## **REQUIRED STATE AGENCY FINDINGS**

## FINDINGS C = Conforming CA = Conforming as Conditioned NC = Nonconforming NA = Not Applicable

Decision Date:	March 20, 2024
Findings Date:	March 20, 2024

Project Analyst:	Gregory F. Yakaboski
Co-Signer:	Gloria C. Hale

**COMPETITIVE REVIEW** 

Project ID #: Facility: FID #: County: Applicant: Project:	Q-12445-23 Aveanna Home Health-Pitt 230895 Pitt Five Points Healthcare of NC, LLC Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination
Project ID #: Facility: FID #: County: Applicant: Project:	Q-12451-23 Bayada Home Health Care, Inc. 230898 Pitt BAYADA Home Health Care, Inc. Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination
Project ID #: Facility: FID #: County: Applicant: Project:	Q-12456-23 Well Care Home Health of Pitt 230901 Pitt Well Care Home Health of Pitt, Inc. Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent

analysis and the comparative analysis.

Given the complexity of this review and the multiple entities involved in projections, the Project Analyst created the table below listing acronyms or abbreviations used in the findings.

Acronyms/Abbreviations Used					
Acronym/Abbreviations Used	Full Term				
HHA	Home Health Agency				
Dup	Duplicated (as related to patients or patient visits)				
Undup	Unduplicated (as related to patients or patient visits)				
CAGR	Compound Annual Growth Rate				
CY	Calendar Year (January 1 – December 31)				
FFY	Federal Fiscal Year (October 1 – September 30)				
FY	Fiscal Year				
NC OSBM	North Carolina Office of State Budget and Management				
SFY	State Fiscal Year (July 1 – June 30)				
SHCC	State Health Coordinating Council				
SMFP	State Medical Facilities Plan				

## **REVIEW CRITERIA**

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.

## C All Applications

## **Need Determination**

The 2023 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional Medicare-certified home health agencies (HHAs) or offices in North Carolina by service area. Application of the need methodology in the 2023 SMFP identified a need for one Medicare-certified HHA in the Pitt County service area. Three applications were received by the Healthcare Planning and Certificate of Need Section ("CON Section" or "Agency") with each proposing to develop one Medicare-certified HHA. However, pursuant to the need determination, only one Medicare-certified HHA may be approved in this review.

## **Policies**

There is one policy in the 2023 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2023 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."

## Project ID #Q-12445-23/Aveanna Home Health-Pitt/Develop a Medicarecertified HHA

Five Points Healthcare of NC, LLC (referred to as "Five Points" or "the applicant") proposes to develop Aveanna Home Health – Pitt (Aveanna), a new Medicare-certified HHA in Greenville, Pitt County.

**Need Determination.** The applicant does not propose to develop more Medicare-certified HHA than are determined to be needed in Pitt County.

**Policy GEN-3.** In Section B, pages 26-28, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on the following:

- The applicant does not propose to develop more Medicare-certified HHAs than are determined to be needed in Pitt County.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* based on the following:

- The applicant adequately documents how the project will promote safety and quality in the delivery of home health services in Pitt County;
- The applicant adequately documents how the project will promote equitable access to home health services in Pitt County; and
- The applicant adequately documents how the project will maximize healthcare value for the resources expended.

# Project ID #Q-12451-23/BAYADA Home Health Care, Inc./Develop a Medicare-certified HHA

BAYADA Home Health Care, Inc. (referred to as "BAYADA, Inc." or "the applicant") proposes to develop BAYADA Home Health Care (BAYADA), a new Medicare-certified HHA in Greenville, Pitt County.

**Need Determination.** The applicant does not propose to develop more Medicare-certified HHA than are determined to be needed in Pitt County.

**Policy GEN-3.** In Section B, pages 27-31, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on the following:

- The applicant does not propose to develop more Medicare-certified HHAs than are determined to be needed in Pitt County.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of home health services in Pitt County;
  - The applicant adequately documents how the project will promote equitable access to home health services in Pitt County; and

• The applicant adequately documents how the project will maximize healthcare value for the resources expended.

# Project ID #Q-12456-23/Well Care Home Health of Pitt /Develop a Medicare-certified HHA

Well Care Home Health of Pitt, Inc. (referred to as "Well Care of Pitt, Inc." or "the applicant") proposes to develop Well Care Home Health of Pitt (Well Care), a new Medicare-certified HHA in Greenville, Pitt County.

**Need Determination.** The applicant does not propose to develop more Medicare-certified HHA than are determined to be needed in Pitt County.

**Policy GEN-3.** In Section B, pages 26-34, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on the following:

- The applicant does not propose to develop more Medicare-certified HHAs than are determined to be needed in Pitt County.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of home health services in Pitt County;
  - The applicant adequately documents how the project will promote equitable access to home health services in Pitt County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

## C All Applications

## Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## Patient Origin

On page 213, the 2023 SMFP defines the service area for Medicare-certified home health agency or office as "...the county in which the agency or office is located. Each of the 100 counties in the state is a separate service area." Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

Aveanna does not currently operate a Medicare-certified HHA in Pitt County. Projected patient origin is shown in the table below.

Projected Patient Origin – Aveanna							
	FY 1 (C	Y 2025)	FY 2 (C	FY 2 (CY 2026)		FY 3 (CY 2027)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total	
Pitt	514	86.8%	773	80.2%	1,036	73.6%	
Craven	20	3.4%	49	5.1%	95	6.8%	
Lenoir	19	3.2%	46	4.8%	90	6.4%	
Beaufort	14	2.3%	33	3.4%	64	4.6%	
Edgecombe	12	2.0%	30	3.1%	57	4.1%	
Martin	9	1.4%	21	2.2%	40	2.9%	
Greene	5	0.9%	13	1.3%	25	1.8%	
Total	592	100.0%	964	100.0%	1,407	100.0%	

Source: Section C, page 34

In Section C, page 34, and in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's projected patient origin is based on its projections of the unmet need for home health (HH) services in Pitt, Craven, Lenoir, Beaufort, Edgecombe, Martin and Greene counties and its projections of market share for the proposed home health agency in those counties through the first three full fiscal years of operation, as described in the applicant's assumptions and methodology in Section Q of the application. The applicant's assumptions are reasonable and adequately supported.

## Analysis of Need

In Section C, pages 36-44, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The 2023 SMFP identifies a need for one additional Medicare-certified home health agency or office in Pitt County. The 2023 SMFP projects a home health need deficit of 558 home health patients by FFY 2024 (page 37).
- The Pitt County home health historical market share, the 2023 SMFP projected growth, and the historical utilization of home health in Pitt County demonstrate the need to expand home health services in Pitt County (pages 38-40).
- The population growth and aging data from NCOSBM for Pitt County (pages 40-41).
- A Medicare-certified home health agency or office serves as a lower cost alternative. Patients who transition from the emergency department to home health services as opposed to transitioning from inpatient hospitalization can result in lower costs and reduction in inpatient readmissions rates (pages 41-42).
- Aveanna has significant experience as a home health provider and has established relationships with hospitals and physicians that can be leveraged to build a referral network in Pitt County. (pages 42-44).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, remarks made at the public hearing, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need for one Medicare-certified home health agency or office in Pitt County, as stated in the 2023 SMFP.
- The applicant's demonstration of need is supported by the historical utilization of home health services in Pitt County.
- The applicant provides publicly available and reliable data and information to support its statements about population growth and utilization of HHA services in Pitt County.

## Projected Utilization

In Section Q, Form C.5, page 102, the applicant provides projected utilization, as illustrated in the following table.

	1 <sup>st</sup> Fu	III FY	2 <sup>nd</sup> Fu	II FY	3 <sup>rd</sup> Fu	ll FY
Augaana	CY 2026		CY 2027		CY 2028	
Aveanna	# of	# of	# of	# of	# of	# of
	Clients	Visits	Clients	Visits	Clients	Visits
Unduplicated Clients by Admitting Discipline						
Nursing	262		427		622	
Physical Therapy	254		414		604	
Speech Therapy						
Occupational Therapy	76		124		181	
Total Unduplicated Clients	592		964		1,407	
Duplicated Clients and Visits by Discipline						
Nursing	311	5,737	506	9,339	738	13,625
Physical Therapy	374	5,566	609	9,060	888	13,218
Speech Therapy	34	277	55	451	80	658
Occupational Therapy	176	1,669	286	2,717	417	3,963
Medical Social Worker	54	88	87	143	128	209
Home Health Aide	52	468	85	763	124	1,113
Total Duplicated Clients and Visits	1,000	13,805	1,628	22,473	2,375	32,787
Duplicated Medicare Clients and Visits						
Full Episodes without Outlier	656	9,473	1,068	15,421	1,558	22,498
Full Episodes with Outlier	5	164	8	267	11	389
Partial Episode Payment (PEP)	5	48	9	78	13	114
Low-Utilization Payment Adjustment (LUPA)	88	240	144	391	209	570
Total Medicare Clients and Visits	754	9,925	1,228	16,156	1,791	23,571

In Section Q, pages 103-109, Form C Utilization – Assumptions and Methodology, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1. *Pitt County Patients in Need of Home Health Care* (page 103). Based on data from the 2023 SMFP, the applicant calculated the compound annual growth rate (CAGR), by age group, for FFY2021 to FFY2024 for Pitt County patients in need of home health care.

Step 2. *FY25-FY28 Projected Pitt County Patients in Need of Home Health Care* (page 104).

The applicant then applied the CAGR calculated in Step 1 for each age group for FFY 2025 through FFY 2028 to project Pitt County patients in need of home health care.

Step 3. *Pitt County Patients Receiving Home Health Care- FFY2021-FFY2024* (page 104).

Based on data from the 2023 SMFP, the applicant calculated the compound annual growth rate (CAGR), by age group, for FFY2021 to FFY2024 for Pitt County patients receiving home health care.

Step 4. *FY25-FY28 Projected Pitt County Patients Receiving Home Health Care* (page 104).

The applicant then applied the CAGR calculated in Step 3 for each age group for FFY 2025 through FFY 2028 to project Pitt County patients that will receive home health care.

## Step 5. *Projected Pitt County Home Health Need Deficit: FFY2024-FFY2028* (page 105).

Utilizing the data from Steps #2 and #4 the applicant then calculated the patient home health need deficit in Pitt County as illustrated in the following table.

Row	Pitt County	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028
А	Patients in need of Home	3,868	3,872	3,881	3,896	3,916
	Health Services					
В	Projected # of patients	3,310	3,155	3,017	2,893	2,783
	receiving Home Health					
	Services					
С	Patient Need Deficit	558	717	864	1,003	1,134
	[Row A-Row B]					
D	Unserved patients in need of	14.4%	18.5%	22.3%	25.7%	29.0%
	home health services as a					
	percent of total patients					
	[Row C / Row A]					

Step 6. Projected Pitt County Home Health Need Deficit, Project Years 1-3 (page 105).

The applicant converts the Federal Fiscal Year (FFY) data into calendar years (CY) to match its fiscal year.

Row		CY2024	CY2025	CY2026	CY2027
	Project Year (PY)	Interim	PY1	PY2	PY3
А	Patients in need of Home Health Services	3,869	3,874	3,885	3,901
В	Patient Need Deficit	598	753	899	1,036
С	Unserved patients in need of home health services as a percent of total patients [Row B / Row A]	15.4%	19.4%	23.1%	26.5%

Step 7. *Existing Home Health Agency Market Share in Pitt County* (page 106). The applicant provides a table showing all the Pitt County patients receiving home health services by which HHA, including each HHA's Pitt County patient market share. The applicant notes that the three existing HHAs located in Pitt County served 94.7% of Pitt County home health patients in FY2022, with an average market share of 31.6%. The applicant notes that in Step #6, the projected number of unserved patients in need of home health services as a percent of total Pitt County patients was 26.5% or 1,036 patients in the third PY (CY2027). The applicant projects to serve all 1,036 such patients by the third PY (CY2027).

## Step 8. *Projected Pitt County Patients to be Served by Aveanna-Pitt: CY2024-CY2027* (page 107).

The applicant projects to serve all 1,036 patients projected to be unserved in Step #6 by PY3 (CY2027).

Row		CY2024	CY2025	CY2026	CY2027
	Project Year (PY)	Interim	PY1	PY2	PY3
A	Patients in need of Home Health Services	3 <i>,</i> 869	3,874	3,885	3,901
В	Projected Market Capture Percentage by Aveanna [Row C / Row A]	6.6%	13.3%	19.9%	26.5%
С	Projected Pitt County patients served by Aveanna	257	514	773	1,036

Step 9.	Pitt County Patient Need Deficit Capture Rate by Aveanna-Pitt: CY2024-
	<i>CY2027</i> (page 107).

Row		CY2024	CY2025	CY2026	CY2027
	Project Year (PY)	Interim	PY1	PY2	PY3
А	Projected Pitt County patients	257	514	773	1,036
	to be served by Aveanna				
В	Projected Pitt County patient	598	753	899	1,036
	need deficit (See Step #6)				
С	Aveanna capture rate of	43.0%	68.2%	86.0%	100.0%
	patient need deficit [Row A /				
	Row B]				

Step 10. *Pitt County Home Health Agency In-migration of existing Pitt County Home Health Agencies* (page 108).

	Pitt County Patient Count	Out-of-Pitt County Patient Count	% of Out-of-Pitt County
CenterWell Home Health	1,923	857	30.8%
Vidant Home Health and Hospice	1,099	335	23.4%
ЗНС	546	182	25.0%
Pitt HHA Average	1,189	458	26.4%

#### **Existing Pitt County HHAs**

Step 11: Contiguous County Home Health Need Deficits (page 108).

The applicant provides the home health need deficits for Craven, Lenoir, Beaufort,

Edgecombe, Martin and Greene counties based on the 2023 SMFP.

Step 12: Total Projected Home Health Patients to be Served by Aveanna (page 109).

The table below includes projections to serve 25% of the 26.4% in-migration target in the project's interim year, 50% of the 26.4% figure in PY1, and 75% of this figure in PY2.

Row		CY2024	CY2025	CY2026	CY2027
	Project Year (PY)	Interim	PY1	PY2	PY3
А	Projected Pitt County patients	257	514	773	1,036
	to be served by Aveanna				
В	Projected Aveanna patients	18	78	191	371
	from contiguous counties				
С	Total projected number of	275	592	964	1,407
	patients to be served by				
	Aveanna [Row A + Row B]				
D	In migration ramp-up	25%	40%	75%	100%
	adjustment				
E	Percentage of out-of-county	6.6%	13.2%	19.8%	26.4%
	patients [Row B / Row C]				

The applicant's utilization projections are summarized in the table below.

Row		CY2024 (Interim)	CY2025 (PY1)	CY2026 (PY2)	CY2027 (PY3)
A	Projected Pitt Patients in Need of Home Health Services	3,869	3,874	3,885	3,901
В	Projected Pitt County Patient Need Deficit	598	753	899	1,036
С	Aveanna Projected Capture Rate of Patient Need Deficit with Ramp Up	43.0%	68.2%	86.0%	100.0%
D	Projected Aveanna Patients from Pitt County	257	514	773	1,036
E	Projected Aveanna Patients from Contiguous Counties	18	78	191	371
F	Total Projected Number of Patients to be Served by Aveanna (Row D + Row E)	275	592	964	1,407
G	Aveanna Projected Market Capture Percentage of Total Pitt County HH Patients with Ramp Up (Row D / Row A)	6.6%	13.3%	19.9%	26.6%

As shown in the table above, the applicant projects to serve 1,407 patients during its third full fiscal year following project completion. This meets the performance standard promulgated in 10A NCAC 14C .2003(2), which requires an applicant to project to serve at least 325 patients by the end of the third full fiscal year following project completion.

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, remarks made at the public hearing, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The applicant's projections of home health patients that it projects to serve are consistent with and supported by the projected 2024 home health deficits for Pitt County and the other service area counties identified in the 2023 SMFP.
- The applicant's projections are supported by the historical market share percentage across Pitt County's existing home health agencies and Aveanna's Cumberland County home health agency historical utilization.
- The applicant's projections are supported by the projected growth of the population in the proposed service area.

## Access to Medically Underserved Groups

In Section C, page 51, the applicant states:

"Aveanna does not exclude or discriminate against any person based upon race, color, age, religion, gender, sexual orientation, marital status, sexual preference, age, national origin, veteran status, disability (mental or physical), communicable disease, or place of national origin for purposes of admission and eligibility to receive services and care. This policy is effective for patients cared for directly by Aveanna's employees and by all contractors and contracted entities that Aveanna Healthcare engages to administer its programs and activities."

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Racial and ethnic minorities	41.8%
Women	53.0%
Persons 65 and older	58.5%
Medicare beneficiaries	58.5%
Medicaid recipients	12.2%

**Source:** Section C, page 53

On page 53, the applicant states it does not maintain information on patients that are considered low-income or disabled but says neither low-income patients nor disabled patients are excluded from services.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide full access to area residents who are medically underserved.
- The applicant provides a copy of its admission policies which state the same in Exhibit L.5.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

## Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## Patient Origin

On page 213, the 2023 SMFP defines the service area for Medicare-certified home health agency or office as "...the county in which the agency or office is located. Each of the 100 counties in the state is a separate service area." Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

BAYADA does not currently operate a Medicare-certified HHA in Pitt County. Projected patient origin is shown in the table below.

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Projected Patient Origin – BAYADA							
	FY 1 (FI	Y 2026)	FY 2 (FFY 2027)		FY 3 (FFY 2028)		
County	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total	
Pitt	544	85.3%	965	91.2%	1,397	93.7%	
Wilson	21	3.4%	21	2.0%	21	1.4%	
Craven	18	2.9%	18	1.7%	18	1.2%	
Lenoir	17	2.7%	17	1.6%	17	1.2%	
Beaufort	12	2.0%	12	1.2%	12	0.8%	
Edgecombe	11	1.7%	11	1.1%	11	0.7%	
Martin	8	1.2%	8	0.7%	8	0.5%	
Greene	5	0.8%	5	0.5%	5	0.5%	
Total	638	100.0%	1,059	100.0%	1,491	100.0%	

**Source:** Section C, page 39

In Section C, page 39, and in the Home Health Patient and Visit Methodology and Assumptions subsection of Section Q, immediately following Form C.5, the applicant provides the assumptions and methodology used to project patient origin. Projected patient origin is reasonable and adequately supported based on the following:

- The applicant projects patient origin based on proportions of deficits in HHA services as published in the 2023 SMFP.
- The applicant is experienced in operating Medicare-certified HHAs in North Carolina and has other agencies in the state that can assist with establishing referral relationships.
- Projected utilization is reasonable and adequately supported. Please see the discussion about projected utilization found below for more details.

## Analysis of Need

In Section C, pages 41-48, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- There is a need determination in the 2023 SMFP for one additional Medicare-certified HHA in Pitt County (page 42).
- The population growth and aging data from NCOSBM for Pitt County and the surrounding counties. (pages 40-41).
- The life expectancy of Pitt County residents has increased across most age groups aged 65 and older between 1990 and 2020 (page 44).
- The applicant states that, based on the 2023 SMFP, utilization of home health services in Pitt County and the proposed service area counties has increased in 18 of the 32 age group categories when compared to the North Carolina average in 2024 (page 45).

- BAYADA has well-respected home health agencies throughout the state, but has none in eastern North Carolina, and it desires to bring those services to the eastern part of the state (page 45).
- Home care has taken on increased importance especially following the COVID-19 pandemic (pages 46-48).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, remarks made at the public hearing, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need determination in the 2023 SMFP for one additional Medicare-certified home health agency in Pitt County.
- The applicant provides publicly available and reliable data and information to support its statements about population growth, life expectancy, and utilization of HHA services in Pitt County.

## Projected Utilization

In Section Q, Form C.5, page 1, the applicant provides projected utilization, as illustrated in the following table.

	BAYADA – Projected Utilization								
	FY 1 (FF	Y 2026)	FY 2 (FF	Y 2027)	FY 3 (FF	Y 2028)			
	# of Clients	# of Visits	# of Clients	# of Visits	# of Clients	# of Visits			
Clients (Undup) by Admitting Discipl	ine								
Nursing	358		595		838				
Physical Therapy	229		380		535				
Occupational Therapy	22		36		51				
Speech Therapy	29		48		67				
Total Clients (Undup)	638		1.059		1,491				
	•				•				
Duplicated Clients and Visits by									
Discipine									
Nursing	567	5,723	1,041	10,511	1,454	14,689			
Physical Therapy	632	4,739	1,176	8,822	1,653	12,397			
Speech Therapy	496	2,131	924	3,971	1,279	5,499			
Occupational Therapy	556	2,168	1,034	4,031	1,451	5,661			
Medical Social Worker	50	55	93	103	130	143			
Home Health Aide	43	211	80	393	112	550			
Total Clients & Visits (Dup)	2,343	15,027	4,348	27,832	6,080	38,938			
Duplicated Medicare Clients and Visits									
Full Episodes w/o Outlier	2,083	13,113	3,895	24,523	5,360	33,750			
Full Episodes w/ Outlier	44	275	82	514	112	707			
Partial Episode Payment (PEP)	51	324	96	605	132	833			
Low-Utilization Payment Adjustment	4	25	7	46	10	63			
Total Medicare Clients & Visits	2,182	13,735	4,080	25,688	5,615	35,352			

In the Home Health Patient and Visit Methodology and Assumptions subsection of Section Q, immediately following Form C.5, the applicant provides the assumptions and methodology used to project patient utilization, as discussed below.

## Step #1: Identify Service Area Home Health Patients

The applicant projects to serve patients from eight counties: Pitt, Beaufort, Craven, Edgecombe, Greene, Lenoir, Martin and Wilson. The 2023 SMFP projects that each of these eight counties will have a home health patient deficit in 2024.

In addition, the applicant calculated that the 2-year CAGR for Pitt County home health patients from FY2022 to FY2024 of 1.33%.

## Step #2: Projected FY2025 through FY2028 Pitt County Home Health Patients

The applicant applied the CAGR calculated in Step #1 to project Pitt County home health patients from FY2025 to FY2028 as illustrated in the table below.

County	FY2024	FY2025	FY2026	FY2027	FY2028	CAGR
Pitt	3,868	3,920	3,972	4,025	4,078	1.33%

Step #3: Projected Home Health Service Area Patient Deficit Captures

The applicant projects that it will capture 95% of the projected 2024 home health patient deficit for Pitt County (530 patients) and 10% of the projected 2024 home health patient deficit for each of the other seven counties BAYADA identified in Step #1.

The first three project years are FY2026, FY2027 and FY2028. The applicant projects to capture 13.71% of the Pitt County HH patient market share for FY2026.

County	Projected FY2024 HH Patients	HH Patients Captured	FY2026 Market Share	
Pitt	3,868	530	13.71%*	

\*Calculation: (Home Health Patients Captured/ Projected FY2024 HH Patients) x 100.

Step #4: Projected FY2026 through FY2028 Home Health Market Share and Patients

The applicant projects to capture 13.71% of the Pitt County HH patient market share for FY2026 and increase market share by 10.28% for each of PY2 (FY2027) and PY3 (FY2028).

Year	r <b>FY2026</b>		FY2028	Market Share Yearly Increase	
Market Share	13.7%	23.99%	34.26%	10.28%	

To project Pitt County HH patients the applicant multiplied the projected Pitt County HH patients from the table in Step #2 by the market share percentages from the table above.

The applicant held the projected HH patients from the seven other counties to 10% of the 2024 projected HH patient deficit for each of the counties as shown in the table in Step #3.

Step #5: Unduplicated Home Health Patients by Service Discipline Admission Based on BAYADA internal North Carolina HH patient data and experience, the applicant projected unduplicated patients by service discipline (skilled nursing, physical therapy, speech therapy and occupational therapy) as will as calculating admission percentage.

Step #6: Unduplicated Home Health Patients by Payor

The applicant provided projected overall payor mix for FY2025 to FY2028 by both percentage and patients by payor category. The applicant provided the methodology and assumptions for these calculations.

Step #7: *Readmitted Patients by Payor* 

Based on BAYADA internal North Carolina HH patient data and experience, the applicant projects 35.0% of Medicare patients will be readmitted.

Step #8: *Medicare Episode Starts* 

The applicant, based on 2022 BAYADA-Guilford internal home health data, BAYADA calculates Medicare episodes utilizing an episode ratio of 1.45 per patient.

Step #9: *Medicare Episode by Reimbursement Type* 

The applicant projected Medicare episode for FY2025 to FY2028 by reimbursement type based on internal BAYADA North Carolina HH patient experience and data.

### Step #10: *Projected Visits by Reimbursement Type*

The applicant projected visits by reimbursement type for FY2025 to FY2028 based on internal BAYADA North Carolina HH patient experience and data.

### Step #11: *Projected Visits by Service Discipline*

The applicant projected visits by service discipline for FY2025 to FY2028 based on internal BAYADA North Carolina HH patient experience and data.

## Step #12: *Projected Duplicated Patients by Service Discipline*

The applicant projected the total number of duplicated patients by service discipline by dividing the total visits by the average number of visits per patient receiving care in that service discipline.

#### Step #13: Summary

The applicant's methodology for its utilization projections is summarized in the table below.

Row		2024	FFY2025	FFY2026 (PY1)	FFY2027 (PY2)	FFY2028 (PY3)
A	Projected Pitt County Home Health Patients (Based on 1.33% CAGR FY 2022 – FY2024)	3,868*	3,920	3,972	4,025	4,078
В	Projected Pitt County HH patient deficit	558*				
С	BAYADA projects it would capture 95.0%, or 530 HH patients, of the projected Pitt County Patient Need Deficit [558 x .95 = 530]. BAYADA then converts that to market share. In 2024 the patient need deficit equates to 13.71% of the projected Pitt County HH patients [530/3,868 = 13.71%]	530				
D	BAYADA then projects to capture 13.71% of the Pitt County HH patient Market Share in PY1 (FFY2026). BAYADA projects to increase its market share by 10.28% for the 2 <sup>nd</sup> and 3 <sup>rd</sup> project years			13.71%	23.99%	34.26%
E	Projected BAYADA Pitt County HH Patients [Row A x Row D].			544	965	1,397
F	Projected BAYADA Patients from Contiguous Counties based on projected capture of 10% of the 2024 HH patient deficit from each county in its projected service area.			92	92	92
G	Total Projected BAYADA HH Patients [Row E+ Row F]			636	1,057	1,489

\*Source: 2023 SMFP, Table 12D, page 249.

As shown in the table above, the applicant projects to serve 1,489 patients during its third full fiscal year following project completion. This meets the performance standard promulgated in 10A NCAC 14C .2003(2), which requires an applicant to project to serve at least 325 patients by the end of the third full fiscal year following project completion.

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, remarks made at the public hearing, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The applicant utilized data from publicly available and reliable sources such as the SMFP.
- The applicant used Pitt County data and data from the other counties in the proposed service area for its projections.
- The applicant projected Pitt County home health patients through FY2028 using the projected 2-year CAGR of 1.33% for FY2022-FY2024.
- The applicant relied on reasonable projected market share and capture of the projected Pitt County home health patient deficit based on its own historical experience serving HHA patients in in North Carolina, its development of referral resources in Pitt County, its commitment to provide access regardless of patient demographics or ability to pay, and its reputation for quality care.
- The applicant's projections of home health patients that it projects to serve are consistent with and supported by the projected 2024 home health deficits for Pitt County and its other service area counties identified in the 2023 SMFP.
- The applicant's projections are supported by the projected growth of the population in the proposed service area.
- There is a need determination in the 2023 SMFP for one additional Medicare-certified home health agency in Pitt County.

## Access to Medically Underserved Groups

In Section C, page 54, the applicant states:

"BAYADA maintains a nondiscrimination policy and is committed to serving all appropriate patients regardless of income, race or ethnicity, gender, disability, age and other characteristics that cause patients to be underserved. .... BAYADA Home Health will extend care services to Medicare and Medicaid, uninsured, underinsured, self-pay and medically indigent patients."

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	11.5%
Racial and ethnic minorities	40.0%
Women	55.0%
Persons 65 and older	86.5%
Medicare beneficiaries	86.5%
Medicaid recipients	10.0%

**Source:** Section C, page 54

On page 54, the applicant states it does not track information or data on people with disabilities who use its services.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide full access to area residents who are medically underserved.
- The applicant provides a copy of its non-discrimination policies in Exhibit C.6.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

## Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## Patient Origin

On page 213, the 2023 SMFP defines the service area for Medicare-certified home health agency or office as "...the county in which the agency or office is located. Each of the 100 counties in the state is a separate service area." Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

Well Care does not currently operate a Medicare-certified HHA in Pitt County. Projected patient origin is shown in the table below.

Projected Patient Origin – Well Care								
	FY 1 (CY 2025)		FY 2 (CY 2026)		FY 3 (CY 2027)			
	# Patients % of Total #		# Patients	% of Total	# Patients	% of Total		
Pitt	446	77.5%	559	70.9%	672	65.0%		
Craven	46	8.0%	90	11.4%	148	14.3%		
Edgecombe	28	4.9%	49	6.2%	77	7.4%		
Greene	12	2.1%	18	2.2%	25	2.4%		
Lenoir	44	7.6%	73	9.2%	112	10.8%		
Total	576	100.0%	789	100.0%	1,034	100.0%		

Source: Section C, page 47

In Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's projected patient origin is based on its projections of the unmet need for home health services in Pitt, Craven, Edgecombe, Greene and Lenoir counties and its projections of market share for the proposed home health agency in those counties through the first three full fiscal years operation, as described in Section Q of the application. The applicant's assumptions are reasonable and adequately supported.

## Analysis of Need

In Section C, pages 48-60, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The 2023 SMFP identified a need for an additional Medicare-certified home health agency in Pitt County and a home health deficit of 558 home health patients by 2024 (pages 48-50).
- Well Care's reputation as a high-quality health care provider (pages 50-52).
- Growth and aging of the population in service area counties (pages 53-55).
- Medicaid access (pages 55-56).
- The prevalence of chronic diseases in Pitt and surrounding counties (pages 56-59).
- The historical use rate and cost savings for home health services (pages 59-60).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, remarks made at the public hearing, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need for one Medicare-certified home health agency or office in Pitt County, as stated in the 2023 SMFP.
- The applicant's statements regarding need are supported by population growth and aging data from NCOSBM for the proposed service area.

## Projected Utilization

In Section Q, pages 120, the applicant provides projected utilization, as illustrated in the following table.

	1 <sup>st</sup> Fu	ll FY	2 <sup>nd</sup> Fu	2 <sup>nd</sup> Full FY 3 <sup>rd</sup> Ful		III FY
Well Care	CY 2025		CY 2026		CY2027	
	# of Clients	# of Visits	# of Clients	# of Visits	# of Clients	# of Visits
Unduplicated Clients by Admitting Discipline						
Nursing	369		505		662	
Physical Therapy	207		284		372	
Speech Therapy	0		0		0	
Occupational Therapy	0		0		0	
Total Unduplicated Clients	576		789		1,034	
Duplicated Clients and Visits by Discipline						
Nursing	479	4,696	817	8,011	1,072	10,506
Physical Therapy	408	3,145	695	5,349	911	7,015
Speech Therapy	54	264	92	450	120	590
Occupational Therapy	264	1,134	451	1,940	592	2,544
Medical Social Worker	140	168	237	284	310	373
Home Health Aide	86	439	148	753	194	988
Total Duplicated Clients and Visits	1,431	9,846	2,440	16,788	3,199	22,016
Duplicated Medicare Clients and Visits						
Full Episodes without Period Outliers	597	7,701	1,033	13,328	1,355	17,480
Full Episodes with Period Outliers	14	277	24	465	31	614
Partial Episodes with Partial Period Payments	1	11	1	12	2	21
Patient Episodes with Low-Utilization						
Payment Adjustments (LUPAs)	68	129	118	223	154	293
Total Medicare Clients and Visits	680	8,118	1,176	14,028	1,542	18,408

In Section Q, Form C.5 Home Health Utilization – Assumptions and Methodology, pages 121-135, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

## Unduplicated Home Health Patients

## Step #1: *Projected Pitt County Home Health Patients* (see pages 121-123).

The applicant projects to serve patients from five counties: Pitt, Craven, Edgecombe, Greene and Lenoir. The applicant notes that per the 2023 SMFP each of the five counties has a projected HH patient deficit in 2024 as illustrated in the table below.

County	HH Patient Deficit
Pitt	-558.05
Craven	-184.45
Edgecombe	-111.59
Greene	-48.04
Lenoir	-173.83

Source: 2023 SMFP, Table 12D, page 248.

Further, the applicant states that for the purposes of projected utilization it projects that unduplicated HH patients will remain constant with the 2024 projected patient utilization from the 2023 SMFP for each of the first three project years: CY2025; CY2026 and CY2027.

## Step #2: *Projected Well Care Share of Pitt County Home Health Patient Deficit* (see pages 123-126).

The applicant projects that it will serve 80% of the projected HH patient deficit for Pitt County and 25% of the projected HH patient deficit for Craven, Edgecombe, Greene and Lenoir counties. The applicant then calculates its projected market share for each of the five counties for the first project year (CY2025) and then grows that market share by 3.0% for Pitt County for second and third project years and by 1.5% and then 2.0% for Craven, Edgecombe, Greene and Lenoir counties.

Step #3: *Projected Home Health Patients Based on Market Share* (see pages 126-127). The applicant projects HH patients for the first three project years based on the calculations from Step #1 and Step #2 as illustrated in the table below.

County	CY2025	CY2026	CY2027
Pitt	446	559	672
Craven	46	90	148
Edgecombe	28	49	77
Greene	12	18	25
Lenoir	44	73	112
Total	576	789	1,034

Step #4: *Well Care Home Health of Pitt, Inc. Total Unduplicated Home Health Patients by Admitting Service Discipline* (see page 127).

The applicant based its projections of unduplicated HH patients by admitting discipline (Nursing and Physical Therapy) based on Well Care's enterprise experience for Medicarecertified home health services.

Step #5: *Well Care Home Health of Pitt, Inc. Total Unduplicated Home Health Patients by Payor Source* (See page 128).

## Duplicated Home Health Patients and Total Projected Home Health Patient Visits

Step #6: *Well Care Home Health of Pitt, Inc. Patient Readmissions* (see pages 128-129). The applicant, based on its experience, projects that 25% of Medicare and Medicaid patients will be admitted more than once in the same year. To be conservative, the applicant did not project any readmissions for commercial insurance or private pay patients.

Step #7: *Medicare Patient Episodes/Periods of Care* (See pages 129-130). The applicant, based on Well Care's HH enterprise experience post PDGM projects 1.5 episodes per Medicare patient.

Step #8: *Projected Patients by Payor Source* (See page 131).

The applicant summarized and combined projected utilization numbers from Step #6 and Step #7.

Step #9: *Projected Visits by Payor Source* (See page 132). The applicant provides a table illustrating visits by payor source based on projected average visits per start of care derived from its NC HH enterprise experience.

Step #10: *Projected Visits by Service Discipline* (See pages 133-134). The applicant provides a table illustrating visits by service discipline based on its NC HH enterprise experience.

Step #11: *Projected Duplicated Clients by Service Discipline* (see page 135). The applicant provides a table illustrating projected duplicated clients by service discipline based on its NC HH enterprise experience.

The applicant's methodology for its utilization projections is summarized in the table below.

Row		2022	2024	CY2025 (PY1)	CY2026 (PY2)	CY2027 (PY3)
А	Projected Pitt County Home Health Patients is 3,767	3,767		3,767	3,767	3,767
	based on Pitt County Home Health Patients Served					
	in 2022 and held constant through CY2027.					
В	Pitt County Project HH Patient Need Deficit in 2024.		558*			
С	Well Care projects it would capture 80.0%, or 446 HH patients, of the projected Pitt County Patient Need Deficit [558 x $.80 = 446$ ]. Well Care then		446			
	converts that to market share. In 2024 the patient					
	need deficit equates to 11.9% of the projected Pitt					
	County HH patients [446/3,767 = 11.9%]					
D	Well Care then projects to capture 11.9% of the Pitt County HH patient Market Share in PY1 (CY2025). Well Care projects to increase its market share by 3.0% for the 2 <sup>nd</sup> and 3 <sup>rd</sup> project years			11.9%	14.9%	17.9%
E	Projected Well Care Pitt County HH Patients [Row A x Row D]			446	559	672
F	Contiguous County Patients- Well Care projects to capture 25% of HH Patient Deficit in 2023 SMFP in Craven, Edgecombe, Greene and Lenoir counties, convert to market share, increase its market share by 1.5% and then 2.0% over the next two years.			130	230	362
G	Total Projected Well Care Home Health Patients [Row E + Row F]			576	789	1,034

\*Source: 2023 SMFP, Table 12D, page 249.

As shown in the table above, the applicant projects to serve 1,034 patients during its third full fiscal year following project completion. This meets the performance standard promulgated in 10A NCAC 14C .2003(2), which requires an applicant to project to serve at least 325 patients by the end of the third full fiscal year following project completion.

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, remarks made at the public hearing, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The applicant utilized data from publicly available and reliable sources such as the SMFP.
- The applicant used Pitt County data and data from the other counties in the proposed service area for its projections.
- The applicant relied on reasonable projected market share and capture of projected Pitt County home health patient deficit, based on its own historical experience serving HHA patients in in North Carolina and its outreach to local providers to develop referral relationships.
- The applicant's projections of home health patients that it projects to serve are consistent with and supported by the projected 2024 home health deficits for Pitt County and its other service area counties identified in the 2023 SMFP.
- There is a need determination in the 2023 SMFP for one additional Medicare-certified home health agency in Pitt County.

## Access to Medically Underserved Groups

In Section C, page 64, the applicant states:

"Well Care does not exclude, deny benefits to, or otherwise discriminate against any person on the ground of race, color, or national origin, sex, age or on the basis of disability in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by Well Care directly or through a contractor or any other entity with which Well Care Home Health Inc. arranges to carry out its programs and activities."

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	21.6%
Racial and ethnic minorities	41.8%
Women	61.0%
Persons 65 and older	88.2%
Medicare beneficiaries	79.5%
Medicaid recipients	12.0%

Source: Section C.6, page 66

On page 66, the applicant states it does not have a method to estimate persons with disabilities that use its services, but that persons with disabilities will have access to Well Care services.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide full access to area residents who are medically underserved.
- The applicant provides a copy of its non-discrimination policies in Exhibit C.6.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

(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, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

## NA

## All Applications

None of the applicants propose to reduce a service, eliminate a service, 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 All Applications

## Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section E, page 62, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- <u>Construct a New Building for the HHA</u>: the applicant states construction of a new building would involve significant costs, unpredictable schedules, and would not be ideal for services delivered mostly in the patient's home; therefore, this was not an effective alternative to meet the need.
- <u>Lease Office Space at a Different Location</u>: the applicant states it looked at multiple sites in Pitt County, and other sites were either not close enough to major roads, not close enough to the majority of the population of Pitt County, or didn't have the right amenities; therefore, this was not an effective alternative to meet the need.

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

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

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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.

## Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section E, page 64, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

• <u>Maintain the Status Quo</u>: the applicant states maintaining the status quo would result in limited services for Pitt County patients and would not give rise to the opportunity to serve Pitt County patients; therefore, this was not an effective alternative to meet the need.

• <u>Build a New Facility</u>: the applicant states that the capital expenditure required to develop a new building, when services are provided in a patient's home, was unreasonable; therefore, this was not an effective alternative to meet the need.

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

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

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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.

## Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section E, pages 74-76, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- <u>Maintain the Status Quo</u>: the applicant states maintaining the status quo doesn't address the projected population growth, especially for those 65 and older, and does not address the need in the 2023 SMFP; therefore, this was not an effective alternative to meet the need.
- <u>Develop the HHA in a Different Location</u>: the applicant states that developing an office in another geographic area of Pitt County does not have the benefits of developing a facility in Greenville which is the county seat, 10<sup>th</sup> largest city in North Carolina, and Greenville and its surrounding areas constitute the major population centers and growth in Pitt County. Greenville also has an extensive healthcare infrastructure. Therefore, this was not an effective alternative to meet the need.

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

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

<u>Conclusion</u> – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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.

(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 All Applicants

## Project ID #Q-12445-23/Aveanna Home Health – Pitt/Develop a Medicarecertified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## **Capital and Working Capital Costs**

On Form F.1a in Section Q, the applicant projects capital costs of \$22,544 for non-medical equipment and \$102,920 for furniture for a total projected capital cost of \$125,464.

Immediately following Form F.1a in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant used vendor estimates to determine some of the projected capital cost.
- The applicant is relying on its own historical experience in developing or acquiring equipment for HHAs.

In Section F.3, page 66, the applicant projects that start-up costs will be \$141,660 and initial operating expenses will be \$1,430,329 during a 32-month initial operating period for a total working capital of \$1,571,990. In Section F, page 67, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant

adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant accounts for delays in obtaining Medicare certification.
- The applicant explains what projections are included in the projected start-up costs and initial operating expenses.

## Availability of Funds

In Section F, pages 64-65 and 67-68, the applicant states the entire projected capital cost of \$125,464 and projected working capital cost of \$1,571,990 will be funded entirely by the applicant's accumulated reserves.

In Exhibit F.2-1, the applicant provides a letter dated October 16, 2023, from the Chief Accounting Officer of Aveanna Healthcare, stating that Aveanna Healthcare has available funds for the proposed project and has committed to using the funds to develop the proposed project. In Exhibit F.2-2, the applicant provides a letter dated October 16, 2023, from Aveanna Healthcare's Interim President for Home Health and Hospice Operations, stating they have the authority to receive and disburse the funding from Aveanna Healthcare on behalf of the applicant and commits to funding the proposed project with those accumulated reserves.

In Exhibit F.2-3, the applicant provides a copy of Form 10-K, the annual form required to be filed with the US Securities and Exchange Commission, for the year ending December 31, 2022. As of December 31, 2022, the applicant had sufficient cash and assets to fund the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides letters from appropriate company officials documenting the availability of funding for the projected capital and working capital needs of the project as well as a commitment to use those funds toward the development of the proposed project.
- The applicant provides documentation filed with the US Securities and Exchange Commission showing availability of sufficient funds.

## **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses by the third full fiscal year following project completion, as shown in the table below.

Revenues and Operating Expenses – Aveanna						
	FY 1 (CY 2025)	FY 2 (CY 2026)	FY 3 (CY 2027)			
Total Visits	13,805	22,473	32,787			
Total Gross Revenues (Charges)	\$2,235,797	\$3,748,789	\$5,633,450			
Total Net Revenue	\$1,682,948	\$2,821,820	\$4,240,458			
Total Net Revenue per Visit	\$122	\$126	\$129			
Total Operating Expenses (Costs)	\$1,757,634	\$2,863,298	\$4,078,334			
Total Operating Expenses per Visit	\$127	\$127	\$124			
Net Profit/(Loss)	(\$74,686)	(\$41,478)	\$162,123			

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.5 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant relies on its own experience in providing care at a different HHA in North Carolina to project financial feasibility.
- The applicant provides adequate explanation for line items not included in the financial pro formas.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

## Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## **Capital and Working Capital Costs**

On Form F.1a in Section Q, the applicant projects capital costs as shown in the table below.

Non-Medical Equipment	\$33,419
Furniture	\$29,592
Consultant Fees	\$37,000
Non-Medical Equipment/Furniture Contingency	\$15,002
Total	\$115,013

Immediately following Form F.1a in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because the applicant provides line-item costs of equipment and furniture.

In Section F, page 68, the applicant projects that start-up costs will be \$276,904 and initial operating expenses will be \$1,000,000 during an 18-month initial operating period for a total working capital of \$1,276,904. In Section F, page 69, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

• The applicant explains what the start-up and initial operating costs are and describes what they are based on.

## **Availability of Funds**

In Section F, pages 66-67 and 70, the applicant states the entire projected capital cost of \$115,013 and projected working capital cost of \$1,276,904 will be funded entirely by the applicant's accumulated reserves.

In Exhibit F.2 (and in identical Exhibit F.3), the applicant provides a letter dated October 10, 2023 from the Chief Financial Officer of BAYADA, stating that BAYADA has available funds for the proposed project and has committed to using the funds to develop the proposed project. The applicant also provides a letter dated October 10, 2023, from a Senior Vice President for Corporate Banking at Citizens Commercial Banking, stating that BAYADA is a client of Citizens Commercial Bank, and stating that the applicant has significant deposits and has enough money in its accounts to fund both the proposed capital and working capital costs.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides letters from an appropriate company official documenting the availability of funding for the projected capital and working capital needs of the project as well as a commitment to use those funds toward the development of the proposed project.
- The applicant provides documentation from a bank where the applicant has accounts showing availability of sufficient funds.

## **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses in the second and third full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – BAYADA						
	FY 1 (FFY 2025)	FY 2 (FFY 2026)	FY 3 (FFY 2027)			
Total Visits	15,027	27,832	38,938			
Total Gross Revenues (Charges)	\$3,354,765	\$6,213,063	\$8,692,321			
Total Net Revenue	\$2,029,633	\$3,758,903	\$5,258,854			
Total Net Revenue per Visit	\$135	\$135	\$135			
Total Operating Expenses (Costs)	\$2,339,656	\$3,660,719	\$5,129,552			
Total Operating Expenses per Visit	\$156	\$132	\$132			
Net Profit/(Loss)	(\$310,023)	\$98,185	\$129,302			

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.5 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides detailed calculations showing projected charges and visits used to project revenues and expenses.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

## Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## **Capital and Working Capital Costs**

On Form F.1a in Section Q, the applicant projects capital costs as shown in the table below.

Non-Medical Equipment	\$20,000
Furniture	\$15,000
Consultant Fees	\$50,000
Contingency	\$15,000
Total	\$100,000

Immediately following Form O in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because the applicant relies on its own historical experience developing new Medicare-certified HHAs.

In Section F, page 80, the applicant projects that start-up costs will be \$43,844 and initial operating expenses will be \$1,000,000 during a 14-month initial operating period for a total working capital cost of \$1,043,844. In Section F, pages 81-82, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant provides a categorical breakdown of the various components included in the projection of start-up costs.
- The applicant projects initial operating expenses based on revenues and operating expenses as provided on Form F.2b.

## <u>Availability of Funds</u>

In Section F, pages 78-79 and 82-83, the applicant states the entire projected capital cost of \$100,000 and projected working capital cost of \$1,043,844 will be funded entirely by the applicant's accumulated reserves.

In Exhibit F.2, the applicant provides a letter dated August 25, 2023 from the Chief Executive Officer of Well Care Home Health, Inc., stating that the applicant is a subsidiary company, that Well Care Home Health, Inc. has funds for the proposed project, and a commitment to using the funds to develop the proposed project. The applicant also provides a letter dated August 25, 2023, from a Senior Vice President at Truist Bank, stating that the applicant is a client of Truist and stating that the applicant has enough money in its accounts to fund both the proposed capital and working capital costs up to \$1,750,000.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides letters from an appropriate company official documenting the availability of funding for the projected capital and working capital needs of the project as well as a commitment to use those funds toward the development of the proposed project.
- The applicant provides documentation from a bank where the applicant has accounts showing availability of sufficient funds.

## **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses by the second and third full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – Well Care						
	FY 1 (CY 2025)	FY 2 (CY 2026)	FY 3 (CY 2027)			
Total Visits	9,846	16,788	22,016			
Total Gross Revenues (Charges)	\$952,971	\$3,258,329	\$4,272,319			
Total Net Revenue	\$713,750	\$2,156,260	\$2,618,830			
Total Net Revenue per Visit	\$72	\$128	\$119			
Total Operating Expenses (Costs)	\$1,235,432	\$1,869,732	\$2,365,064			
Total Operating Expenses per Visit	\$125	\$111	\$107			
Net Profit/(Loss)	(\$521,682)	\$286,528	\$253,767			

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form O in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

• The applicant provides detailed calculations showing projected charges and visits used to project revenues.

- The applicant explains the assumptions used to project expenses.
- The applicant relies on its historical experience in operating North Carolina Medicarecertified HHAs.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.
- (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 All Applications

In Chapter 12, page 213, the 2023 SMFP defines the service area for a Medicare-certified home health agency or office as "...the county in which the agency or office is located. Each of the 100 counties in the state is a separate service area." Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

There are currently three Medicare-certified HHAs in Pitt County. Information about each of those agencies is provided below.
License Number	Name	In-County Patients	Out-of-County Patients	Total patients
HC0328	CenterWell Home Health	1,840	746	2,586
HC0509	3HC	457	127	584
HC1443	Vidant Home Health and Hospice	1,009	301	1,310

Source: 2023 SMFP, Table 12A: Inventory of Licensed Medicare-Certified Home Health Agencies or Offices, page 220.

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section G, page 74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing Medicare-certified HHAs in Pitt County. The applicant states:

"The 2023 SMFP includes a need determination for a Medicare-certified home health agency in Pitt County. .... Pitt County has a limited number of in-county home health providers, with just three agencies that have offices in Pitt County currently serving residents of the county. Pitt County residents receive home health services from providers in seven counties besides Pitt, from as far away as Wake County."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2023 SMFP for the proposed Medicare-certified HHA.
- The applicant adequately demonstrates that the proposed Medicare-certified HHA is needed in addition to the existing or approved Medicare-certified HHAs in Pitt County.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section G, page 75, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing Medicare-certified HHAs in Pitt County. The applicant states:

"The 2023 State Medical Facilities Plan identifies a need determination for one Medicare-certified home health agency based on a projected 2024 home health patient deficit of 395.84 patients in Pitt County. The 2023 State Medical Facilities Plan would not have generated a need for an additional Medicare-certified home health agency if the need did not exist and would not duplicate existing home health services.

Additionally, after reviewing the projected increase in population growth and aging in the service area, increase in Pitt County life expectancies, and the utilization of home health services in the service area, support for an additional home health agency in Pitt County exists."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2023 SMFP for the proposed Medicare-certified HHA.
- The applicant adequately demonstrates that the proposed Medicare-certified HHA is needed in addition to the existing or approved Medicare-certified HHAs in Pitt County.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described above.

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section G, page 88, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing Medicare-certified HHAs in Pitt County. The applicant states:

"As evidenced by the need determination for an additional Medicare-certified home health agency in Pitt County in the 2023 SMFP, the projected number of Pitt County patients who will need home health services will exceed the projected number of patients to be served by existing providers. The State considers the existing home health agencies serving Pitt County inadequate to meet the growing demand for home health services by Pitt County residents and has determined a need for one additional home health agency.

...

For these reasons, the proposed new home health agency will not result in any unnecessary duplication of the existing home health agencies located in Pitt County."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2023 SMFP for the proposed Medicare-certified HHA.
- The applicant adequately demonstrates that the proposed Medicare-certified HHA is needed in addition to the existing or approved Medicare-certified HHAs in Pitt County.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 all the reasons described 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 All Applications

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

2023 Pitt Home Health Review
Project ID #'s: Q-12445-23; Q-12451-23, Q-12456-23
Page 40

Aveanna – Projected FTEs					
FY 1 (CY 2026) FY 2 (CY 2027) FY 3 (CY 20					
Office Manager (Executive Director)	1.00	1.00	1.00		
Scheduler/Office Support	2.00	4.00	6.00		
Registered Nurses	1.80	3.10	4.40		
Licensed Practical Nurses	1.80	3.10	4.40		
Physical Therapists	1.80	3.05	4.30		
Occupational Therapists	1.10	1.85	2.60		
Speech Therapists	0.20	0.35	0.50		
Physical Therapy Assistant	1.80	3.05	4.30		
Medical Social Workers	0.10	0.15	0.20		
Home Health Aide	0.40	0.65	0.90		
Clinical Manager	1.00	1.00	1.00		
Total	13.00	21.30	29.60		

The assumptions and methodology used to project staffing salaries are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 76-77, the applicant describes the methods it will use to recruit or fill new positions and its proposed training and continuing education programs.

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
- Written comments
- Responses to comments

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

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

2023 Pitt Home Health Review
Project ID #'s: Q-12445-23; Q-12451-23, Q-12456-23
Page 41

BAYADA – Projected FTEs					
FY 1 (FFY 2026) FY 2 (FFY 2027) FY 3 (FFY 20					
Administrator	1.00	1.00	1.00		
Clinical Manager	1.00	1.00	1.00		
Client Services Associates	1.00	1.00	1.00		
RN Transitional Care Manager	1.00	1.00	1.00		
Registered Nurses	2.27	3.41	5.83		
Licensed Practical Nurses	1.34	2.01	3.44		
Physical Therapists	3.75	6.99	9.82		
Speech Therapists	1.72	3.21	4.44		
Occupational Therapists	1.72	3.19	4.48		
Home Health Aides	0.16	0.30	0.42		
Medical Social Worker	0.06	0.12	0.17		
Total	15.03	23.22	32.60		

The assumptions and methodology used to project staffing salaries are provided both before and following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 77-79, the applicant describes the methods it will use to recruit or fill new positions and its existing and proposed training and continuing education programs. Supporting documentation is provided in Exhibits H.2 and H.3.

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
- Written comments
- Responses to comments

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

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Well Care – Projected FTEs					
	FY 1 (CY 2025)	FY 2 (CY 2026)	FY 3 (CY 2027)		
Director of Operations	1.0	1.0	1.0		
Clerical/Medical Records	1.0	1.0	1.0		
Marketing/Business Development	1.0	1.5	2.0		
Clinical Manager	1.0	1.0	1.0		
Medical Social Worker	0.2	0.3	0.4		
Registered Nurses	1.6	2.6	3.4		
Licensed Practical Nurses	1.3	2.3	2.9		
Home Health Aides	0.3	0.5	0.6		
Physical Therapists	1.1	1.8	2.3		
PT Assistants	0.9	1.5	2.0		
Occupational Therapists	0.4	0.7	0.9		
OT Assistants	0.4	0.6	0.7		
Speech Therapists	0.2	0.3	0.4		
Total	10.4	15.1	18.6		

The assumptions and methodology used to project staffing salaries are provided both before and following Form O in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 89-94, the applicant describes the methods it will use to recruit or fill new positions and its existing training and continuing education programs. Supporting documentation is provided in Exhibit H.3.

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
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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 All Applications

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## Ancillary and Support Services

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 79-80, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits C.1-1 and I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently operates two additional Medicare-certified HHAs in North Carolina and has experience with the provision of necessary ancillary and support services.
- In Exhibit I.1, the applicant provides a letter from the Interim President of Home Health and Hospice Operations at Aveanna, committing to providing the necessary ancillary and support services.

## **Coordination**

In Section I, page 80, the applicant describes Aveanna's 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 based on the following:

- The applicant states it has worked to introduce the agency and the proposed plans to the Pitt County community.
- In Exhibit I.2, the applicant provides letters of support from local health care and social service providers documenting their support for Aveanna and the proposed project.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## Ancillary and Support Services

In Section I, page 81, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, page 82, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1 (Tab 11). The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently operates additional Medicare-certified HHAs in North Carolina and has experience with the provision of necessary ancillary and support services.
- In Exhibit I.1, the applicant provides a letter from the Regional Director of BAYADA Home Health Care, Inc., committing to providing the necessary ancillary and support services.
- In Exhibit I.1, the applicant also provides a letter from a provider of ancillary services supporting the proposed project and which states the provider would provide ancillary services to BAYADA.

## **Coordination**

In Section I, page 83, the applicant describes BAYADA's proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2 (Tab 12). The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses the strategies and plans it will use to build relationships with other local health care and social service providers.
- In Exhibit I.2, the applicant provides a letter of support from a local health care provider documenting their support for BAYADA and the proposed project.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

## Ancillary and Support Services

In Section I, page 95, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 95-96, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently operates other Medicare-certified HHAs in North Carolina and has experience with the provision of necessary ancillary and support services that support care transitions from existing healthcare providers, such as ECU Health, to its other markets.
- In Exhibit I.1, the applicant provides letters from potential providers of ancillary and support services that support the project and also offer to provide ancillary and support services to the applicant.

## **Coordination**

In Section I, page 96, the applicant describes Well Care's existing 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 based on the following:

- The applicant currently operates other Medicare-certified HHAs in North Carolina and has established relationships with local health care and social service providers that support care transitions from existing healthcare providers, such as ECU Health, to its other markets.
- In Exhibit I.2, the applicant provides letters of support from local health care and social service providers documenting their support for Well Care and the proposed project.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(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

## All Applications

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. Therefore, Criterion (9) is not applicable to this review.

- (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

## All Applications

None of the applicants are 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.

## NA

## All Applications

None of the applicants propose to construct any new space or make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the healthrelated 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 ... persons [with disabilities], 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;

## NA

## All Applications

None of the applications involve an existing facility in Pitt County. Therefore, Criterion (13a) is not applicable to this review.

(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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

## NA

## All Applications

None of the applications involve an existing facility in Pitt County. Therefore, Criterion (13b) is not applicable to this review.

(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 All Applications

Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section L, page 90, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Aveanna Projected Payor Mix – 3 <sup>rd</sup> FY 2028			
Payor Category % of Total Patients Served			
Self-Pay	2.4%		
Medicare*	58.5%		
Medicaid*	12.2%		
Insurance*	26.8%		
Total	100.0%		

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 2.4% of services will be provided to self-pay patients, 58.5% of services to Medicare patients, and 12.2% of services to Medicaid patients.

In Section L, page 89, the applicant provides the assumptions and methodology used to project the payor mix. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant relied on license renewal application (LRA) data from the three existing Pitt County HHAs to project Medicare payor mix.
- The applicant relied on the historical experience of its existing HHA in Cumberland County for the rest of the payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section L, page 93, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

BAYADA Projected Payor Mix – 3 <sup>rd</sup> FFY 2028			
Payor Category	% of Total Patients Served		
Self-Pay	0.5%		
Medicare*	86.5%		
Medicaid*	10.0%		
Insurance*	2.0%		
Other (Indigent)	1.0%		
Total	100.0%		

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 0.5% of services will be provided to self-pay patients, 86.5% of services to Medicare patients, and 10.0% of services to Medicaid patients.

In Section L, pages 93-94, and in Section Q, Form C.5 *Home Health Patient and Visit Methodology and Assumptions* Step 6, the applicant provides the assumptions and methodology used to project the payor mix. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant provides the timeline for licensure, certification, and admission of patients from different payors that forms the basis of its projections.
- The applicant relied on its historical experience.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section L, page 105, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Well Care Projected Payor Mix – 3 <sup>rd</sup> FY (CY2027)			
Payor Category	% of Total Patients Served		
Charity Care	1.0%		
Medicare*	79.5%		
Medicaid*	12.0%		
Insurance*	6.5%		
TRICARE	1.0%		
Total	100.0%		

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 1% of services will be provided to charity care patients, 79.5% of services to Medicare patients, and 12% of services to Medicaid patients.

In Section L, pages 105-107, the applicant provides the assumptions and methodology used to project the payor mix. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant relies on its historical experience with its existing home care experience via Well Care Home Health, Inc. in Pitt County.
- The applicant adjusted its projections based on the demographics of Pitt County.
- The applicant explains why changes in the Medicaid program impacted its projections.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(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 All Applications

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section L, page 91, the applicant adequately describes the range of means by which patients will have access to the proposed services.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section L, page 96, the applicant adequately describes the range of means by which patients will have access to the proposed services.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section L, page 108, the applicant adequately describes the range of means by which patients will have access to the proposed services.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 All Applications

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section M, page 93, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states it intends to provide students in health professional training programs the opportunity to get hands-on experience.
- In Exhibit M.1, the applicant provides copies of letters it has sent to several colleges and programs that are in the Pitt County area, offering their agency as a potential option for students.

## Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section M, page 98, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states any health professional training programs in the area will have access to BAYADA for training.
- In Exhibit M.1, the applicant provides copies of letters it sent to several colleges and programs that are in the Pitt County area, offering their agency as a potential option for students.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

In Section M, page 109, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states that health professional training programs in the area will have access to Well Care for training and that Well Care already collaborates with various training programs in North Carolina via its other home health agencies.
- In Exhibit M.2, the applicant provides a letter from Coastal Carolina Community College, offering support for the proposed project and discussing plans for expanding the existing clinical training agreement to include the proposed new Pitt County home health agency.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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.

# С

# All Applications

In Chapter 12, page 213, the 2023 SMFP defines the service area for a Medicare-certified home health agency or office as "...the county in which the agency or office is located. Each of the 100 counties in the state is a separate service area." Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

There are currently three Medicare-certified HHAs in Pitt County. Information about each of those agencies is provided below.

License Number	Name	In-County Patients	Out-of-County Patients	Total patients
HC0328	CenterWell Home Health	1,840	746	2,586
HC0509	3HC	457	127	584
HC1443	Vidant Home Health and Hospice	1,009	301	1,310

Source: 2023 SMFP, Table 12A: Inventory of Licensed Medicare-Certified Home Health Agencies or Offices, page 220.

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 94, the applicant states:

"Aveanna's proposed project is expected to enhance competition in the service area. As a high quality provider of home health care for over three decades, Aveanna has the experience and expertise to promptly establish a Medicare-certified agency in Pitt County, expand access to home health services, ensure access by the medically underserved, and promote competition as a new home health alternative for Pitt County residents. The proposed project will better meet the needs of Pitt County patients in need of home health services by expanding the list of available home health providers, ensuring convenient access to home health services and timely provision of care to the communities throughout Pitt County."

Regarding the impact of the proposal on cost effectiveness, in Section B, on page 28, the applicant states:

..., Aveanna has invested in state-of-the-art documentation, technology, recruitment, hiring and training programs and procedures. Lastly, the proposed Medicare-certified agency will achieve some operational efficiencies through the sharing of various resources with its existing licensed home health agencies, including IT infrastructure, policies and procedures, billing and collections, and other administrative functions, thereby making the Aveanna proposal a cost-effective one."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section B, on page 26, the applicant states:

"Aveanna believes that the proposed project will promote safety and quality in the delivery of healthcare services. As an established provider of home health services and private duty nursing services both in North Carolina and nationwide, Aveanna is known for providing high quality services and expects the proposed project to expand its delivery of home health services while upholding its high-quality reputation."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section B, on page 28, the applicant states:

"..., patients are admitted for care without regard to race, color, age, religion, gender, sexual orientation, marital status, sexual preference, age, national origin, veteran status, disability, communicable disease, or national origin. For the purpose of serving the uninsured and indigent, Aveanna has an established policy for admitting and providing care to patients unable to pay for services."

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on all the reasons described above.

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 100, the applicant states:

"The proposed project will enhance competition because the office will be costeffective based on economies of scale and the existing availability of corporate resources such as staff training and an ongoing national recruitment campaign. BAYADA excels in the recruitment of highly trained staff and can afford to pay highly competitive salaries because as a nonprofit it is focused on delivering excellent service with compassion, excellence, and reliability."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 101, the applicant states:

"The BAYADA office will have a core staff of highly skilled and experienced home health personnel that can quickly implement services and achieve high utilization in the initial months of operation. High utilization reduces the fixed cost per visit and translates to greater cost effectiveness. Offering an extensive array of treatment options

and advanced therapies supports the development of the most appropriate plan of care, resulting in cost savings and better patient outcomes."

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 101-102, the applicant states:

"The proposed BAYADA Home Health office in Greenville will promote safety and quality based on implementation of a new home health office that fully complies with licensure requirements and CMS quality reporting programs. ... The BAYADA Home Health Quality Assurance and Performance Improvement Plan is comprehensive and includes North Carolina specific standards that relate to the random sample of active and closed client records. The BAYADA Annual Program Review demonstrates that the evaluation is agency specific, criteria based, and multi-disciplinary in scope."

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 102, the applicant states:

"BAYADA maintains a non-discriminatory policy and serves all patients regardless of age, race, color, creed, national origin, disability, sex, or ability to pay. The proposed home health office will provide care to all persons, consistent with the availability of qualified staff. The BAYADA Home Health and Home Care offices in North Carolina serve patients that are un-insured, under-insured, self-pay, and indigent. The proposed home health office will provide care to these patients. BAYADA does not discriminate and currently serves many home care patients with physical disabilities."

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on all the reasons described above.

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110, the applicant states:

"The proposed project to develop a new Medicare-certified home health agency in Pitt County will promote competition in the service area because it will establish a new Medicare-certified home health agency in Pitt County operated by an experienced, high-quality provider. Well Care determined its proposed agency will result in a greater level of efficiency and access for patients, referral sources, and staff to serve its existing and projected patient volume from Pitt County."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 110-111, the applicant states:

"This project will have a positive impact on the cost effectiveness of services, as the development of a new Medicare-certified home health agency in Pitt County will not increase the charges or projected reimbursement for these services, which are established by Medicare, Medicaid, and/or existing private payor contracts.

•••

Well Care has made concerted efforts to control its costs in order to provide services at the lowest reasonable cost to Pitt County residents.

•••

..., Well Care Health can leverage its current staffing and experience with its Intake, Quality Assurance, Performance Improvement, Education, Finance, and other support departments to glean efficiencies and ensure operational success with the addition of home health services in Pitt County."

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 111-112, the applicant states:

"Well Care is dedicated to ensuring quality care and patient safety through compliance with all applicable licensure and certification standards established in regard to home health agencies. Well Care will maintain the highest standards and quality of care, consistent with the high standard that it has sustained throughout its history of providing home health services.

...

Well Care's New Hanover, Davie and Wake County home health agencies received a 5 Star Quality Rating from CMS and exceeds statewide and national averages for many quality measures."

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 112, the applicant states:

"Well Care will ensure that its home health services are available and accessible by any patient having a clinical need for such services.

As a certified provider under Title XVIII (Medicare), Well Care will provide its services to the elderly. Services to low-income persons will be provided by Well Care as a certified provider under Title XIX (Medicaid). Well Care will continue to be a participating Medicare and Medicaid provider to serve the elderly and medically indigent populations in Pitt County and surrounding communities.

..., [the applicant] will comply with applicable Federal civil rights laws and will not discriminate on the basis of race, color, national origin, age, disability, gender, or sexual orientation. [The applicant] will not exclude people or treat them differently because of race, color, national origin, age, disability, gender, or sexual orientation."

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on all the reasons described 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 All Applications

# Project ID #Q-12445-23/Aveanna/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

On Form O in Section Q, the applicant identifies the Medicare-certified HHAs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of two Medicare-certified HHAs located in North Carolina.

In Section O.5, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy at either of the Medicare-certified HHAs listed on Form O. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care that occurred in either of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and considering the quality of care provided at both Medicare-certified HHAs, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

# Project ID #Q-12451-23/BAYADA/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

On Form O in Section Q, the applicant identifies the Medicare-certified HHAs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 11 Medicare-certified HHAs located in North Carolina.

In Section O, page 108, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy at any of the Medicare-certified HHAs listed on Form O. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, 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 all 11 Medicare-certified HHAs, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

# Project ID #Q-12456-23/Well Care/Develop a Medicare-certified HHA

The applicant proposes to develop a new Medicare-certified HHA in Pitt County.

On Form O in Section Q, the applicant identifies the Medicare-certified HHAs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of five Medicare-certified HHAs located in North Carolina.

In Section O, page 116, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy at any of the Medicare-certified HHAs listed on Form O. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, 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 all five Medicare-certified HHAs, 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.

G.S. 131E-183(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.

## С

## All Applications

The Criteria and Standards for Home Health Services, promulgated in 10A NCAC 14C .2000, are applicable to all applications in this review.

## 10A NCAC 14C .2003 PERFORMANCE STANDARDS

An applicant proposing to develop a new Medicare-certified home health agency pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization for each of the first three full fiscal years of operation following completion of the project;
- -C- Aveanna. On Form C.5 in Section Q, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project.
- -C- **BAYADA.** On Form C.5 in Section Q, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project.
- -C- Well Care. On Form C.5 in Section Q, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project.
- (2) project to serve at least 325 residents of the proposed service area during the third full fiscal year of operation following completion of the project; and
- -C- Aveanna. On Form C.5 in Section Q, the applicant projects to serve at least 325 residents of the proposed service area during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- **BAYADA.** On Form C.5 in Section Q, the applicant projects to serve at least 325 residents of the proposed service area during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- Well Care. On Form C.5 in Section Q, the applicant projects to serve at least 325 residents of the proposed service area during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (3) provide the assumptions and methodology used to provide the projected utilization required in Item (1) of this Rule.

- -C- Aveanna. In Section Q, pages 103-109, Form C Utilization Assumptions and Methodology the applicant provides the assumptions and methodology used to provide the projected utilization required in Item (1) of this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- **BAYADA.** In the Home Health Patient and Visit Methodology and Assumptions subsection of Section Q, immediately following Form C.5, the applicant provides the assumptions and methodology used to provide the projected utilization required in Item (1) of this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- Well Care. In Section Q, Form C.5 Home Health Utilization Assumptions and Methodology, pages 121-135, the applicant provides the assumptions and methodology used to provide the projected utilization required in Item (1) of this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

## **COMPARATIVE ANALYSIS**

Pursuant to G.S. 131E-183(a)(1) and the 2023 SMFP, no more than one Medicare-certified home health agency or office may be approved for Pitt County in this review. Because the three applications in this review collectively propose to develop three additional Medicare-certified home health agencies or offices, all the applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- Project ID # Q-12445-23/Aveanna/Develop a Medicare-certified home health agency
- Project ID # G-12451-23/**BAYADA**/Develop a Medicare-certified home health agency
- Project ID # G-12456-23/Well Care/Develop a Medicare-certified home health agency

## **Conformity with Statutory and Regulatory Review Criteria**

All applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, all applications are equally effective alternatives.

## **Scope of Services**

Generally, the application proposing to provide the broadest scope of services is the more effective alternative with regard to this comparative factor. With regard to scope of services, all of the applications submitted are in response to the need determination in the 2023 SMFP for one Medicare-certified home health agency in Pitt County. All of the applicants propose to develop one Medicare-certified home health agency in Pitt County. Regarding this comparative factor, all of the applicants are equally effective alternatives.

## Access by Service Area Residents

The 2023 SMFP defines the service area for home health agency or office as "... the county in which the agency or office is located. Each of the 100 counties in the state is a separate service area." Thus, the service area for this review is Pitt County. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for an additional Medicare-certified home health agency or office in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Number and Percentage of Service Area Unduplicated Residents Projected to be Served in Pitt County, 3 <sup>rd</sup> Full Fiscal Year					
Applicant# of Pitt CountyTotal #% of TotalResidentsof ResidentsResidentsResidents					
Aveanna	1,036	1,407	73.6%		
BAYADA	1,397	1,491	93.7%		
Well Care	672	1,034	65.0%		

Source: Tables in Section C.3 of the respective applications.

As shown in the table above, **BAYADA** projects to serve both the highest number and percentage of service area residents during the third full fiscal year following project completion. Therefore, regarding projected service to residents of the service area, the application submitted by **BAYADA** is the most effective alternative.

## Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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."

## **Projected Access by Medicaid Recipients**

For each applicant in this review, the following table compares: a) the total number of unduplicated patients in the third full fiscal year of operation; b) the number of unduplicated Medicaid patients in the third full fiscal year of operation; and c) unduplicated Medicaid patients as a percentage of total unduplicated patients. Generally, the application proposing the higher number of Medicaid patients is the more effective alternative with regard to this comparative factor.

3 <sup>rd</sup> Full Fiscal Year					
Applicant	Total Number of Unduplicated Patients	Total Number of Unduplicated Medicaid Patients	Unduplicated Medicaid Patients as Percentage of Total		
Aveanna	1,407	169	12.0%		
BAYADA	1,491	149	10.0%		
Well Care	1,034	67	6.5%		

Source: The total number of unduplicated patients is from Form C.5 of the applications, and the Medicaid percentage is from Section L.3 of the applications. The number of unduplicated Medicaid patients was calculated by multiplying the Medicaid percentage from the table in Section L.3 to the applicant's projections of total unduplicated patients in the third full fiscal year of operation from Form C.5.

As shown in the table above, **Aveanna** projects to serve the highest percentage and the highest number of unduplicated Medicaid patients in the third full fiscal year of operation. Therefore, the application

submitted by **Aveanna** is the most effective alternative with regard to projected access by Medicaid recipients.

## **Projected Access by Medicare Recipients**

For each applicant in this review, the following table compares: a) the total number of duplicated patients in the third full fiscal year of operation; b) the number of duplicated Medicare patients in third full fiscal year of operation; and c) duplicated Medicare patients as a percentage of total duplicated patients. Generally, the application proposing the highest number of Medicare patients is the more effective alternative with regard to this comparative factor.

3 <sup>rd</sup> Full FY					
Applicant	Total Number of Duplicated Patients	Total Number of Duplicated Medicare Patients	Duplicated Medicare Patients as a Percentage of Total		
			Duplicated Patients		
Aveanna	2,375	1,791	75.4%		
BAYADA	6,080	5,615	92.4%		
Well Care	3,199	1,542	48.2%		

Source: Form, C.5 of the applications

As shown in the table above, **BAYADA** projects to serve the highest number and the highest percentage of duplicated Medicare patients in the third full fiscal year of operation. The application submitted by **BAYADA** is the most effective alternative with regard to projected access by Medicare recipients.

## **Competition, Access to a New or Alternative Provider**

The following table illustrates the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer Medicare-certified home health agencies or offices than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

License Number	Name	In-County Patients	Out-of-County Patients	Total patients
HC0328	CenterWell Home Health	1,840	746	2,586
HC0509	3HC	457	127	584
HC1443	Vidant Home Health and Hospice	1,009	301	1,310

Source: 2023 SMFP, Table 12A: Inventory of Licensed Medicare-Certified Home Health Agencies or Offices, page 220.

As shown in the table above, there are three providers of Medicare-certified home health agencies or offices in Pitt County. None of the applicants currently operate a Medicare-certified home health agency or office located in Pitt County. Therefore, all of the applicants are equally effective alternatives with regard to this comparative factor.

## Average Number of Visits per Unduplicated Patient

The majority of home health care services are covered by Medicare, which does not reimburse on a per visit basis. Rather, Medicare reimburses on a per episode basis. Thus, there is a financial disincentive to providing more visits per Medicare episode. The following table shows the average number of visits per unduplicated patient projected by each applicant in the third full fiscal of operation. Generally, the application proposing the highest number of visits per unduplicated patient is the more effective alternative with regard to this comparative factor.

3 <sup>rd</sup> Full FY					
Total Number of Applicant Unduplicated Patients		Total Projected Number of Visits	Average Number of Visits per Unduplicated Patient*		
Aveanna	1,407	32,787	23.3		
BAYADA	1,491	38,938	26.1		
Well Care	1,034	22,016	21.3		

Source: Form C.5 of the applications.

\*The average number of visits per unduplicated patient was calculated by dividing the projected number of visits by the applicant's projections of total unduplicated patients in the third full fiscal year of operation.

As shown in the table above, **BAYADA** projects the highest average number of visits per unduplicated patient in the third full fiscal year of operation. Therefore, the application submitted by **BAYADA** is the most effective alternative with regard to the projected number of visits per unduplicated patient.

## Projected Average Net Revenue per Visit

The following table compares projected average net revenue per visit in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average net revenue per visit is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

3 <sup>rd</sup> Full FY					
Applicant	Total Projected Number of Visits	Total Net Revenue	Average Net Revenue per Visit		
Aveanna	32,787	\$4,240,458	\$129.33		
BAYADA	38,938	\$5,258,854	\$135.06		
Well Care	22,016	\$2,618,830	\$118.95		

Source: Form C.5 and Form F.2b of the applications

As shown in the table above, **Well Care** projects the lowest average net revenue per visit in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Well Care** is the most effective alternative.

## **Projected Average Net Revenue per Unduplicated Patient**

Average net revenue per unduplicated patient in the third full fiscal year of operation was calculated by dividing projected net revenue (Form F.2b) by the projected number of unduplicated patients from Form C.5 of the applications, as shown in the table below. Generally, the application proposing the lowest average net revenue per unduplicated patient is the more effective alternative with regard to the comparative factor.

3 <sup>rd</sup> Full FY					
Applicant	Total Number of Unduplicated	Total Net Revenue	Average Net Revenue per Unduplicated Patient		
Applicant	Patients				
Aveanna	1,407	\$4,240,458	\$3,013.83		
BAYADA	1,491	\$5,258,854	\$3,527.07		
Well Care	1,034	\$2,618,830	\$2,532.72		

Source: Form C.5 and Form F.2b of the application

As shown in the table above, **Well Care** projects the lowest average net revenue per unduplicated patient in the third full fiscal year of operation. Therefore, the application submitted by **Well Care** is the most effective alternative with regard to average net revenue per unduplicated patient.

## **Projected Average Total Operating Cost per Visit**

The following table compares projected average operating expense per visit in the third full fiscal year following project completion for each agency. Generally, regarding this factor, the application proposing the lowest average operating expense per visit is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

3 <sup>rd</sup> Full FY					
Applicant	Total Projected Number of Visits	Total Operating Expenses	Average Operating Cost per Visit		
Aveanna	32,787	\$4,078,334	\$124.39		
BAYADA	38,939	\$5,129,552	\$131.73		
Well Care	22,016	\$2,365,064	\$107.42		

Source: Form C.5 and Form F.3b of the applications

As shown in the table above, **Well Care** projects the lowest average operating expense per visit in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Well Care** is the most effect alternative.

## Ratio of Average Net Revenue per Visit to Average Total Operating Cost per Visit

The ratios in the table below were calculated by dividing the average net revenue per visit in the third full fiscal year of operation by the average total operating expenses per visit. Generally, the application proposing the lowest ratio is the more effective alternative with regard to this comparative factor. However, the ratio must equal one or greater in order for the proposal to be financially feasible. The applications are listed in the table below.

3 <sup>rd</sup> Full FY					
Applicant	Average Net Revenue per Visit	Average Total Operating Cost per Visit	Ratio of Average Net Revenue to Average Total Operating Cost per Visit*		
Aveanna	\$129.33	\$124.39	1.04		
BAYADA	\$135.06	\$131.73	1.03		
Well Care	\$118.95	\$107.42	1.11		

Source: Form C.5 and Form F.2b and F.3b of the applications

\*average net revenue per visit/ average total operating cost per visit

As shown in the table above, **BAYADA** projects the lowest ratio of average net revenue per visit to average total operating cost per visit in the third full fiscal year of operation. Therefore, the application submitted by **BAYADA** is the most effective alternative with regard to the projected ratio of average net revenue per visit to average total operating cost per visit in the third full fiscal year of operation.

## Nursing and Home Health Aide Salaries

The tables below compare the proposed annual salary for registered nurses, licensed practical nurses and home health aides in the third full fiscal year of operation, as reported by the applicants in Form H of the application. Generally, the application proposing the highest annual salary is the more effective alternative with regard to this comparative factor.

Average Annual Salaries – 3 <sup>rd</sup> Full Fiscal Year					
Applicant	Registered	Licensed Practical	Home Health		
Applicant	Nurses	Nurses	Aides		
Aveanna	\$110,125	\$70,232	\$55,062		
BAYADA	\$111,824	\$69 <i>,</i> 566	\$48,026		
Well Care	\$108,726	\$71,843	\$46,987		

Source: Form H from each application

Salaries are a significant contributing factor in recruitment and retention of staff. As shown in the tables above, **BAYADA** projects the highest average annual salary for registered nurses, **Well Care** projects the highest average annual salary for licensed practical nurses and **Aveanna** projects the highest average annual salary for home health aide positions in the third full fiscal year of operation. Therefore, the applications submitted by **BAYADA**, **Well Care** and **Aveanna** are all equally effective alternatives with regard to average annual salaries.

## Summary

The following table lists the comparative factors and indicates whether each application was determined most effective, more effective, less effective or least effective with regard to the factor.

Comparative Factor	Aveanna	BAYADA	Well Care
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective	Equally Effective
Scope of	Equally	Equally	Equally
Services	Effective	Effective	Effective
Access by Service Area Residents	Less Effective	More Effective	Less Effective
Projected Access-Medicaid Recipients	More Effective	Less Effective	Less Effective
Projected Access -Medicare Recipients	Less Effective	More Effective	Less Effective
Competition, Access to a New or Alternative Provider	Equally Effective	Equally Effective	Equally Effective
Average Number of Visits per Unduplicated Patient	Less Effective	More Effective	Less Effective
Projected Average Net Revenue per Visit	Less Effective	Less Effective	More Effective
Projected Average Net Revenue per Unduplicated Patient	Less Effective	Less Effective	More Effective
Projected Average Total Operating Cost per Visit	Less Effective	Less Effective	More Effective
Ratio of Average Net Revenue per Visit to Average Total Operating Cost per Visit	Less Effective	More Effective	Less Effective
Nursing and Home Health Aide Salaries	Equally Effective	Equally Effective	Equally Effective

All of the applications are conforming to all applicable statutory and regulatory review criteria, and thus approvable standing alone. All three applications propose a total of three Medicare-certified home health agencies or offices, and the need determination is for only one Medicare-certified home health agency or office. Therefore, only one Medicare-certified home health agency or office can be approved.

As shown in the table above, **BAYADA** was determined to be the most effective or more effective alternative for the following four comparative factors:

- Access by Service Area Residents
- Projected Access- Medicare Recipients
- Average Number of Visits per Unduplicated Patient
- Ratio of Average Net Revenue per Visit to Average Total Operating Cost per Visit

As shown in the table above, **Well Care** was determined to be the most effective or more effective alternative for the following three comparative factors:

- Projected Average Net Revenue per Visit
- Projected Average Net Revenue per Unduplicated Patient
- Projected Average Total Operating Cost per Visit

As shown in the table above, **Aveanna** was determined to be the most effective or more effective alternative for the following comparative factor:

• Projected Access-Medicaid Recipients

## DECISION

Each application is individually conforming to the need determination in the 2023 SMFP for one Medicare-certified home health agency in Pitt County. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of Medicare-certified home health agencies that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **BAYADA** is the most effective alternative proposed in this review for the development of one Medicare-Certified home health agency and is approved.

While the applications submitted by **Aveanna** and **Well Care** are approvable standing alone, the approval of all three applications would result in the approval of more Medicare-certified home health agencies than are determined to be needed, and therefore, the applications submitted by **Aveanna** and **Well Care** are denied.

The application submitted by **BAYADA**, Project ID# Q-12451-23, is approved subject to the following conditions:

- **1.** BAYADA Home Health Care, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall develop one Medicare-certified home health agency or office in Pitt County pursuant to the need determination in the 2023 SMFP.
- 3. Upon completion of the project, the certificate holder shall be licensed for no more than one new Medicare-certified home health agency or office in Pitt County.
- 4. Progress Reports:
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <u>https://info.ncdhhs.gov/dhsr/coneed/progressreport.html</u>.
  - b. The certificate holder shall complete all sections of the Progress Report form.
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
  - d. The first progress report shall be due on October 1, 2024.
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

6. The certificate holder 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.