GENERAL ASSEMBLY OF NORTH CAROLINA 1995 SESSION

CHAPTER 395 SENATE BILL 396

AN ACT TO ENCOURAGE REGULATED ARRANGEMENTS AMONG PHYSICIANS WHEN THE ARRANGEMENT WILL HELP CONTROL COSTS, IMPROVE ACCESS, IMPROVE QUALITY, OR IMPLEMENT MANDATED HEALTH CARE REFORMS.

The General Assembly of North Carolina enacts:

Section 1. This act shall be known as the Physician Cooperation Act of 1995.

Sec. 2. Chapter 90 of the General Statutes is amended by adding the following new Article to read:

"<u>ARTICLE 1E.</u>

"Certificate of Public Advantage.

"§ 90-21.24. Findings.

The General Assembly of North Carolina makes the following findings:

- (1) That technological and scientific developments in health care have enhanced the prospects for further improvement in the quality of care provided to North Carolina citizens.
- (2) That the cost of improved technology and improved scientific methods for the provision of health care contributes substantially to the increasing cost of health care. Cost increases make it increasingly difficult for physicians in rural areas of North Carolina to offer care.
- (3) That cooperative agreements among physicians, hospitals, and others for the provision of health care services may foster improvements in the quality of health care for North Carolina citizens, moderate increases in cost, and improve access to needed services in rural areas of North Carolina.
- (4) That physicians are often in the best position to identify and structure cooperative arrangements that enhance quality of care, improve access, and achieve cost-efficiency in the provision of care.
- (5) That federal and State antitrust laws may prohibit or discourage cooperative arrangements that are beneficial to North Carolina citizens, despite their potential for or actual reduction in competition, and that such agreements should be permitted and encouraged.
- (6) That competition as currently mandated by federal and State antitrust laws should be supplanted by a regulatory program to permit and encourage cooperative agreements between physicians or between physicians, hospitals, and others, that are beneficial to North Carolina

citizens when the benefits of cooperative agreements outweigh their disadvantages caused by their potential or actual adverse effects on competition.

(7) That regulatory as well as judicial oversight of cooperative agreements should be provided to ensure that the benefits of cooperative agreements permitted and encouraged in North Carolina outweigh any disadvantages attributable to any reduction in competition likely to result from the agreements.

"<u>§ 90-21.25. Definitions.</u>

As used in this Article, the following terms have the meanings specified:

- (1) 'Attorney General' means the Attorney General of the State of North Carolina, or any attorney to whom the Attorney General delegates authority and responsibility to act pursuant to this Article;
- (2) 'Cooperative agreement' means an agreement among two or more physicians, or between a physician, hospital, or any other person or persons, for the sharing, allocation, or referral of patients, personnel, instructional programs, support services and facilities, or medical, diagnostic, or laboratory facilities or equipment, or procedures or other services traditionally offered by physicians. Cooperative agreement shall not include any agreement that would permit self-referrals of patients by a health care provider that is otherwise prohibited by law;
- (3) 'Department' means the North Carolina Department of Human Resources;
- (4) 'Federal or State antitrust laws' means any and all federal or State laws prohibiting monopolies or agreements in restraint of trade, including, but not limited to, the federal Sherman Act, Clayton Act, and Federal Trade Commission Act, and the North Carolina laws codified in Chapter 75 of the General Statutes;
- (5) <u>'Hospital' means any hospital required to be licensed under Chapter</u> <u>131E or 122C of the General Statutes;</u>
- (6) 'Person' means any individual, firm, partnership, corporation, association, public or private institution, political subdivision, or government agency;
- (7) 'Physician' means an individual licensed to practice medicine pursuant to Article 1 of this Chapter.

"§ 90-21.26. Certificate of public advantage; application.

(a) A physician and any person who is a party to a cooperative agreement with a physician may negotiate, enter into, and conduct business pursuant to a cooperative agreement without being subject to damages, liability, or scrutiny under any State antitrust law if a certificate of public advantage is issued for the cooperative agreement, or in the case of activities to negotiate or enter into a cooperative agreement, if an application for a certificate of public advantage is filed in good faith. It is the intention of the General Assembly that immunity from federal antitrust laws shall also be conferred by this statute and the State regulatory program that it establishes.

(b) Parties to a cooperative agreement may apply to the Department for a certificate of public advantage governing that cooperative agreement. The application must include an executed written copy of the cooperative agreement or letter of intent with respect to the agreement, a description of the nature and scope of the activities and cooperation in the agreement, any consideration passing to any party under the agreement, and any additional materials necessary to fully explain the agreement and its likely effects. A copy of the application and all additional related materials shall be submitted to the Attorney General at the same time the application is made to the Department.

"§ 90-21.27. Procedure for review; standards for review.

(a) The Department shall review the application in accordance with the standards set forth in subsection (b) of this section and shall hold a public hearing with the opportunity for the submission of oral and written public comments in accordance with rules adopted by the Department. The Department shall determine whether the application should be granted or denied within 90 days of the date of filing of an application. Provided, however, that the Department may extend the review period for a specified period of time upon notice to the parties.

(b) The Department shall determine that a certificate of public advantage should be issued for a cooperative agreement, if it determines that the applicant has demonstrated by clear and convincing evidence that the benefits likely to result from the agreement outweigh the disadvantages likely to result from a reduction in competition from the agreement.

In evaluating the potential benefits of a cooperative agreement, the Department shall consider whether one or more of the following benefits may result from the cooperative agreement:

- (1) Enhancement of the quality of health care provided to North Carolina citizens;
- (2) Preservation of other health care facilities in geographical proximity to the communities traditionally served by those facilities;
- (3) Lower costs of, or gains in the efficiency of delivering, health care services;
- (4) Improvements in the utilization of health care resources and equipment;
- (5) Avoidance of duplication of health care resources; and
- (6) The extent to which medically underserved populations are expected to utilize the proposed services.

In evaluating the potential disadvantages of a cooperative agreement, the Department shall consider whether one or more of the following disadvantages may result from the cooperative agreement:

- (1) The extent to which the agreement may increase the costs or prices of health care at the locations of parties to the cooperative agreement;
- (2) The extent to which the agreement may have an adverse impact on patients in the quality, availability, and price of health care services;

- (3) The extent to which the agreement may reduce competition among the parties to the agreement and the likely effects thereof;
- (4) The extent to which the agreement may have an adverse impact on the ability of health maintenance organizations, preferred provider organizations, managed health care service agents, or other health care payors to negotiate optimal payment and service arrangements with hospitals, physicians, allied health care professionals, or other health care providers;
- (5) The extent to which the agreement may result in a reduction in competition among physicians, allied health professionals, other health care providers, or other persons furnishing health care services; and
- (6) The availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to any reduction in competition.

In making its determination, the Department may consider other benefits or disadvantages that may be identified.

"<u>§ 90-21.28. Issuance of a certificate.</u>

If the Department determines that the likely benefits of a cooperative agreement outweigh the likely disadvantages attributable to reduction of competition as a result of the agreement by clear and convincing evidence, and the Attorney General has not stated any objection to issuance of a certificate during the review period, the Department shall issue a certificate of public advantage for the cooperative agreement at the conclusion of the review period. Such certificate shall include any conditions of operation under the agreement that the Department, in consultation with the Attorney General, determines to be appropriate in order to ensure that the cooperative agreement and activities engaged in pursuant thereto are consistent with this Article and its purpose to limit health care costs. The Department shall include conditions to control prices of health care services provided under the cooperative agreement. Consideration shall be given to assure that access to health care is provided to all areas of the State. The Department shall publish its decisions on applications for certificates of public advantage in the North Carolina Register.

"<u>§ 90-21.29. Objection by Attorney General.</u>

If the Attorney General is not persuaded that the applicant has demonstrated by clear and convincing evidence that the benefits likely to result from the agreement outweigh the likely disadvantages of any reduction of competition to result from the agreement as set forth in G.S. 90-21.27, the Attorney General may, within the review period, state an objection to the issuance of a certificate of public advantage and may extend the review period for a specified period of time. Notice of the objection and any extension of the review period shall be provided in writing to the applicant, together with a general explanation of the concerns of the Attorney General. The parties may attempt to reach agreement with the Attorney General on modifications to the agreement or to conditions in the certificate so that the Attorney General no longer objects to issuance of a certificate. If the Attorney General withdraws the objection and the Department maintains its determination that a certificate should be issued, the Department shall issue a certificate of public advantage with any appropriate conditions as soon as practicable following withdrawal of the objection. If the Attorney General does not withdraw the objection, a certificate shall not be issued.

"§ 90-21.30. Record keeping.

The Department shall maintain on file all cooperative agreements for which certificates of public advantage are in effect and a copy of the certificate, including any conditions imposed. Any party to a cooperative agreement who terminates an agreement shall file a notice of termination with the Department within 30 days after termination. These files shall be public records as set forth in Chapter 132 of the General Statutes.

"§ 90-21.31. Review after issuance of certificate.

If at any time following the issuance of a certificate of public advantage, the Department or the Attorney General has questions concerning whether the parties to the cooperative agreement have complied with any condition of the certificate or whether the benefits or likely benefits resulting from a cooperative agreement may no longer outweigh the disadvantages or likely disadvantages attributable to a reduction in competition resulting from the agreement, the Department or the Attorney General shall advise the parties to the agreement and either the Department or the Attorney General shall request any information necessary to complete a review of the matter.

"§ 90-21.32. Periodic reports.

(a) During the time that a certificate is in effect, a report of activities pursuant to the cooperative agreement must be filed every two years with the Department on or by the anniversary day on which the certificate was issued. A copy of the periodic report shall be submitted to the Attorney General at the same time it is filed with the Department. A report shall include all of the following:

- (1) <u>A description of the activities conducted pursuant to the agreement.</u>
- (2) <u>Price and cost information.</u>
- (3) The nature and scope of the activities pursuant to the agreement anticipated for the next two years and the likely effect of those activities.
- (4) A signed certificate by each party to the agreement that the benefits or likely benefits of the cooperative agreement as conditioned continue to outweigh the disadvantages or likely disadvantages of any reduction in competition from the agreement as conditioned.
- (5) <u>Any additional information requested by the Department or the Attorney General.</u>

<u>The Department shall give public notice in the North Carolina Register that a report</u> has been received. After notice is given, the public shall have 30 days to file written comments on the report and on the benefits and disadvantages of continuing the certificate of public advantage. Periodic reports, public comments, and information submitted in response to a request shall be public records as set forth in Chapter 132 of the General Statutes. (b) Failure to file a periodic report required by this section after notice of default, or failure to provide information requested pursuant to a review under G.S. 90-21.31 are grounds for revocation of the certificate by the Attorney General or the Department.

The Department shall review each periodic report, public comments, and (c) information submitted in response to a request under G.S. 90-21.31 to determine whether the advantages or likely advantages of the cooperative agreement continue to outweigh the disadvantages or likely disadvantages of any reduction in competition from the agreement, and to determine what, if any, changes in the conditions of the certificate should be made. In the review the Department shall consider the benefits and disadvantages set forth in G.S. 90-21.27. Within 60 days of the filing of a periodic report, the Department shall determine whether the certificate should remain in effect and whether any changes to the conditions in the certificate should be made. Provided, however, that the Department may extend the review period an additional 30 days. If the Department or Attorney General determines that the parties to the cooperative agreement have not complied with any condition of the certificate, the Department or the Attorney General shall revoke the certificate and the parties shall be notified. If the certificate is revoked, the parties shall be entitled to no benefits under this Article, beginning on the date of revocation. If the Department determines that the certificate should remain in effect and the Attorney General has not stated any objection to the certificate remaining in effect during the review period, the certificate shall remain in effect subject to any changes in the conditions of the certificate imposed by the Department. The parties shall be notified in writing of the Department's decision and of any changes in the conditions of the certificate. The Department shall publish its decision and any changes in the conditions in the North Carolina Register.

If the Department determines that the benefits or likely benefits of the agreement and the unavoidable costs of terminating the agreement do not continue to outweigh the disadvantages or likely disadvantages of any reduction in competition from the agreement, or if the Attorney General objects to the certificate remaining in effect based upon a review of the benefits and disadvantages set forth in G.S. 90-21.27, the Department shall notify the parties to the agreement in writing of its determination or the objections of the Attorney General and shall provide a summary of any concerns of the Department or Attorney General to the parties.

"§ 90-21.33. Right to judicial action.

(a) Any applicant or other person aggrieved by a decision to issue or not issue a certificate of public advantage is entitled to judicial review of the action or inaction in superior court. Suit for judicial review under this subsection shall be filed within 30 days of public notice of the decision to issue or deny issuance of the certificate. To prevail in any action for judicial review brought under this subsection, the plaintiff or petitioner must establish that the determination by the Department or the Attorney General was arbitrary or capricious.

(b) Any party or other person aggrieved by a decision to allow the certificate to remain in effect or to make changes in the conditions of the certificate is entitled to judicial review of the decision in superior court. Suit for judicial review under this subsection shall be filed within 30 days of public notice of the decision to allow the

certificate to remain in effect or to make changes in the conditions of the certificate. To prevail in any action for judicial review brought under this subsection, the plaintiff or petitioner must establish that the determination by the Department or the Attorney General was arbitrary or capricious.

(c) If the Department or the Attorney General determines the certificate should not remain in effect, the Attorney General may bring suit in the Superior Court of Wake County on behalf of the Department or on its own behalf to seek an order to authorize the cancellation of the certificate. To prevail in the action, the Attorney General must establish that the benefits resulting from the agreement are outweighed by the disadvantages attributable to reduction in competition resulting from the agreement.

(d) In any action instituted under this section, the work product of the Department or the Attorney General or his staff is not a public record under Chapter 132 of the General Statutes and shall not be discoverable or admissible, nor shall the Attorney General or any member of the Attorney General's staff be compelled to be a witness, whether in discovery or at any hearing or trial.

"<u>§ 90-21.34. Fees for applications and periodic reports.</u>

(a) The Department and the Attorney General shall establish and collect administrative fees for filing of an application for a certificate of public advantage based on the total cost of the project for which the application is made, in an amount not to exceed fifteen thousand dollars (\$15,000), and an administrative fee for filing each periodic report required to be filed in an amount not to exceed two thousand five hundred dollars (\$2,500). The fee schedule established should generate sufficient revenue to offset the costs of the program. An application filing fee must be paid to the Department at the time an application for a certificate of public advantage is submitted pursuant to G.S. 90-21.26. A periodic report filing fee must be paid to the Department at the time a periodic report is submitted to it pursuant to G.S. 90-21.32.

(b) If the Department or the Attorney General determines that consultants are needed to complete a review of an application, an additional application fee may be established by prior agreement with the applicants before the application is considered. The amount of the additional fee may not exceed the costs of contracting with the necessary consultants. The additional fee shall not be considered in determining whether an application fee exceeds the maximum application fee amount set in subsection (a) of this section.

"<u>§ 90-21.35. Department and Attorney General authority.</u>

<u>The Department and Attorney General shall adopt rules to conduct review of applications for certificates of public advantage and of periodic reports filed in connection therewith and to bring actions in the Superior Court of Wake County as required under G.S. 90-21.33. This Article shall not limit the authority of the Attorney General under federal or State antitrust laws.</u>

"§ 90-21.36. Effects of certificate of public advantage; other laws.

(a) Activities conducted pursuant to a cooperative agreement for which a certificate of public advantage has been issued are immunized from challenge or scrutiny under State antitrust laws. In addition, conduct in negotiating and entering into a cooperative agreement for which an application for a certificate of public advantage is

filed in good faith shall be immune from challenge or scrutiny under State antitrust laws, regardless of whether a certificate is issued. It is the intention of the General Assembly that this Article shall also immunize covered activities from challenge or scrutiny under any noncompetition provisions of the federal antitrust law.

(b) Nothing in this Article shall exempt physicians or others from compliance with State or federal laws governing certificate of need, licensure, or other regulatory requirements.

(c) Any dispute among the parties to cooperative agreement concerning its meaning or terms is governed by normal principles of contract law."

Sec. 3. The Department of Human Resources shall report to the 1999 General Assembly a summary and analysis of the effects of this act, including the results of efforts to assure access to health care and to control increases in health care costs and recommendations, if any, for amendments to this act.

Sec. 4. This act becomes effective October 1, 1995.

In the General Assembly read three times and ratified this the 10th day of July, 1995.

Dennis A. Wicker President of the Senate

Harold J. Brubaker Speaker of the House of Representatives