Project Description:

Three new separately licensed single specialty ambulatory surgical facilities with two operating rooms each.

CRITERIA	CRITERIA BASIC PRINCIPLE AND THE RATIONALE
 Establish a special need determination for three new separately licensed single specialty ambulatory surgical facilities with two operating rooms each, such that there is a need identified for one new ambulatory surgical facility in each of the three following service areas: Mecklenburg, Cabarrus, Union counties (Charlotte Area) Guilford, Forsyth counties (Triad) Wake, Durham, Orange counties (Triangle) 	Value At least one county in each of the groups of counties has a current population greater than or equal to 200,000 and more than 50 total ambulatory/shared operating rooms and at least 1 separately licensed Ambulatory Surgery Center. Locating facilities in high population areas with a large number of operating rooms and existing ambulatory surgery providers prevents the facilities from harming hospitals in rural areas, which need revenue from surgical services to offset losses from other necessary services such as emergency department services.
In choosing among competing demonstration project facilities, priority will be given to facilities which are owned wholly or in part by physicians.	Value Giving priority to demonstration project facilities owned wholly or in part by physicians is an innovative idea with the potential to improve safety, quality, access and value. Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
 Each demonstration project facility shall provide care to the indigent population, as described below: The percentage of the facility's total revenue that is attributed to self-pay and Medicaid revenue shall be at least seven percent, which shall be calculated as follows: The Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid cases divided by the total revenues for all surgical cases performed in the facility. Following are examples of the calculation of self pay and Medicaid revenue: 	Access Requiring service to indigent patients promotes equitable access to the services provided by the demonstration project facilities.

CRITERIA	CRITERIA BASIC PRINCIPLE AND THE RATIONALE
If Medicare allows \$300 for a surgical procedure and a self-pay patient pays the facility \$0, \$300 is considered self-pay revenue.	
If Medicare allows \$300 for a surgical procedure and a self-pay patient pays the facility \$50, \$250 is considered self-pay revenue.	
If Medicare allows \$300 for a surgical procedure and Medicaid pays the facility \$225, then \$75 is considered Medicaid revenue.	
Demonstration project facilities shall report utilization and payment data to the statewide data processor as required by G.S. 131E-214.2.	
The Agency will monitor compliance with indigent care requirements by analyzing payment data submitted by the facilities.	
Demonstration project facilities shall complete a "Surgical Safety Checklist (adapted for use in the US)" before each surgery is performed. Note: "Surgical Safety Checklist is based on the WHO Surgical Safety Checklist developed by: World Health Organization"	Safety and Quality Implementing a system for measuring and reporting quality promotes identification and correction of quality of care issues and overall improvement in the quality of care provided.
Each demonstration project facility shall develop a system to measure and report patient outcomes to the Agency for the purpose of monitoring the quality of care provided in the facility. If patient outcome measures are available for a facility's particular surgical specialty, the facility shall identify those measures and may use them for reporting patient outcomes. If patient outcome measures are not available, the facility shall	
develop its own patient outcome measures that will be reported	

CRITERIA	CRITERIA BASIC PRINCIPLE AND THE RATIONALE
to the Agency. Demonstration project facilities shall submit annual reports to the Agency regarding the results of patient outcome measures. Examples of patient outcome measures include: wound infection rate, post-operative infections, post- procedure complications, readmission, and medication errors.	
Demonstration project facilities are encouraged to develop systems which will enhance communication and ease data collection, for example, electronic medical records that support interoperability with other providers.	Safety and Quality, Access, Value Electronic medical records improve the collection of quality and access to care data and collecting data is the first step in monitoring and improving quality of care and access. Interoperability facilitates communication among providers, enhancing care coordination.
Demonstration project facilities are encouraged to provide open access to physicians.	Access Services will be accessible to a greater number of surgical patients if the facility has an open access policy for physicians.
Physicians affiliated with the demonstration project facilities are required to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities, with the following caveat:	Safety and Quality Encouraging physicians to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities helps prevent a decrease in the quality of the overall healthcare system resulting from lack of
This requirement has to be available to the physicians and not denied based upon charges that physicians are engaging in competitive behavior by providing services at a facility that is perceived to be in competition with the hospital if it is so happens that the CON is issued to an organization other than the hospital.	resources.
Facilities shall obtain a license no later than two years from the date of issuance of the certificate of need, unless this requirement is changed in a subsequent State Medical Facilities Plan.	Access and Value Timely project completion increases access to services and enhances project value.
The Single Specialty Ambulatory Surgery Work Group values the collective wisdom of the North Carolina Hospital Association and the North Carolina Medical Society and	Safety and Quality, Access and Value Collaboration between the North Carolina Hospital Association and the North Carolina Medical Society in an effort to develop

requests that the two organizations work together to assist the demonstration project facilities in developing quality measures and increasing access to the underserved. Facility's compliance with the demonstration project criteria in the State Medical Facilities Plan. The Agency may specify the reporting requirements and reporting format. The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility therafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a precified neriod of time repardless of the results of the data	CRITERIA	CRITERIA BASIC PRINCIPLE AND THE RATIONALE
demonstration project facilities in developing quality measures and increasing access to the underserved. all three Basic Principles. Facilities will provide annual reports to the Agency showing the facility's compliance with the demonstration project criteria in the State Medical Facilities Plan. The Agency may specify the reporting requirements and reporting format. Safety and Quality, Access, Value The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specially ambulatory surgical facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Atorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a	requests that the two organizations work together to assist the	quality measures and increase access to the underserved promotes
 Facilities will provide annual reports to the Agency showing the facility's compliance with the demonstration project criteria in the State Medical Facilities Plan. The Agency may specify the reporting requirements and reporting format. Safety and Quality, Access, Value Timely monitoring enables the Agency to determine if facilities fail to meet criteria and to take corrective action if facilities fail to meet criteria. This ensures that all three Basic Principles are met by the demonstration project criteria. The Agency will perform an evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 	demonstration project facilities in developing quality measures	all three Basic Principles.
 facility's compliance with the demonstration project criteria in the State Medical Facilities Plan. The Agency may specify the reporting requirements and reporting format. The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that a facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 	and increasing access to the underserved.	
 the State Medical Facilities Plan. The Agency may specify the reporting requirements and reporting format. The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility threafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 	Facilities will provide annual reports to the Agency showing the	Safety and Quality, Access, Value
reporting requirements and reporting format. The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility threafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a	facility's compliance with the demonstration project criteria in	Timely monitoring enables the Agency to determine if facilities
The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a		are meeting criteria and to take corrective action if facilities fail to
The Agency will perform an evaluation of each facility at the end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a	reporting requirements and reporting format.	meet criteria. This ensures that all three Basic Principles are met
 end of the first calendar year the facility is in operation and will perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 		by the demonstration project facilities.
 perform an annual evaluation of each facility thereafter. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 	The Agency will perform an evaluation of each facility at the	
Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a		
 that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 	perform an annual evaluation of each facility thereafter. The	
 towards meeting the demonstration project criteria. The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 		
The Agency will evaluate each facility after each facility has been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a		
 been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 	towards meeting the demonstration project criteria.	
 been in operation for five years. If the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 		
 the facilities are meeting or exceeding all criteria, the work group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 group encourages the State Health Coordinating Council to consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 	· · · ·	
 consider allowing expansion of single specialty ambulatory surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 surgical facilities beyond the original three demonstration sites. The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 		
 The Agency may require corrective action if the Agency determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) Award time limited CONs, that is, CONs that expire after a 		
 determines that a facility is not meeting or is not making good progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 progress towards meeting the demonstration project criteria. Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 Below is a summary of two options the agency has explored, in conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 	progress towards meeting the demonstration project criteria.	
 conjunction with the Attorney General's Office that could be included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 included as a part of the demonstration project. (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
 (The analysis of each option shown below was provided by Jeff Horton.) 1. Award time limited CONs, that is, CONs that expire after a 		
Horton.)1. Award time limited CONs, that is, CONs that expire after a		
1. Award time limited CONs, that is, CONs that expire after a		
-	Horton.)	
-	1 Award time limited CONs that is CONs that expire after a	
	specified period of time, regardless of the results of the data	

CRITERIA	CRITERIA BASIC PRINCIPLE AND THE RATIONALE
provided by the facilities. After the CONs expire, the facilities' licenses shall no longer be valid and shall not be renewed. The SHCC could recommend new need determinations for new single specialty OR demonstration projects for which new CON applications would be filed. CONs for the new single specialty OR demonstration project facilities could not be automatically awarded to the expired demonstration project facilities.	
Analysis: Given it would cost millions of dollars to develop an ambulatory surgical facility as part of the demonstration project, if the CON were to expire, it is unlikely any persons would be willing (or financing institution would be willing to lend money) to develop such a facility since there would be no guarantee the provider could continue to provide services beyond the expiration date.	
2. Rely on existing CON law to enforce compliance with the conditions of the CON. The conditions could include reporting requirements for a specified time period.	
The following is part of current law: If the Agency determines that a facility is not in compliance with any one of the demonstration project criteria, the Department, in accordance with G.S. 131E-190, "may bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized for injunctive relief, temporary or permanent, requiring the recipient, or its successor, to materially comply with the representations in its application. The Department may also bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized to enforce the provisions of this subsection and G.S. 131E-181(b) and the rules adopted in accordance with this subsection and G.S. 131E-181(b)."	

	CRITERIA BASIC PRINCIPLE AND THE RATIONALE
Analysis: The agency believes the current law is sufficient to address shortcomings concerning the inability or unwillingness of a demonstration project provider to comply with conditions contained in the CON. Although each action the agency takes against a provider is handled on a case-by-case basis, we believe invoking enforcement actions, when necessary, will achieve the intended purpose of getting providers to comply with provisions contained in the CON. If the provider is unable or unwilling to comply with the conditions in the CON, enforcement could be used to revoke the CON.	