acquire new major medical technology as defined by 10A NCAC 14C .3102(4).*”

10A NCAC 14C .3105 SUPPORT SERVICES

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.8, page 37, the applicant identifies all ancillary and support services required to support the proposed interventional radiology room. In Exhibit 7, the applicant provides a copy of a letter from the President of CMC-Pineville documenting that all of these services are currently available at CMC-Pineville.

10A NCAC 14C .3106 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*
 - (2) *trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.*
- C- In Section VII.1(b), page, 87 and Exhibits 16-17, the applicant provides documentation that trained and qualified staff will be employed and that trained technical staff and support personnel will work with the manufacturer and operators of the interventional radiology equipment.
- (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- As noted in Exhibit 17, and as documented in Exhibit 18, the applicant provides copies of the curricula vitae of all the physicians who will treat patients in the interventional radiology room, documenting that they have the required education and training.
- (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- In Section II.8, pages 38-39, and Exhibit 17, the applicant provides documentation that staff training is and will continue to be provided for certification in cardiopulmonary resuscitation and basic cardiac life support (BCLS).
- (2) *an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.*

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- C- In Section II.8, page 39, and Exhibit 20, the applicant provides documentation of an organized program of staff education and training.