JOINT LEGISLATIVE
HEALTH CARE OVERSIGHT COMMITTEE

REPORT TO THE
1997 GENERAL ASSEMBLY
OF NORTH CAROLINA

1998 REGULAR SESSION

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TABLE OF CONTENTS

May 18, 1998

TO THE MEMBERS OF THE 1997 GENERAL ASSEMBLY (REGULAR SESSION 1998):

The Joint Legislative Health Care Oversight Committee herewith submits to you for your consideration its report pursuant to G.S. 120-70.111(b).

Respectfully submitted,

Senator Anthony E. Rand

Representative Lanier M. Cansler

Co-chairs
Joint Legislative Health Care Oversight Committee

JOINT LEGISLATIVE
ADMINISTRATIVE PROCEDURE OVERSIGHT COMMITTEE

Membership
1997-1999

Senate Appointees	House Appointees
Senator Anthony E. Rand - Co-chair	Representative Lanier M. Cansler
Senator James S. Forrester	Representative Joanne W. Bowie
Senator Wib Gulley	Representative Debbie A. Clary
Senator Fletcher L. Hartsell, Jr.	Representative James W. Crawford, Jr..
Senator Beverly M. Perdue	Representative Theresa H. Esposito
Senator Robert A. Raucho	Representative Edd Nye
Senator Leslie J. Winner	Representative Thomas E. Wright

Committee Staff:

Linda Attarian, Committee Counsel

John Young, Committee Staff

Susan Sabre, Bill Drafting Division

Betty Harrison, Committee Clerk

STATUTORY CHARGE

The Joint Legislative Health Care Oversight Committee was established by Section 22.1 of S.L. 1997-443 (S352) as Article 12M of Chapter 120 of the General Statutes, to "review, on a continuing basis, the provision of health care and health care coverage . . . in order to make . . . recommendations to the General Assembly. . . [and to] . . . study the delivery availability and cost of health care in North Carolina" and related matters. A copy of the statute is found in Exhibit A.

The Committee consists of fourteen members of the General Assembly, seven members of the Senate appointed by the President Pro Tempore of the Senate and seven members of the House of Representative appointed by the Speaker of the House. Each of the appointing authorities designates one of the appointees to serve a co-chair. The Committee is co-chaired by Senator Anthony E. Rand and Representative Lanier M. Cansler. A complete list of members is found on page 2.

COMMITTEE PROCEEDINGS

During the 1997-98 fiscal year, the Committee met six times prior to reporting to the 1998 Session: January 13, 1998, February 10, 1998, March 10, 1998, May 7, 1998. The Committee met a final time on May 18, 1998 to finalize its recommendations and approve its report.

An orientation session was held for all members at the January 13, 1998 meeting. Information was provided on the study topics and issues referred to the Committee for study by the Legislative Research Commission and an overview of the health-related bills pending for consideration in the 1998 Session. During the next several meetings the Committee's deliberations focused on the following: 1) the Governor's proposal for expanding health coverage for uninsured children in response to the enactment of the State Children's Health Insurance Program (SCHIP) under Title XXI of the Social Security Act; 2) the future impact of managed care in North Carolina; 3) proposed amendments to the Pharmacy Practice Act; 4) Senate Bill 866, Prescription Drugs/Competition); 5) proposed legislation to clarify how health information should be handled to ensure that the privacy of the information is properly protected; 6) proposed legislation to license provider sponsored organizations to contract with Medicare to provide health care services to Medicare beneficiaries enrolled in a recently established Medicare managed care program called Medicare+Choice program; 7) and the legal and practical concerns of health care providers related to the implementation of the recently enacted law creating a method for an individual to exercise a right to consent to or refuse to consent to mental health treatment. Detailed information on the last five (3-7) issues is found under **SECTION I - FINDINGS AND RECOMMENDATIONS, SECTION II - LEGISLATIVE PROPOSALS and SECTION III - LEGISLATIVE ENDORSEMENTS.**

SUBCOMMITTEE PROCEEDINGS

Pharmacy Issues Subcommittee:

Membership

Representative Jim Crawford, Chairman
Representative Edd Nye
Representative Thomas Wright
Senator Jim Forrester
Senator Wib Gulley
Senator Beverly Perdue

Scope Of Study:

The Pharmacy Issues Subcommittee was appointed by the Co-Chairmen of the Joint Legislative Health Care Oversight Committee on February 10, 1998. The subcommittee was directed to study the proposed amendments to the Pharmacy Practice Act and Senate Bill 866, Third Edition, concerning managed care, prescription drug reimbursements and market competition in the retail drug industry. The subcommittee was asked to report any legislative recommendations to the full Committee prior to the beginning of the 1998 General Session.

Recommendation:

The subcommittee met five times and recommends to the Joint Legislative Health Care Oversight Committee the following legislation.

AN ACT TO AMEND THE PHARMACY PRACTICE ACT, for introduction to the 1998 General Session. (See **SECTION II - LEGISLATIVE PROPOSAL #1**).

SB 866, THIRD EDITION. (See SECTION III).

Further details on the activities of the Pharmacy Issues Subcommittee are found in **EXHIBIT B, Pharmacy Issues Subcommittee Final Report.**

Health Care Information Privacy Subcommittee:

Membership:

Senator Wib Gulley, Chairman
Senator Leslie Winner
Senator Fletcher Hartsell
Representative Ed Nye
Representative Theresa Esposito
Representative Joanne Bowie

Scope of Study:

The Health Care Information Privacy Subcommittee was appointed by the Co-Chairs of the Joint Legislative Health Care Oversight Committee on February 10, 1998 and was directed to study emerging issues related to the integrity and privacy of health information. The Subcommittee was asked to report its findings concerning the adequacy of North Carolina law to protect the privacy of health information and any legislative recommendation for the 1998 General Session.

Recommendation:

The subcommittee recommends **AN ACT TO PROTECT THE PRIVACY OF HEALTH INFORMATION**, for introduction to the 1998 General Session. (See **SECTION II, LEGISLATIVE PROPOSAL #2**).

Further details on the activities of the Health Care Information Privacy Subcommittee are found in **EXHIBIT C, Health Care Information Privacy Subcommittee Final Report.**

SECTION I

FINDINGS AND RECOMMENDATIONS OF THE JOINT LEGISLATIVE HEALTH CARE OVERSIGHT COMMITTEE

1997-98 FISCAL YEAR

Findings and Recommendations #1

AMENDMENTS TO THE PHARMACY PRACTICE ACT

Background: The Pharmacy Practice Act has not been revised since 1983 and portions of the Act do not adequately reflect today's professional pharmacy practice. The Committee was urged to consider several proposed amendments to the Act amending several of the proposals that would have expanded the scope of the Board's legal authority and the scope of pharmaceutical practice so dramatically that they did not have the full support of other health care providers.

Finding: The Committee finds that the Pharmacy Practice Act should be amended on an incremental basis and that due to the limited duration of the 1998 General Session (Short Session), legislative recommendations for consideration during the Short Session should have a broad base of support from the parties affected by the legislation.

Recommendation: The Committee recommends the following legislative changes to the Pharmacy Practice Act: (See **SECTION II - LEGISLATIVE PROPOSAL #1**)

- The composition of the five pharmacist members of the Board of Pharmacy should be amended to include two pharmacists who practice in a chain community pharmacy setting, two who practice in an independent pharmacy setting and one who practices in a health care facility setting.
- A definition of "pharmacy technician" should be included in the Pharmacy Practice Act.
- Pharmacy permit holders should be statutorily obligated to provide sufficient technology, automation and personnel in their pharmacy.
- The ratio of pharmacists to pharmacy technicians in any given pharmacy shall be no more than one to three unless the Board approves a larger ratio at a specific location.
- Businesses located outside the State that ship or mail medical equipment or devices into this State should be required to obtain the appropriate permit from the Board of Pharmacy.
- In the event of a declared disaster or emergency, the Board should be authorized to waive the requirements that it is held to under the Practice Act in order to facilitate the delivery of drugs and devices to the public.
- The Board should have the authority to discipline a licensee even though that person resides in another state.
- The Practice Act should include a provision authorizing the Board to adopt rules to govern the electronic transmission of prescriptions .

Findings and Recommendations #2

HEALTH CARE INFORMATION PRIVACY

Background: Health information is personal and sensitive information which, if inaccurately collected, documented, or improperly used or released, may cause significant harm to a patient's interests in privacy and health care. Benefits of electronic health information include:

1. Facilitating timely, authorized communications of more complete health information that is now available through paper-based systems;
2. Improving the accuracy, integrity, and security of health information;
3. Providing access to medical knowledge bases;
4. Enhancing efficiencies of health care; and
5. Facilitating health care research and health care quality improvement.

Finding: Health care organizations in North Carolina increasingly are utilizing computers and networks to improve patient care and to lower the cost of providing care, yet the full benefit of such technology has yet to be achieved. And, with more and more sensitive patient information being stored in computers and exchanged over networks, it is imperative that the law is clear on the rules for protecting the patient's reasonable expectation of privacy in the use of the patient's health information. Consistent with the need to protect privacy, it is also imperative that barriers be eliminated to the use of modern health information systems. However, because of outdated and inadequate laws in North Carolina, patients and caregivers do not know what their rights and obligations are with respect to health information and; therefore, both are at substantial risk with unknown consequences. Legislation should be enacted that will clarify how computerized health information should be collected, used, stored, and disclosed.

Recommendation: The Committee recommends that legislation should be enacted that will ensure that health information is: 1) secure, private, accurate, and reliable; 2) properly disclosed or modified; and 3) accessible only to those with a legitimate need for the information. (See **SECTION II - LEGISLATIVE PROPOSAL #2**).

Findings and Recommendations # 3

ADVANCED INSTRUCTIONS FOR MENTAL HEALTH TREATMENT

Background: SB 757, "An Act to Establish Advanced Instruction for Mental Health Treatment," was enacted during the 1997 Session of the General Assembly. The Act recognized

as a matter of public policy that an individual's right to control his or her medical care, and to have that right exercised on behalf of the individual by an agent chosen by the individual, applies to decisions related to mental health treatment. The Act also created an additional, non-exclusive method for an individual to exercise the right to consent to or refuse mental health treatment when the individual lacks sufficient understanding or capacity to make or communicate mental health treatment decisions.

Finding: The Committee finds that health care providers and others have identified significant legal, public policy, and practical concerns related to implementing Advanced Instructions for Mental Health Treatment under the provisions of SB 757 as enacted. These interested parties are concerned that the process established by SB 757 is flawed and as a result of those flaws, may not be implemented effectively to accomplish the legitimate public policy objectives of the Act.

Recommendation: The Committee recommends that the law related to Advanced Instructions for Mental Health Treatment should be amended to clarify the process by which decisions related to mental health treatment for legally incompetent patients are made by persons with the legal authority to act for the patient and that those decisions reflect instructions by the patient about his or her mental health treatment. (See **SECTION II LEGISLATIVE PROPOSE #3**).

Finding and Recommendation #4

PROVIDER-SPONSORED ORGANIZATION MEDICARE LICENSING

Background: Provider sponsored organizations (PSOs) are health care delivery networks owned or controlled and operated by providers. Their business is contracting to deliver health care services to licensed health plans, self-insured employers, and other group purchasers. Such systems, also referred to as integrated delivery systems, are most commonly formed by physicians and hospitals and can provide an array of health care services to patients under a variety of payment mechanisms, including risk-sharing arrangements through contracts with HMOs. A few States have passed laws specifically recognizing these types of entities.

Until the enactment of the Balanced Budget Act of 1997 (BBA), PSOs were eligible to participate in the Medicare program only if they met the requirements for a risk contract under section 1876 of the Social Security Act. Under section 1876(b) of the Act and implementing regulations at 42 CFR Part 417, Medicare contracting prepaid health plans must be licensed by the State. The Social Security Act now explicitly provides an exception to this requirement for PSOs. PSO are

the only organization eligible to participate in Medicare+Choice program without State licensure. However, for the most part, a PSO plan is required to meet the same requirements as other coordinated care plans that participate in the program. An organization interested in entering into a contract with Medicare as a PSO must first apply to its State for licensure as a risk-bearing entity. Only a PSO that is denied licensure by the State based on any of the following three criteria may obtain a waiver from HCFA in order to be certified to contract with Medicare:

- The State failed to complete action on a licensing application within 90 days.
- The State denied the licensing application based on discriminatory treatment.
- The State denied the licensing application based on the organization's failure to meet solvency requirements, and there is a difference between the State's solvency requirements and the Federal solvency requirements.

PSOs that receive a federal waiver must meet Medicare solvency standards, but are still subject to State consumer protection and quality assurance standards.

Following either State licensure or approval of a federal waiver, the organization then applies to the Health Care Financing Administration that administers Medicare, (HCFA), to participate in the Medicare+Choice program as a PSO. HCFA will review the application first to determine whether the organization meets the federal PSO definition and related requirements. HCFA will then will determine whether the organization meets the general Medicare+Choice requirements, including solvency standards. State-licensed PSOs must meet the solvency standards as required by their State, not the Medicare PSO solvency standards.. However, the proposed legislation incorporates the federal solvency standards.

Finding: The Committee finds that provider sponsored organizations are beneficial to North Carolina citizens who are Medicare beneficiaries and should be encouraged, subject to appropriate federal and State regulation.

Recommendation: The Committee recommends that the legislation be enacted to license provider sponsored organizations to contract with the Health Care Financing Administration to provide health care services to Medicare+Choice beneficiaries. (See **SECTION II - LEGISLATIVE PROPOSAL #4.**).

Finding and Recommendation #5

SENATE BILL 866 (3RD. EDITION) PRESCRIPTION DRUG/COMPETITION

Background:

The Legislative Research Commission authorized the Joint Legislative Health Care Oversight Committee to study issues related to prescription drug competition in the interim period between the 1997 and 1998 Regular Sessions. [Sec. 2.7, S.L. 483 (SB 32)]. As authorized, the Committee conducted a thorough study of Senate Bill 866 (3rd Edition), "Prescription Drugs/Competition." SB 866 passed 3rd reading in the Senate on April 30, 1997, and was referred to the House Insurance subcommittee on Health on May 27, 1997. It is currently pending in that committee.

Finding:

The Joint Legislative Health Care Oversight Committee carefully considered the impact SB 866 is expected to have on the financial stability of independent pharmacies, health care costs, prescription drug market competition, managed care and the public's health. The Committee heard from health care providers, payers, consumers, retail pharmacists and other interested parties. As a result of its review, the Committee finds that the legislation is will have a beneficial affect on the financial viability of independent pharmacies.

Recommendation:

The Committee requests that the House Insurance Committee on Health, where the bill currently is pending consider giving SB 866 (Third Edition) a favorable report during the 1998 Regular Session. (See **SECTION IV, ENDORSEMENTS**).

SECTION II

LEGISLATIVE PROPOSALS
OF THE
JOINT LEGISLATIVE
HEALTH CARE OVERSIGHT COMMITTEE

1997-98 FISCAL YEAR

LEGISLATIVE PROPOSAL #1

AN ACT TO AMEND THE PHARMACY ACT, AS RECOMMENDED BY THE JOINT LEGISLATIVE HEALTH CARE OVERSIGHT COMMISSION..

Short Title: Amend Pharmacy Practice Act

Statute(s) Affected:
G.S. 90-85.6 Board of Pharmacy; creation; membership; qualification of members
G.S. 90-85.7 Board of Pharmacy; selection; vacancies; commission; per-diem; removal
G.S. 90-85.15A Pharmacy technician (new selection)
G.S. 90-85.21 Pharmacy permit
G.S. 90-85.22 Device and medical equipment permits
G.S. 90-85.25 Disasters and emergencies
G.S. 90-85.38 Disciplinary authority

Agency Affected: Board of Pharmacy

Interested Parties: NC Pharmacy Association; Pharmacists, Pharmacy permit holders; and Unlicensed pharmacy personnel.

Explanation of Proposal: The Pharmacy Practice Act has not been amended since 1982. The proposed legislation will bring various provisions of the Act up to date to reflect current pharmacy practices in North Carolina.

Appropriations and Fees: No.

Effective Date: October 1, 1998.

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1997

H D

HOUSE DRH6372-LFZ006E(3.10)

Short Title: Amend Pharmacy Practice Act. (Public)

Sponsors:

Referred to:

A BILL TO BE ENTITLED

AN ACT TO AMEND THE PHARMACY PRACTICE ACT, AS RECOMMENDED BY THE JOINT LEGISLATIVE HEALTH CARE OVERSIGHT COMMISSION.

The General Assembly of North Carolina enacts:

Section 1. G.S. 90-85.6 reads as rewritten:

"**§ 90-85.6. Board of Pharmacy; creation; membership; qualification of members.**

(a) Creation. -- The responsibility for enforcing the provisions of this Article and the laws pertaining to the distribution and use of drugs is vested in the Board. The Board shall adopt reasonable rules for the performance of its duties. The Board shall have all of the duties, powers and authorities specifically granted by and necessary for the enforcement of this Article, as well as any other duties, powers and authorities that may be granted from time to time by other appropriate statutes. The Board may establish a program for the purpose of aiding in the recovery and rehabilitation of pharmacists who have become addicted to controlled substances or alcohol, and the Board may use money collected as fees to fund such a program.

(b) Membership. -- The Board shall consist of six members, one of whom shall be a representative of the public, and the remainder of whom shall be pharmacists.

(c) Qualifications. -- The public member of the Board shall not be a health care provider or the spouse of a health care provider. He shall not be enrolled in a program to prepare him to be a health care provider. ~~The public member of the Board shall be a resident of this State at the time of his appointment and while serving as a Board member. The pharmacist members of the Board shall be residents of this State at the time of their appointment and while serving as Board members.~~ All members of the Board shall be residents of the State at the time of their

appointment and while serving as Board members. Of the five pharmacist members, two shall practice in a chain community pharmacy setting, two others shall practice in an independent community pharmacy setting, and one other shall practice in a health care facility setting."

Section 2. G.S. 90-85.7(a) reads as rewritten:

"**§ 90-85.7. Board of Pharmacy; selection; vacancies; commission; term; per diem; removal.**

(a) The Board of Pharmacy shall consist of six persons. Five of the members shall be licensed as pharmacists within this State and shall be elected and commissioned by the Governor as hereinafter provided. Pharmacist members shall be chosen in an election held as hereinafter provided in which every person licensed to practice pharmacy in North Carolina and residing in North Carolina shall be entitled to vote. Pharmacist members of the Board shall be nominated and selected without regard to geographic location. Each pharmacist member of said Board shall be elected for a term of five years and until his successor shall be elected and shall qualify. Members chosen by election under this section shall be elected upon the expiration of the respective terms of the members of the present Board of Pharmacy. No pharmacist shall be nominated for membership on said Board, or shall be elected to membership on said Board, unless, at the time of such nomination, and at the time of such election, he is licensed to practice pharmacy in North Carolina. In case of death, resignation or removal from the State of any pharmacist member of said Board, the pharmacists members of the Board shall elect in his place a pharmacist who meets the criteria set forth in subsection (c) of G.S. 90-85.6 and in this section to fill the unexpired term.

One member of the Board shall be a person who is not a pharmacist and who represents the interest of the public at large. The Governor shall appoint this member.

All Board members serving on ~~June 30, 1989,~~ October 1, 1998, shall be eligible to complete their respective terms. At the time of expiration of the first term ending after October 1, 1998, a health care facility pharmacist member shall be elected. The two vacancies occurring in 1999 shall be filled by a community chain pharmacist member and a community independent pharmacist member. For all term expirations thereafter, each vacancy shall be filled with a licensed pharmacist practicing in the site which creates a Board with the composition required by subsection (c) of G.S. 90-85.6. No member appointed or elected to a term on or after July 1, 1989, shall serve more than two complete consecutive five-year terms. The Governor may remove any member appointed by him for good cause shown and may appoint persons to fill unexpired terms of members appointed by him.

It shall be the duty of a member of the Board of Pharmacy, within 10 days after receipt of notification of his appointment and commission, to appear before the clerk of the superior court of the county in which he resides and take and subscribe an oath to properly and faithfully discharge the duties of his office according to law."

Section 3. Article 4 of Chapter 90 is amended by adding a new section to read:

"**§ 90-85.15A. Pharmacy technician.**

A pharmacy technician is a person designated and supervised by the pharmacist to assist in the nondiscretionary functions involved in dispensing a prescription. A pharmacy technician must be registered with the Board of Pharmacy. Administrative support personnel and cashiers are not technicians."

Section 4. G.S. 90-85.21(a) reads as rewritten:

"(a) In accordance with Board regulations, each pharmacy in North Carolina shall annually register with the Board on a form provided by the Board. The application shall identify the pharmacist-manager of the pharmacy and all pharmacist personnel and pharmacy technicians employed in the pharmacy. All pharmacist-managers shall notify the Board of any change in pharmacist personnel within 30 days of such change."

Section 5. G.S. 90-85.22 is amended by adding a new subsection to read:

"(c) Any place of business located outside the State that ships, mails, or delivers in any manner, devices or medical equipment to the user of the equipment in this State shall comply with the provisions of this section and G.S. 90-85.24, and rules adopted by the Board governing these locations, unless compliance would result in violation of the laws or regulations of the state where the place of business is located."

Section 6. G.S. 90-85.25 reads as rewritten:

"**§ 90-85.25. ~~Disaster reports.~~ Disasters and emergencies.**

(a) In the event of an occurrence which the Governor of the State of North Carolina has declared as a disaster or when the Governor has declared a state of emergency, the Board may waive the requirements of this Article in order to facilitate the delivery of drugs and devices to the public.

(b) The pharmacist in charge of a pharmacy shall report within 10 days to the Board any disaster, accident, theft, or emergency which may affect the strength, purity, or labeling of drugs and devices in the pharmacy."

Section 7. G.S. 90-85.38(a) reads as rewritten:

"(a) The Board may, in accordance with Chapter 150B of the General Statutes, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew a license to practice pharmacy, or require licensees to successfully complete remedial education if the ~~licensee~~ licensee, whether currently residing in this State or not, has:

(1) Made false representations or withheld material information in connection with securing a license or permit;

(2) Been found guilty of or plead guilty or nolo contendere to any felony in connection with the practice of pharmacy or the distribution of drugs;

(3) Indulged in the use of drugs to an extent that renders him unfit to practice pharmacy;

(4) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;

(5) A physical or mental disability that renders him unfit to practice pharmacy with reasonable skill, competence and safety to the public;
(6) Failed to comply with the laws governing the practice of pharmacy and the distribution of drugs;
(7) Failed to comply with the rules and regulations of the Board;
(8) Engaged in, or aided and abetted an individual to engage in, the practice of pharmacy without a license; or
(9) Was negligent in the practice of pharmacy."

Section 8. G.S. 106-134.1 is amended by adding a new subsection to read:

"(f) A prescription transmitted electronically from a prescriber to a pharmacy without the legal signature of the prescriber may be dispensed only pursuant to rules adopted jointly by the Board of Pharmacy and the Medical Board."

Section 9. This act becomes effective October 1, 1998.

Section By Section Summary
Amend Pharmacy Practice Act

DRH6372-LFZ-006E(3.10)

Bill Section	Summary of Provisions	Page & Line #
1.	**Amends G.S. 90-85.6** the statute creating the Board of Pharmacy. The bill changes the composition of the five pharmacist members of the Board to specify that 2 must be employees in a chain pharmacy; 2 must be employed in an independent pharmacy and one must be employed in a heath care facility.	Page 2, lines 1-4.
2.	**Amends G.S. 90-85.7** relating to the election of the Board members by making conforming changes to reflect the proposed change in Board make-up.	Page 2, lines 13-14, 23, and 29-35 and page 3, lines 2-5.
3.	**Adds a new section** to the Act to define a "pharmacy technician" as a person designated to assist the pharmacist in the nondiscretionary functions involved in filling prescriptions.	Page 3, lines 2-5.
5.	**Amends G.S. 90-85.22,** the statute that requires any NC dispenser dispenses pharmaceutical devises or delivers medical equipment to users to obtain a permit from the Board. The bill expands the Board's jurisdiction by requiring dispensers located OUTSIDE the State to also obtain a permit from the Board, and pay the required fees.	Page 3, lines 14-19.
6.	**Adds a new subsection to G.S. 90-85.25** to authorize the Board to waive its rules in order to facilitate the delivery of drugs and devices to the public when a disaster or state of emergency has been declared.	Page 4, lines 22-25
7.	**Amends G.S. 90-85.38(a),** by authorizing the Board to discipline a licensee whether or not that licensee resides in North Carolina.	Page 4, line 33
8.	**Amends G.S. 106-134.1,** (requiring certain drugs to be dispensed only pursuant to a prescription) by requiring prescriptions transmitted electronically without legal signatures, to be dispensed only in accordance to rules adopted jointly by the Board of Pharmacy and the Medical Board.	Page 5, lines 12-14

LEGISLATIVE PROPOSAL #2

AN ACT TO PROTECT THE PRIVACY OF HEALTH INFORMATION, AS RECOMMENDED BY THE JOINT LEGISLATIVE HEALTH CARE OVERSIGHT COMMITTEE

Short Title: Health Care Information Privacy

Statute(s) Affected: Adds a new Chapter 132A to the General Statutes.

Agency Affected: Department of Health and Human Services, and the Department of Insurance, licensing bodies and other state agencies that are custodians of identifying health information.

Interested Parties: Health care providers, state agencies, academic medical centers, payers, consumers, integrated health care delivery systems, HMOs, lawyers, patient advocates, pharmaceutical and research organizations, and licensing bodies.

Explanation of Proposal: The legislation:

- Establishes rules for when a person's confidential health information may be disclosed and to whom;
- Defines rules for security to protect confidentiality while information is stored and when it is disclosed to others;
- Articulates certain rights of patients, including the right to view health information and to suggest corrections or amendments to that information;
- Requires secure computerized systems that control access and provide audit trails; and
- Integrates state requirements for information systems with those at the federal level.

Fiscal Impact: The proposed legislation does not include a state appropriation or fee. Anticipated costs include those necessary for education and training of staff, and any modification of existing storage and retrieval systems to comply with security and tracking standards. Cost savings are expected due largely to the administrative efficiencies of computerized systems over paper systems.

Effective Date: July 1, 1999, except that the provisions pertaining to (1) subpoenas, search warrants, requests for discovery and court orders; (2) establishment of a master person index; (3) repeal of the "quill pen rule"; and (4) electronic signatures provisions become effective when the act becomes law.

A copy of the proposed legislation and section-by-section explanation begin on the next page.

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1997

H D

98-LFZ-010B(3.11)

Short Title: Health Care Information Privacy. (Public)

Sponsors:

Referred to:

A BILL TO BE ENTITLED

AN ACT TO PROTECT THE PRIVACY OF HEALTH INFORMATION, AS RECOMMENDED BY THE JOINT LEGISLATIVE HEALTH CARE OVERSIGHT COMMITTEE.

The General Assembly of North Carolina enacts:

Section 1. The General Statutes are amended by adding a new Chapter to read:

"Chapter 132A.

"Health Information Privacy Act.

"ARTICLE 1.

"Legislative Findings and Definitions.

"**§ 132A-1-1. Legislative findings.**

(a) The General Assembly finds that health information is personal and sensitive information which, if inaccurately collected, documented, or improperly used or released may cause significant harm to a patient's interests in privacy and health care. Benefits of electronic health information include:

(1) Facilitating timely, authorized communications of more complete health information that is now available through paper-based systems;

(2) Improving the accuracy, integrity, and security of health information;

(3) Providing access to medical knowledge bases;

(4) Enhancing efficiencies of health care; and

(5) Facilitating health care research and health care quality improvement.

(b) The General Assembly finds that it is in the public interest to establish legislative policies and guidelines to ensure that health information is:

(1) Secure, private, accurate, and reliable;

(2) Properly disclosed or modified; and

(3) Accessible only to those with a legitimate need for the information.

(c) Certain types of information, such as information about HIV infection, AIDS, mental health, or substance abuse, are so highly sensitive that more strict requirements for disclosure are needed.

"**§ 132A-1-2. Definitions.**

As used in this Chapter, unless the context otherwise requires:

(1) 'Audit' means an assessment, communication evaluation, analysis determination, investigation, or prosecution of a custodian, provider, or facility, to identify, determine, evaluate, or monitor practices, services, or products concerning the applicability of, compliance with or availability of:

a. Legal, fiscal, quality assurance, quality control, risk management, utilization review, medical, professional or scientific standards or practices, or aspects of performance or potential liability relating to:

1. The delivery of or payment for present or future health care, health care services, health care products, or health care equipment;

2. Health care fraud or fraudulent claims regarding health care, health care services or equipment, or related activities and items;

3. Security of health information; and

4. Coordination of or planning for present or future services among providers or facilities;

b. Requirements for and oversight of licensing and professional discipline, accreditation, credentialing, or certification, including peer review; or

(5) Facilitating health care research and health care quality improvement.

(b) The General Assembly finds that it is in the public interest to establish legislative policies and guidelines to ensure that health information is:

(1) Secure, private, accurate, and reliable;

(2) Properly disclosed or modified; and

(3) Accessible only to those with a legitimate need for the information.

(c) Certain types of information, such as information about HIV infection, AIDS, mental health, or substance abuse, are so highly sensitive that more strict requirements for disclosure are needed.

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a. Legal, fiscal, quality assurance, quality control, risk management, utilization review, medical, professional or scientific standards or practices, or aspects of performance or potential liability relating to:

1. The delivery of or payment for present or future health care, health care services, health care products, or health care equipment;

2. Health care fraud or fraudulent claims regarding health care, health care services or equipment, or related activities and items;

3. Security of health information; and

4. Coordination of or planning for present or future services among providers or facilities;

b. Requirements for and oversight of licensing and professional discipline, accreditation, credentialing, or certification, including peer review; or

c. Future health care services or health care products provided by the custodian, provider, or facility to, or case management related to, a patient currently or previously served by the custodian, provider, or facility.

(2) 'Custodian' means any person operating in a business, professional, or governmental capacity that collects, creates, receives, obtains, maintains, uses, analyzes, or transmits identifying health information, including a college, employer, facility, payer, health oversight agency, health researcher, penal institution, provider, public health authority, school, State agency, third-party administrator, or university.

(3) 'Directory information' means the following information concerning a patient who is an inpatient or outpatient or who is currently receiving emergency health care in a health care facility:

a. The presence of the patient at the facility, including room, bed number, or telephone number;

b. Date of admission; and

c. The patient's health status whether 'critical', 'poor', 'fair', 'good', 'excellent', or a term denoting a similar condition.

(4) 'Electronic' means electrical, digital, magnetic, optical, electromagnetic, or other form of technology that entails capabilities similar to these technologies.

(5) 'Electronic agent' means a computer program or other electronic or automated means used, selected, or programmed by a person to initiate or respond to electronic records or performances in whole or in part without review by an individual.

(6) 'Electronic record' means a record created, stored, generated, received or communicated by electronic means such as computer equipment or programs, electronic data interchange, electronic voice mail, facsimile, telex, telecopying, scanning, and similar technologies.

(7) 'Electronic signatures' means any signatures in electronic form, attached to or logically

associated with an electronic record, executed or adopted by a person or the person's electronic agent with an intent to sign the electronic record.

(8) 'Facility' means any place where health care is regularly provided by a provider.

(9) 'Health care' means:

a. Preventive, diagnostic, therapeutic, rehabilitative, maintenance, investigational, experimental, cosmetic, reconstructive, or palliative care, including assistance with disease or symptom management and maintenance, counseling, service, laboratory test, or procedure:

1. With respect to the physical or mental condition of a patient; or

2. Affecting the structure or function of the human body or any part of the human body including the banking of blood, sperm, ova, organs, or any other tissue.

b. Any sale or dispensing of a drug, device, durable or disposable goods or equipment, or other health care related item to a patient, or for the use of a patient pursuant to a prescription, a purpose specified in a. of this subdivision.

(10) 'Health information' means any data, information, or orders, including advance directives, documents granting anatomical gifts, biological samples from the human body from which information can be drawn, films, videotapes, consent forms, genetic sequences, digitized images, sound recordings, and demographic information recorded or stored in any form that:

a. Relates to a specific patient's past, present, or future health care or condition, including the patient's individual cells and their components or personal and family medical history;

b. Was created or obtained by a custodian in connection with health care diagnosis, treatment, screening, counseling, intake, or discharge of a patient or related to the application for, or enrollment of, a patient

associated with an electronic record, executed or adopted by a person or the person's electronic agent with an intent to sign the electronic record.

(8) 'Facility' means any place where health care is regularly provided by a provider.

(9) 'Health care' means:

a. Preventive, diagnostic, therapeutic, rehabilitative, maintenance, investigational, experimental, cosmetic, reconstructive, or palliative care, including assistance with disease or symptom management and maintenance, counseling, service, laboratory test, or procedure:

1. With respect to the physical or mental condition of a patient; or

2. Affecting the structure or function of the human body or any part of the human body including the banking of blood, sperm, ova, organs, or any other tissue.

b. Any sale or dispensing of a drug, device, durable or disposable goods or equipment, or other health care related item to a patient, or for the use of a patient pursuant to a prescription, a purpose specified in a. of this subdivision.

(10) 'Health information' means any data, information, or orders, including advance directives, documents granting anatomical gifts, biological samples from the human body from which information can be drawn, films, videotapes, consent forms, genetic sequences, digitized images, sound recordings, and demographic information recorded or stored in any form that:

a. Relates to a specific patient's past, present, or future health care or condition, including the patient's individual cells and their components or personal and family medical history;

b. Was created or obtained by a custodian in connection with health care diagnosis, treatment, screening, counseling, intake, or discharge of a patient or related to the application for, or enrollment of, a patient

in a reimbursement plan, or for insurance use; or

c. Was obtained by or from a provider, facility, a patient, a member of the patient's family, or any other person about a patient and in connection with a patient's health care.

(11) 'Health oversight agency' means a public agency or other person that receives a disclosure of, uses, maintains, or discloses health information while acting in the capacity of a person authorized by law or recognized by a government agency to perform or oversee the performance of an audit.

(12) 'Health research' means scientific, actuarial, survey, or statistical research based upon health information, including clinical investigations governed by the Code of Federal Regulations, Chapter I of Title 21. Health research does not include disclosure of health information for purposes of providing health care, peer review, audit functions, or reporting to State and federal authorities.

(13) 'Identifying health information' means a collection of health information that includes the name, address, social security number, unique identifier established by State or federal law, likenesses or other information which readily identifies a patient's personal identity, could be used or manipulated to identify a patient by foreseeable method with reasonable accuracy and speed, or could be linked or matched by a foreseeable method to any other information in order to identify a patient. Identifying health information includes information stored in a master person index authorized by G.S. 132A-3-5. Health information shall not be considered identifying health information solely based on the inclusion in a collection of health information of a code assigned to a patient by a custodian if that code does not consist of or contain symbols that could be used to readily identify a patient with reasonable accuracy and speed from sources external to the custodian.

(14) 'Identifying provider information' means the collection of health information that includes the name, address, social security number, medical

billing number, employer identification number, likenesses, or other information by which the identity of a health care provider can readily be determined with reasonable accuracy and speed, or could be linked or matched by a foreseeable method to any other information in order to identify a provider. The term does not include a unique identification code assigned to a provider by a custodian and used and disclosed only internally to the custodian if that code does not consist of or contain symbols that could be used to identify readily a health care provider with reasonable accuracy and speed from sources external to the custodian.

(15) 'Master person index' means an index indicating the existence and general location of medical records of patients held by a custodian to facilitate the request for the information under circumstances permitted by this Chapter.

(16) 'Medical record' means identifying health information which is maintained in a health information collection, storage, and retrieval system of the custodian in the usual course of health care in accordance with applicable standards of practice.

(17) 'Patient' means an individual who is requesting, receives, or has received health care, or another person legally empowered to authorize the disclosure of a patient's identifying health information to the extent necessary to effect the terms or purposes of the individual's grant of authority.

(18) 'Payer' means a person acting in a business capacity who undertakes to furnish health insurance, disability insurance, life insurance, workers' compensation insurance, or otherwise to pay for all or some of health care services rendered to the patient.

(19) 'Person' means an individual, government, governmental subdivision, agency or authority, association, corporation, firm, limited liability company, partnership, society, estate, trust, joint venture, or any other legal entity.

(20) 'Provider' means:

billing number, employer identification number, likenesses, or other information by which the identity of a health care provider can readily be determined with reasonable accuracy and speed, or could be linked or matched by a foreseeable method to any other information in order to identify a provider. The term does not include a unique identification code assigned to a provider by a custodian and used and disclosed only internally to the custodian if that code does not consist of or contain symbols that could be used to identify readily a health care provider with reasonable accuracy and speed from sources external to the custodian.

(15) 'Master person index' means an index indicating the existence and general location of medical records of patients held by a custodian to facilitate the request for the information under circumstances permitted by this Chapter.

(16) 'Medical record' means identifying health information which is maintained in a health information collection, storage, and retrieval system of the custodian in the usual course of health care in accordance with applicable standards of practice.

(17) 'Patient' means an individual who is requesting, receives, or has received health care, or another person legally empowered to authorize the disclosure of a patient's identifying health information to the extent necessary to effect the terms or purposes of the individual's grant of authority.

(18) 'Payer' means a person acting in a business capacity who undertakes to furnish health insurance, disability insurance, life insurance, workers' compensation insurance, or otherwise to pay for all or some of health care services rendered to the patient.

(19) 'Person' means an individual, government, governmental subdivision, agency or authority, association, corporation, firm, limited liability company, partnership, society, estate, trust, joint venture, or any other legal entity.

(20) 'Provider' means:

a. A person licensed, certified, registered, or otherwise authorized by State or federal law to provide health care in the ordinary course of business or practice of profession;
b. A State or federal program that directly provides health care; or
c. A student training to provide health care acting under the supervision of a provider described in a. of this subdivision.

(21) 'Sign' means the execution or adoption of a signature by a person or the person's electronic agent.

"ARTICLE 2.
"Patient Interests.

"§ 132A-2-1. Patient's examination and copying of health information.

(a) Upon a written request from a patient to examine or copy the patient's medical record, a custodian who is a provider or facility shall, within a reasonable time of the receipt of the request, at the custodian's option, make the patient's medical record available for examination during regular business hours or provide a copy to the patient.

(b) If, in the professional judgment of the provider, it would be injurious to the mental or physical health of the patient who is the subject of the health information or in violation of the provider's professional ethical responsibilities to disclose (pursuant to subsection (a) of this section) certain identifying health information to the patient; the provider is not required to provide the information to the patient, but shall upon written request of the patient disclose the information to another provider designated by the patient.

(c) A patient shall not have a right of access to health information compiled and used by a custodian solely for purposes of audit, peer review, or other administrative functions, to information protected by an evidentiary privilege of a person other than the patient, or information collected about the patient for or during a clinical trial monitored by an institutional review board when such trial is not complete.

"§ 132A-2-2. Request for amendment.

(a) A patient or provider treating a patient may request that a facility or provider amend identifying health information in a patient's medical record maintained by the provider or facility.

(b) Upon a request for an amendment, the custodian shall either amend the medical record or inform the patient or provider

in writing of the reasons for refusal to amend the medical record. If the custodian refuses to amend the record, the patient or provider shall be entitled to add a statement about the disagreement to the disputed identifying health information.

(c) When amending a medical record, the custodian shall add the amending information to the patient's identifying health information without affecting the original information.

"**§ 132A-2-3. Health information confidentiality; public records.**

(a) A custodian shall maintain, as confidential, identifying health information. Disclosures of identifying health information may be made only as authorized by this Chapter.

(b) Unless otherwise provided by this section or by other law, identifying health information is not a public record.

(c) No recipient of identifying health information shall use or redisclose identifying health information except for the purpose and authority under which the disclosure was made, or as otherwise authorized in this Chapter.

(d) A custodian's employees, agents, and contractors shall be subject to this Chapter to the same extent as the custodian.

(e) No person shall use health information that is not identifying health information for the purpose of identifying an individual patient unless the person is authorized under this Chapter to receive disclosures of the information as identifying health information.

(f) No person shall use health information that is not identifying provider information for the purpose of identifying an individual provider unless the person is authorized under this Chapter to receive disclosures of the information as identifying provider information.

(g) The records established pursuant to G.S. 132A-3-4(a)(4) may only be disclosed as follows:

(1) To a patient, subject to G.S. 132A-2-1(c);

(2) To a custodian for audit functions, except for records recording peer review functions;

(3) To health oversight agencies to the extent these records relate to the performance of authorized audit function; or

(4) By order pursuant to G.S. 132A-3-3(b)(4).

(h) When practicable, disclosures of identifying health information shall be limited only to information which the disclosing party reasonably believes is necessary to accomplish the purpose of the disclosure, except to the extent that disclosure is authorized by a patient or compelled by G.S. 132A-

in writing of the reasons for refusal to amend the medical record. If the custodian refuses to amend the record, the patient or provider shall be entitled to add a statement about the disagreement to the disputed identifying health information.

(c) When amending a medical record, the custodian shall add the amending information to the patient's identifying health information without affecting the original information.

"**§ 132A-2-3. Health information confidentiality; public records.**

(a) A custodian shall maintain, as confidential, identifying health information. Disclosures of identifying health information may be made only as authorized by this Chapter.

(b) Unless otherwise provided by this section or by other law, identifying health information is not a public record.

(c) No recipient of identifying health information shall use or redisclose identifying health information except for the purpose and authority under which the disclosure was made, or as otherwise authorized in this Chapter.

(d) A custodian's employees, agents, and contractors shall be subject to this Chapter to the same extent as the custodian.

(e) No person shall use health information that is not identifying health information for the purpose of identifying an individual patient unless the person is authorized under this Chapter to receive disclosures of the information as identifying health information.

(f) No person shall use health information that is not identifying provider information for the purpose of identifying an individual provider unless the person is authorized under this Chapter to receive disclosures of the information as identifying provider information.

(g) The records established pursuant to G.S. 132A-3-4(a)(4) may only be disclosed as follows:

(1) To a patient, subject to G.S. 132A-2-1(c);

(2) To a custodian for audit functions, except for records recording peer review functions;

(3) To health oversight agencies to the extent these records relate to the performance of authorized audit function; or

(4) By order pursuant to G.S. 132A-3-3(b)(4).

(h) When practicable, disclosures of identifying health information shall be limited only to information which the disclosing party reasonably believes is necessary to accomplish the purpose of the disclosure, except to the extent that disclosure is authorized by a patient or compelled by G.S. 132A-

3-2(b) or G.S. 132A-3-3(b)(4), in which case all information so authorized or compelled to be disclosed shall be disclosed.

(i) A disclosing custodian may in good faith rely upon representations made by a requesting person pursuant to this Chapter as to the authority and purpose for which a disclosure is being sought. A requesting person is in violation of this Chapter for misrepresenting the authority and purpose for which a disclosure is being sought, for seeking a disclosure for a purpose that is not authorized by this Chapter, or for seeking a disclosure for a purpose that is authorized by this Chapter but that does not apply to the role, position, or authority of the requesting person.

"ARTICLE 3.

"Health Information Communications.

"§ 132A-3-1. Authorization to disclose health information.

(a) Except for disclosures otherwise authorized by this Chapter, a custodian may disclose a patient's identifying health information only with authorization of the patient. A custodian shall not condition coverage or treatment of a patient based on the patient's refusal to authorize disclosures not permitted by this Chapter, except when this disclosure is essential to the health and safety of the provider or to the patient's treatment, coverage, or payment.

(b) A custodian shall retain a patient's authorization to disclose identifying health information with the patient's health information. A patient's authorization, to be valid, shall have the following:

(1) The patient's identity;

(2) A dated written or electronic signature of the patient;

(3) A description of the health information to be disclosed;

(4) The name or title of a person or either (i) the description of a group to whom the information is to be disclosed or (ii) the description of the class of persons to whom the information is to be disclosed; and

(5) A statement of the purposes for which the information is to be used.

(c) A patient's authorization to disclose identifying health information may also include any of the following:

(1) Any limitation on the scope of disclosure that may be made by the recipient in carrying out the

authorized purpose for which the disclosure is requested;

(2) An acknowledgment from the patient that the patient understands that the authorization is valid for the time period stated unless revoked; or

(3) Any other information believed by the custodian to be needed to facilitate the authorization or to inform the patient as to the patient's rights with respect to the authorization.

(d) A patient may revoke or amend an authorization at any time, except to the extent that the custodian has acted in reliance on the authorization.

(e) An authorization under subsection (b) of this section shall remain effective for the time specified by the patient in the authorization. If no time is specified, an authorization shall remain effective for one year.

"**§ 132A-3-2. Disclosures and uses of health information.**

(a) When a disclosure authorized pursuant to this section, other than as authorized by the patient or mandated by other law, may be accomplished without undue burden by disclosing health information that is not identifying health information, a custodian shall in good faith use reasonable efforts to disclose only health information that is not identifying health information.

(b) A custodian shall disclose identifying health information to federal, State, or local law enforcement authorities or to other federal or State authorities only as provided in G.S. 132A-3-3 or pursuant to mandatory disclosure obligations as otherwise provided by State or federal law.

(c) A custodian may disclose identifying health information about a patient without the patient's authorization if the disclosure is to be to the patient or:

(1) To a provider currently providing authorized health care to a patient or to a referring provider who continues to provide authorized health care to a patient if the information is necessary to provide health care to the patient, and the patient does not object to the disclosure. This subdivision shall not impose on the custodian a duty to inquire of or inform the patient of the disclosure either before or after the disclosure is made;

(2) To another provider in the same group practice or provider network, or to a custodian under contract with the group practice or provider network, for

authorized purpose for which the disclosure is requested;

(2) An acknowledgment from the patient that the patient understands that the authorization is valid for the time period stated unless revoked; or

(3) Any other information believed by the custodian to be needed to facilitate the authorization or to inform the patient as to the patient's rights with respect to the authorization.

(d) A patient may revoke or amend an authorization at any time, except to the extent that the custodian has acted in reliance on the authorization.

(e) An authorization under subsection (b) of this section shall remain effective for the time specified by the patient in the authorization. If no time is specified, an authorization shall remain effective for one year.

"**§ 132A-3-2. Disclosures and uses of health information.**

(a) When a disclosure authorized pursuant to this section, other than as authorized by the patient or mandated by other law, may be accomplished without undue burden by disclosing health information that is not identifying health information, a custodian shall in good faith use reasonable efforts to disclose only health information that is not identifying health information.

(b) A custodian shall disclose identifying health information to federal, State, or local law enforcement authorities or to other federal or State authorities only as provided in G.S. 132A-3-3 or pursuant to mandatory disclosure obligations as otherwise provided by State or federal law.

(c) A custodian may disclose identifying health information about a patient without the patient's authorization if the disclosure is to be to the patient or:

(1) To a provider currently providing authorized health care to a patient or to a referring provider who continues to provide authorized health care to a patient if the information is necessary to provide health care to the patient, and the patient does not object to the disclosure. This subdivision shall not impose on the custodian a duty to inquire of or inform the patient of the disclosure either before or after the disclosure is made;

(2) To another provider in the same group practice or provider network, or to a custodian under contract with the group practice or provider network, for

the purpose of providing patient health care within the practice or network;

(3) To a provider with a need for information to treat a condition that poses an immediate threat to a patient's health;

(4) Unless otherwise limited by G.S. 90-21.4, to a member of a patient's immediate family, a legal guardian of a patient, or to a person with whom the patient is known to have a close personal relationship, when the attending provider reasonably believes that notification is necessary to avoid serious jeopardy to the health of a patient and the patient lacks the capacity to authorize the disclosure;

(5) Necessary because in a provider's opinion, a person is in serious and imminent danger or a person is likely to commit a violent felony or violent misdemeanor. This subdivision not shall impose a duty upon the provider to disclose health information;

(6) To a custodian that originally disclosed the information;

(7) To a health oversight agency performing authorized audit functions;

(8) To perform internal audit functions within a custodian's organization;

(9) To agents, employees, and contractors of a custodian for the purpose of:

a. Providing health care to a patient; or

b. Performing administrative services for or on behalf of a custodian;

(10) If not prohibited by federal or State law, to a health researcher for health research;

(11) To a provider to confirm a past method or outcome of a course of treatment performed by the provider;

(12) To a successor in interest of a custodian that is or was a provider, facility, or payer for the patient whose information is being disclosed;

(13) To a payer for the purpose of conducting an audit of provider's operation or service related to services billed or care provided; and

(14) Directory information, unless the patient has instructed the custodian not to make the disclosure or unless the disclosure of the location of the

patient would reveal that the patient may be receiving mental health or substance abuse treatment. This subdivision shall not impose on the custodian a duty to inquire of or inform the patient of the disclosure either before or after the disclosure is made.

None of the limitations prescribed in this section shall relieve any person of any mandatory disclosure obligation concerning health information as otherwise prescribed by law.

"§ 132A-3-3. Subpoenas, search warrants, requests for discovery and court orders.

(a) The provisions of G.S. 1A-1, Rule 45(c), shall apply to all identifying health information authorized to be disclosed under subdivisions (1) and (2) of subsection (b) of this section as if this information were hospital medical records. If this authorization is refused or is not obtainable, the requesting party must obtain an order as provided in subdivision (4) of subsection (b) of this section requiring disclosure before identifying health information may be released by the custodian for use in discovery, a hearing, or a trial except when this information is to be disclosed pursuant to subdivision (3) of subsection (b) of this section.

(b) A patient's medical record or other health information shall be disclosed by a custodian pursuant to a civil, criminal, or administrative subpoena, search warrant, or request for discovery in any federal or State judicial or administrative investigation or proceeding only if:

(1) The patient, or the patient's attorney, acting with the consent of the patient, has authorized the disclosure in writing;

(2) The patient is deceased and the disclosure is authorized in writing by the executor or administrator of the patient's estate, or, if the estate is unadministered, by the next of kin;

(3) The information disclosed is to be used in the patient's involuntary commitment, adjudication of incompetency, or guardianship proceeding;

(4) A federal or State court or an administrative agency having subpoena power over the custodian and having jurisdiction of a matter in which the health information may be relevant, orders the disclosure as necessary for the proper administration of justice or health oversight as required by law, in

patient would reveal that the patient may be receiving mental health or substance abuse treatment. This subdivision shall not impose on the custodian a duty to inquire of or inform the patient of the disclosure either before or after the disclosure is made.

None of the limitations prescribed in this section shall relieve any person of any mandatory disclosure obligation concerning health information as otherwise prescribed by law.

"**§ 132A-3-3. Subpoenas, search warrants, requests for discovery and court orders.**

(a) The provisions of G.S. 1A-1, Rule 45(c), shall apply to all identifying health information authorized to be disclosed under subdivisions (1) and (2) of subsection (b) of this section as if this information were hospital medical records. If this authorization is refused or is not obtainable, the requesting party must obtain an order as provided in subdivision (4) of subsection (b) of this section requiring disclosure before identifying health information may be released by the custodian for use in discovery, a hearing, or a trial except when this information is to be disclosed pursuant to subdivision (3) of subsection (b) of this section.

(b) A patient's medical record or other health information shall be disclosed by a custodian pursuant to a civil, criminal, or administrative subpoena, search warrant, or request for discovery in any federal or State judicial or administrative investigation or proceeding only if:

(1) The patient, or the patient's attorney, acting with the consent of the patient, has authorized the disclosure in writing;

(2) The patient is deceased and the disclosure is authorized in writing by the executor or administrator of the patient's estate, or, if the estate is unadministered, by the next of kin;

(3) The information disclosed is to be used in the patient's involuntary commitment, adjudication of incompetency, or guardianship proceeding;

(4) A federal or State court or an administrative agency having subpoena power over the custodian and having jurisdiction of a matter in which the health information may be relevant, orders the disclosure as necessary for the proper administration of justice or health oversight as required by law, in

which case, unless an original is compelled, a copy of the medical record shall suffice; or

(5) The information is disclosed to a presiding judge or designee by a presiding judge pursuant to G.S. 1A-1, Rule 45, for purposes of determining use of identifying health information in discovery or at trial. This information shall not be open for inspection or copying by any person, including the parties to a case, until the order has been entered and then only in accordance with the order.

(c) Nothing in this section shall be construed to waive the privilege between a patient and a provider or to require any communications privileged under law to be disclosed, unless a patient's authorization or court order pursuant to subdivision (4) of subsection (b) of this section is obtained.

"**§ 132A-3-4. Responsibilities of custodians as to disclosures.**

(a) Custodians shall adopt and implement technical, contractual, and physical policies and safeguards to effect the requirements of this Chapter and shall undertake to carry out these policies and safeguards to protect against reasonably anticipated threats to the confidentiality, security, accuracy, and integrity of health information maintained, used, or disclosed by the custodian. These policies and safeguards shall include:

(1) Providing for internal disciplinary and corrective measures for violations of the custodian's policy for implementing the requirements of this Chapter;

(2) Requiring that each employee, agent, or contractor having access to identifying health information sign a statement agreeing to comply with the policies and safeguards adopted by the custodian;

(3) Providing periodic training of employees, agents, and contractors having access to identifying health information as to their obligations and liabilities under this Chapter;

(4) Maintaining a record of the creation, revision, or disclosure of identifying health information, including without limitation to whom an authorized disclosure is made; and

(5) Limiting, to the extent practicable, the disclosure to that which is legitimately needed to be known in order to perform authorized functions.

(b) A custodian need not maintain a record of:

(1) Access or disclosures made pursuant to G.S. 132A-3-2(c)(1), (2), (9), or (14) unless the information is maintained as an electronic record; or

(2) Oral disclosures made to a patient or made pursuant to G.S. 132A-3-2(c)(1), (2), (4), or (9)a.

"**§ 132A-3-5. Master person index.**

(a) A custodian may maintain or participate in and use, directly or through a contractor, a master person index. A custodian utilizing a master person index shall disclose or permit access to the index only to a custodian who has entered into a written agreement requiring protection of confidentiality of health information as required in this Chapter with the disclosing custodian. A master person index may utilize a unique identifier to identify patients and custodians.

(b) Notwithstanding subsection (a) of this section, the existence of the following medical records shall not be disclosed in a master person index unless the requesting party has authority under State or federal law to receive a disclosure of the information:

(1) Confidential information as defined in G.S. 122C-3(9);

(2) Information and records regulated by G.S. 130A-143; and

(3) Identifying health information that is otherwise maintained by a health care provider or health care facility and is identified by the provider as being related to a patient's evaluation, diagnosis, or treatment of HIV infection, AIDS, substance abuse, or mental health condition.

(c) Access to an entry in a master person index indicating the existence of identifying health information shall not be permitted except to the extent that the disclosure of the information sought is authorized pursuant to G.S. 132A-3-1, 132A-3-2, or 132A-3-3.

"**§ 132A-3-6. Electronic and other medical records.**

Notwithstanding any other State law, if a custodian maintains and preserves health information or signatures utilizing electronic, optical, or other technology and media, a custodian shall not be required to maintain a separate paper copy of the health information or signatures. However, if a person receiving a disclosure requests the disclosure in a paper form, the custodian shall not refuse to provide the requested information in a paper form, unless another medium is required by State or federal law.

(1) Access or disclosures made pursuant to G.S. 132A-3-2(c)(1), (2), (9), or (14) unless the information is maintained as an electronic record; or

(2) Oral disclosures made to a patient or made pursuant to G.S. 132A-3-2(c)(1), (2), (4), or (9)a.

"**§ 132A-3-5. Master person index.**

(a) A custodian may maintain or participate in and use, directly or through a contractor, a master person index. A custodian utilizing a master person index shall disclose or permit access to the index only to a custodian who has entered into a written agreement requiring protection of confidentiality of health information as required in this Chapter with the disclosing custodian. A master person index may utilize a unique identifier to identify patients and custodians.

(b) Notwithstanding subsection (a) of this section, the existence of the following medical records shall not be disclosed in a master person index unless the requesting party has authority under State or federal law to receive a disclosure of the information:

(1) Confidential information as defined in G.S. 122C-3(9);

(2) Information and records regulated by G.S. 130A-143; and

(3) Identifying health information that is otherwise maintained by a health care provider or health care facility and is identified by the provider as being related to a patient's evaluation, diagnosis, or treatment of HIV infection, AIDS, substance abuse, or mental health condition.

(c) Access to an entry in a master person index indicating the existence of identifying health information shall not be permitted except to the extent that the disclosure of the information sought is authorized pursuant to G.S. 132A-3-1, 132A-3-2, or 132A-3-3.

"**§ 132A-3-6. Electronic and other medical records.**

Notwithstanding any other State law, if a custodian maintains and preserves health information or signatures utilizing electronic, optical, or other technology and media, a custodian shall not be required to maintain a separate paper copy of the health information or signatures. However, if a person receiving a disclosure requests the disclosure in a paper form, the custodian shall not refuse to provide the requested information in a paper form, unless another medium is required by State or federal law.

"**§ 132A-3-7. Authentication of persons and information; electronic signatures.**

(a) When used in connection with health information, health care delivery, or transactions iinvolving health care, health care services, equipment, or supplies, or payments therefor, electronic signatures shall have the same legal effect as written signatures. Other authentication techniques recognized as having comparable or superior reliability to written or electronic signatures shall be acceptable for identification of any individual, entity, or health information associated with an individual or entity.

(b) All individuals authorized by a custodian to authenticate health information utilizing an authentication technique requiring a secure code shall sign an agreement with the custodian to the effect that only the individual will use or permit access to the code assigned to the individual.

"ARTICLE 4.

"General Provisions.

"**§ 132A-4-1. Safe harbors.**

(a) Notwithstanding any other provision of this Chapter, no custodian or employee, agent, or contractor of a custodian shall be liable for actions authorized to be taken under this Chapter when the custodian or employee, agent, or contractor of the custodian:

(1) Acted in good faith and in reliance upon health information disclosed consistent with this Chapter;

(2) Disclosed health information in good faith and in reliance upon a request for disclosure when the request identified a purpose for which disclosure is authorized under this Chapter;

(3) Disclosed health information as authorized by this Chapter, and the transmission of the information was interrupted, or an error in the transmission otherwise was caused, by a common carrier or enhanced service provider while facilitating the disclosure;

(4) Disclosed identifying health information in good faith reliance on an authorization provided by this Chapter;

(5) Is protected by a statutory immunity related to identifying health information; or

(6) Acted in good faith and in reliance upon recommendations, guidelines, or specifications implemented by the custodian that address the

subject matter of this Chapter and that are designed to protect patients from the damages complained of, in whole or in part, and which recommendations, guidelines, or specifications are:

a. Adopted by the United States Secretary of Health and Human Services; or

b. To the extent not preempted by or inconsistent with recommendations, guidelines, or specifications authorized by subdivision (1) of this section, recommendations, guidelines, or specifications recommended by the following organizations as model standards or specifications if adopted by the Office of State Planning or the Department of Health and Human Services pursuant to the rule-making procedures of the Administrative Procedures Act, Chapter 150B of the General Statutes, which agency may rely on the temporary rule-making procedures to utilize technology on a timely basis:

1. The National Committee on Vital and Health Statistics;
2. The National Uniform Billing Committee;
3. The National Uniform Claim Committee;
4. The North Carolina Health Care Information and Communications Alliance, Inc.;
5. The Workgroup for Electronic Data Interchange; or
6. Other public purpose organizations created under section 501(c) of the Internal Revenue Code and certified by Executive Order of the Governor as having the technical capability and breadth of representation in the health care community to address the subject matter of this Chapter in the public interest.

(b) Until the time that these recommendations, specifications, or guidelines are adopted as set forth in subsubdivision b. of subdivision (6) of subsection (a) of this section, the recommendations, guidelines, or specifications recommended by the organizations set forth in this subsubdivision as model standards or specifications shall constitute prima facie evidence of an

subject matter of this Chapter and that are designed to protect patients from the damages complained of, in whole or in part, and which recommendations, guidelines, or specifications are:

a. Adopted by the United States Secretary of Health and Human Services; or

b. To the extent not preempted by or inconsistent with recommendations, guidelines, or specifications authorized by subdivision (1) of this section, recommendations, guidelines, or specifications recommended by the following organizations as model standards or specifications if adopted by the Office of State Planning or the Department of Health and Human Services pursuant to the rule-making procedures of the Administrative Procedures Act, Chapter 150B of the General Statutes, which agency may rely on the temporary rule-making procedures to utilize technology on a timely basis:

1. The National Committee on Vital and Health Statistics;
2. The National Uniform Billing Committee;
3. The National Uniform Claim Committee;
4. The North Carolina Health Care Information and Communications Alliance, Inc.;
5. The Workgroup for Electronic Data Interchange; or
6. Other public purpose organizations created under section 501(c) of the Internal Revenue Code and certified by Executive Order of the Governor as having the technical capability and breadth of representation in the health care community to address the subject matter of this Chapter in the public interest.

(b) Until the time that these recommendations, specifications, or guidelines are adopted as set forth in subsubdivision b. of subdivision (6) of subsection (a) of this section, the recommendations, guidelines, or specifications recommended by the organizations set forth in this subsubdivision as model standards or specifications shall constitute prima facie evidence of an

appropriate standard of care that may be relied on by a Custodian.

"§ 132A-4-2. Civil remedies.

(a) Subject to G.S. 132A-4-1 and Chapter 1D of the General Statutes, a custodian or an employee, agent, or contractor of a custodian shall be subject to civil liability for damages incurred by a person with respect to the patient's identifying health information to the extent that these damages arise out of the intentional or negligent act or omission of a custodian in violation of the requirements of this Chapter.

(b) If a patient believes that a custodian, employee, agent, or contractor of a custodian has failed to comply with its obligations under this Chapter with respect to the patient's identifying health information, a patient may apply to a court of competent jurisdiction for appropriate equitable relief.

(c) Any agreement purporting to limit the liability arising from violations of this Chapter, other than pursuant to a settlement agreement, is void.

"§ 132A-4-3. Conflicting laws.

(a) This Chapter does not restrict a custodian from complying with obligations imposed by federal health care payment programs, federal law or State law compelling disclosure. This Chapter shall not apply if and to the extent portions of it may be preempted by the Employee Retirement Income Security Act of 1974. To the extent the provisions of this Chapter conflict with other State law, the provisions of this Chapter shall control unless the other State law specifically states that it is an exception to a specific provision of this Chapter unless this Chapter conflicts with another State statute governing the nondisclosure of identifying health information held by a health oversight agency for the purposes of peer review, professional review, or other professional disciplinary or corrective action. In these two cases, that other statute shall control.

(b) G.S. 132A-2-1, 132A-2-2, 132A-3-4(a)(4), and 132A-4-2 shall not apply to disclosures of identifying health information regulated by Article 39 of Chapter 58 of the General Statutes. Health information regulated by Article 39 of Chapter 58 of the General Statutes may also be disclosed as permitted by that Article or G.S. 132A-3-1 and G.S. 132A-3-2(b) and (c).

(c) G.S. 132A-2-1 and G.S. 132A-3-2(c) shall not apply to disclosures of identifying health information regulated by Chapter 122C of the General Statutes.

(d) G.S. 132A-3-2(c) shall not apply to disclosures of identifying health information regulated by G.S. 130A-143 when a custodian is acting pursuant to that section.

(e) This Chapter does not apply to a telecommunications common carrier or an enhanced service provider if they are certified or subject to regulation:

(1) Under Chapter 62 of the General Statutes; or

(2) By the Federal Communications Commission pursuant to federal law.

(f) Except as provided in G.S. 132A-2-3(e) and (f), this Chapter does not regulate the disclosure of health information that is not identifying health information.

"**§ 132A-4-4. Rules of construction.**

Except as otherwise required by law, this Chapter does not require the disclosure of trade secrets or other commercial information."

Section 2. This act becomes effective July 1, 1999, except that G.S. 132A-3-3, 132A-3-5, 132A-3-6, and 132A-3-7 become effective when this act becomes law. Custodians who comply with this act prior to its effective date may rely on G.S. 132A-4-1 as to causes of action that accrue after their compliance.

(d) G.S. 132A-3-2(c) shall not apply to disclosures of identifying health information regulated by G.S. 130A-143 when a custodian is acting pursuant to that section.

(e) This Chapter does not apply to a telecommunications common carrier or an enhanced service provider if they are certified or subject to regulation:

(1) Under Chapter 62 of the General Statutes; or

(2) By the Federal Communications Commission pursuant to federal law.

(f) Except as provided in G.S. 132A-2-3(e) and (f), this Chapter does not regulate the disclosure of health information that is not identifying health information.

"**§ 132A-4-4. Rules of construction.**

Except as otherwise required by law, this Chapter does not require the disclosure of trade secrets or other commercial information."

Section 2. This act becomes effective July 1, 1999, except that G.S. 132A-3-3, 132A-3-5, 132A-3-6, and 132A-3-7 become effective when this act becomes law. Custodians who comply with this act prior to its effective date may rely on G.S. 132A-4-1 as to causes of action that accrue after their compliance.

Section by Section Summary
Health Care Information Privacy Act
98-LFZ-010B(3.11)

Bill Provision	Summary	Statute Section Page Number
Purpose.	To facilitate the benefits of electronic information and to establish a clear legislative policy to ensure the accuracy, security, integrity and reliability of health information.	132A-1-1 Page 1.
Definitions.	The following terms are defined: Audit, Custodian, Directory information, Electronic, Electronic agent, Electronic record, Electronic signatures,	132A-1-2 Page 2. Page 4.
	Facility, Health care, Health information, Health oversight agency, Health research, Identifying health information, Identifying provider information,	Page 5.
	Master person index, Medical record, Patient, Payer, Person, Provider, Sign.	Page 6.
Patient's privacy interests.	Establishes patient's right of access to **examine and copy** the patient's own health information.	132A-2-1(a) Page 7.
	Establishes procedure to **request to amend** information the patient believes is inaccurate or incomplete.	132A-2-2(a) Page 7.
	Places a duty to maintain the confidentiality of identifying health information upon the custodian of that information, and the custodian's employees, and agents.	132A-2-3 Page 8.
	Provides protections against linking non-identifying information to identify the patient or provider.	132A-2-3(e) & (f) Page 8.
	Prohibits unauthorized use by the recipient of disclosed identifying health information.	132A-2-3(c) Page 8.
	The recipient may use or redisclose identifying information **only** for the purpose and under the authority of the original disclosure.	132A-2-3(h) Page 8.

Bill Provision	Summary	Statute Section Page Number
Authorization to disclose health information.	Prohibits custodian from disclosing identifying health information without patient's authorization, unless disclosure is otherwise authorized by law. Requires the custodian to keep a patient's authorization to disclose with the patient's health information. Establishes the minimum requirements for a patient's authorization to disclose to be valid. Provides that the patient may revoke or amend authorization, except to the extent custodian has relied upon it. Authorization is effective for time specified by the patient or if not specified, one year.	132A-3-1(a) Page 9. 132A-3-1(b) Page 9. 132A-3-1-(d) & (e) Page 10.
Rules of disclosure and use of health information.	Obligates disclosing party to make a reasonable effort to disclose or use non-identifying health information whenever sufficient to achieve the purpose of the disclosure. Requires mandatory disclosures as currently required by law (to law enforcement, to report suspected abuse, pursuant to a court order).	132A-3-2(a) Page 10. 132A-3-2(b) Page 10.

When disclosure is allowed without consent.	Sets forth circumstances in which identifying health information **may** be disclosed, including:
	
	* to provide health care to the patient:
	  * to a provider currently caring for the patient
	  * to a referring provider (if the patient does not object);
	  * to another provider in the same group practice or provider network.
		132A-3-2(c) Page 10-11.
		
		132A-3-2 (c)(1) & (c)(2) Pages 8-9.

	*to provide care in case of an immediate threat to the patient's health;	132A-3-2(c)(3) Page 11.

Bill Provision	Summary	Statute Section an Page Number
When disclosure is allowed without consent, continued.	* to protect against serious and imminent danger;	132A-3-2(c)(3) Page 11.
	* to protect against violent felony or misdemeanor;	
	* to the custodian that originally reported the information to verify the accuracy of the information;	132A-3-2(c)(6) Page 11.
	* to a health oversight agency for audit functions;	132A-3-2(c)(7) Page 11.
	* to agents, employees of the custodian if necessary to patient care or to perform administrative services;	132A-3-2(c)(9) Page 11.
	* to a health researcher for health research if permitted by federal or State law;	132A-3-2(c)(10) Page 11
	* For custodian's internal audit;	132A-3-2(c)(8) Page 11.
	* directory information;	132A-3-2(c)(14) Page 11.
	* to a group policyholder when necessary for audit of a service already provided;	132A-3-2(c)(13) Page 11.
	* to a provider to confirm or compare treatment;	132A-3-2(c)(11) Page 11.
	* to a custodian's successor in interest (e.g., Executor or Administrator of Estate)	132A-3-2(c)(12) Page 11
Subpoenas, search warrants, discovery requests, and court orders.	Provides that identifying health information is to be treated as if the information were medical records.	132A-3-3(a) Page 12.
	Access to health information for legal purposes requires: • patient authorization • authorization from deceased patient's representative **or** • a court order.	132A-3-3(b) Page 12.

Bill Provision	Summary	Statute Section Page Number
Custodian responsibilities.	* Requires custodians to **develop policies and safeguards** to protect the confidentiality, security, accuracy, and integrity of health information; * **training of employees** having access to identifying health information; * **internal punishment for violation;** * **limiting disclosure to information needed to accomplish purpose;** • **audit trails showing disclosure** (except disclosures made for the purpose of providing ongoing health care to the patient **unless** communicated electronically, or oral disclosures to a patient or to family members if the patient lacks mental capacity).	132A-3-4(a) Page 13. 132A-3-4(a)(3) Page 13. 132A-3-4(a)(1) Page 13. 132A-3-4(a)(5) Page 13. 132A-3-4(a)(4) Page 13.
Patient Information Locator.	Permits the creation by a custodian of an index that: * points to the location of medical records held by the custodian; * enables access to complete patient record for health care if authorized; * custodian may participate in locator; * does not include "sensitive" information, unless authorized.	132A-3-5 Page 14.
Electronic medical records.	Allows a custodian to maintain and preserve health information solely in electronic form, (**paper records are no longer required**).	132A-3-6 Page 14.
Electronic signatures.	Provides that electronic authentication of individuals, entities and associated health information is authorized. Prohibits the disclosure of an individual's security code (password).	132A-3-7 Page 15.

Bill Provision	Summary	Statute Section Page Number
afe harbors (from liability).	Provides **safe harbor for compliance** with standards.	132A-4-1 Pages 15-16.
Civil remedies.	Provides **civil liability** for violation of the law, including negligence action and injunctions. **Criminal liability** under computer crimes law and statutes governing mental health facilities are not affected.	132A-4-2 Page 17.
Conflict of existing laws.	Does not preempt disclosure obligations imposed by federal health care payment programs. Does not preempt State and federal law compelling or prohibiting disclosure. (Does not affect federal law regarding substance abuse). To the extent the provisions of this Chapter conflict with existing State law the provisions of this Chapter will control unless: * the other State law is specifically exempted ; OR * the State law governs the nondisclosure of identifying health information held by a health oversight agency for the purposes of peer review, professional review, or other professional disciplinary or corrective action.	132A-4-3(a) Pages 13-14. 132A-4-3(a) Page 14. 132A-4-3(a) Page 14.
Conflict of existing laws, continued.	The following provisions do not apply to **insurance information** governed by Article 39 of Chapter 58: * patient's examination and copying * request for amendment * authorization requirement for disclosure * custodian responsibilities * civil remedies All other provisions apply.	132A-4-3(b) Page 17.

Bill Provision	Summary	Statute Section Page Number
Conflict of existing laws, continued.	The following provisions do not apply to **mental health** information governed by Chapter 122C: * patient's examination and copying * disclosures without consent [132A-3-2(c)] All other provisions apply.	132A-4-3(c) Page 17.
	The following provisions do not apply to **communicable disease information** governed by Chapter 130A: * disclosures without consent [132A-3-2(c)] All other provisions apply.	132A-4-3(d) Page 17.
	Does not apply to a **telecommunications common carrier** or an enhanced service provider if they are certified and subject to regulation under Chapter 62 of the General Statutes (Public Utilities) or by the Federal Communications Commission.	132A-4-3(e) Page 18.
Rules of construction.	This Chapter is to be construed as NOT requiring the disclosure of trade secrets or other confidential commercial information.	132A-4-4 Page 18.
Effective dates.	The act will become effective **July 1, 1999**, except that G.S. 132A-3-3 (subpoenas, court orders, etc.), 132A-3-5 (master patient index), 132A-3-6 (electronic and paper records), and 132A-3-7 (authentication of persons and information by electronic signatures), are effective when the act becomes law.	Page 14.

LEGISLATIVE PROPOSAL #3

AN ACT TO MAKE NECESSARY TECHNICAL CORRECTIONS TO CHAPTER 442 OF THE 1997 SESSION LAWS, "AN ACT TO ESTABLISH ADVANCED INSTRUCTION FOR MENTAL HEALTH TREATMENT."

Short Title: Advance Directives Corrections

Statute Affected: Article 3 of Chapter 122C by adding a new Part 2, Advance Instruction for Mental Health Treatment.

Agency Affected: Department of Health and Human Services

Interested Parties: health care providers, people with mental illness, lawyers, mental health advocates

Explanation of Proposal: The legislation is intended to address practical concerns related to implementing the recently enacted "Advanced Instructions for Mental Health Treatment".

Appropriations and/or Fees: No.

Effective Date: When the act becomes law.

GENERAL ASSEMBLY OF NORTH CAROLINA

DRAFT

SESSION 1997

H FOR REVIEW ONLY D

98-LFZ-021(5.8)

(THIS IS A DRAFT AND IS NOT READY FOR INTRODUCTION)

Short Title: Advance Directives Corrections. (Public)

Sponsors: .

Referred to:

A BILL TO BE ENTITLED

AN ACT TO MAKE NECESSARY TECHNICAL CORRECTIONS TO CHAPTER 442 OF THE 1997 SESSION LAWS, "AN ACT TO ESTABLISH ADVANCE INSTRUCTION FOR MENTAL HEALTH TREATMENT", AS RECOMMENDED BY THE JOINT LEGISLATIVE HEALTH OVERSIGHT COMMITTEE.

The General Assembly of North Carolina enacts:

Section 1. Chapter 442 of the 1997 Session Laws is amended to make necessary technical corrections.

Section 2. This act is effective upon becoming law.

LEGISLATIVE PROPOSAL #4

AN ACT TO CREATE PROVIDER SPONSORED LICENSING.

Short Title:	PSO Medicare Licensing
Statute(s) Affected:	Adds a new Article (17) to Chapter 131E of the General Statutes G.S. 58-67-10(b)
Agency Affected:	Department of Health and Human Services and the Department of Insurance
Interested Parties:	health care providers, payers, Medicare beneficiaries, HMOs and other managed care plans.
Explanation of Proposal:	The proposed legislation would authorize the Department of Health and Human Services, acting through the Medical Care Commission, to license provider sponsored organizations as risk bearing entities to contract with Medicare to provide health care services to Medicare beneficiaries enrolls in the Medicare+Choice Plan.
Appropriations:	PSO's will be required to pay the Department $250.00 fee for filing an application for a license; $500.00 fee for each annual renewal; and $100.00 fee for filing each quarterly report.
Fees:	Not specified on the bill. Fiscal note is pending.
Effective Date:	July 1, 1998.

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1997

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98-LFZX-018(4.17)

Short Title: PSO Medicare Licensing. (Public)

Sponsors:

Referred to:

A BILL TO BE ENTITLED

AN ACT TO CREATE MEDICARE PROVIDER SPONSORED ORGANIZATION LICENSING.

The General Assembly of North Carolina enacts:

Section 1. Chapter 131E of the General Statutes is amended by adding a new Article to read:

"Article 17. Provider Sponsored Organization Licensing.

"§ 131E-275. General provisions.

(a) The General Assembly acknowledges that section 1855, et seq., of the federal Social Security Act permits provider sponsored organizations that are organized and licensed under State law as risk-bearing entities, or that are otherwise certified as such by the federal government, to be eligible to offer health insurance or health benefits coverage in each State in which the provider sponsored organization offers a Medicare+Choice plan. The General Assembly declares that provider sponsored organizations are beneficial to North Carolina citizens who are Medicare beneficiaries and should be encouraged, subject to appropriate regulation by the Department of Health and Human Services, acting through the Medical Care Commission. The General Assembly further declares that, because provider sponsored organizations provide health care directly and assume responsibility for the provision of Health Care Services to Medicare beneficiaries under the requirements of the federal Medicare program, they require different regulatory oversight to

protect the public than health maintenance organizations and insurance companies. The General Assembly further declares that the organizers and operators of provider sponsored organizations which are licensed under the terms of this Article as risk-bearing entities authorized to contract directly with the federal Medicare+Choice program shall not be subject to Chapter 58 or the insurance laws of this State, unless otherwise specified in this Article.

(b) As set forth in this Article, the Department of Health and Human Services, acting through the Medical Care Commission, shall be the agency of the State authorized to license provider sponsored organizations to contract with Medicare to provide health care services to Medicare beneficiaries and to engage in the other related activities described in this Article.

(c) Each provider sponsored organization shall obtain a license from the Department or shall otherwise be certified by the federal government prior to establishing, maintaining, and operating a health care plan in this State for Medicare+Choice beneficiaries.

"§ 131E-276. Definitions.

As used in this Article, unless the context clearly implies otherwise, the following definitions apply:

(1) "Beneficiary" or "beneficiaries" means a beneficiary or beneficiaries of the Medicare+Choice program who are enrolled with the provider sponsored organization (PSO) under the terms of a contract between the PSO and the Medicare program.

(2) "Commissioner" means the Commissioner of Insurance of North Carolina.

(3) "Current assets" means cash, marketable securities, accounts receivable, and other current items that will be converted into cash within 12 months.

(4) "Current liabilities" means accounts payable and other accrued liabilities, including payroll, claims, and taxes that will need to be paid within 12 months.

(5) "Current ratio" means the ratio of current assets divided by current liabilities calculated at the end of any accounting period.

(6) "Department" means the Department of Health and Human Services acting through the North Carolina Medical Care Commission.

(7) "Emergency services" shall have the same meaning as for that term defined in G.S. 58-50-61(a)(5).

protect the public than health maintenance organizations and insurance companies. The General Assembly further declares that the organizers and operators of provider sponsored organizations which are licensed under the terms of this Article as risk-bearing entities authorized to contract directly with the federal Medicare+Choice program shall not be subject to Chapter 58 or the insurance laws of this State, unless otherwise specified in this Article.

(b) As set forth in this Article, the Department of Health and Human Services, acting through the Medical Care Commission, shall be the agency of the State authorized to license provider sponsored organizations to contract with Medicare to provide health care services to Medicare beneficiaries and to engage in the other related activities described in this Article.

(c) Each provider sponsored organization shall obtain a license from the Department or shall otherwise be certified by the federal government prior to establishing, maintaining, and operating a health care plan in this State for Medicare+Choice beneficiaries.

"§ 131E-276. Definitions.

As used in this Article, unless the context clearly implies otherwise, the following definitions apply:

(1) "Beneficiary" or "beneficiaries" means a beneficiary or beneficiaries of the Medicare+Choice program who are enrolled with the provider sponsored organization (PSO) under the terms of a contract between the PSO and the Medicare program.

(2) "Commissioner" means the Commissioner of Insurance of North Carolina.

(3) "Current assets" means cash, marketable securities, accounts receivable, and other current items that will be converted into cash within 12 months.

(4) "Current liabilities" means accounts payable and other accrued liabilities, including payroll, claims, and taxes that will need to be paid within 12 months.

(5) "Current ratio" means the ratio of current assets divided by current liabilities calculated at the end of any accounting period.

(6) "Department" means the Department of Health and Human Services acting through the North Carolina Medical Care Commission.

(7) "Emergency services" shall have the same meaning as for that term defined in G.S. 58-50-61(a)(5).

(8) "Health Care Delivery Assets" means any tangible asset that is part of a PSO operation, including hospitals, medical facilities, and their ancillary equipment, and any property that may reasonably be required for the PSO's principal office or for any purposes that may be necessary in the transaction of the business of the PSO.

(9) "Health plan contract" or "Medicare contract" means a PSO's direct contract with the United States Department of Health and Human Services under section 1857 of the federal Social Security Act.

(10) "Out-of-network services" means health care items or services that are covered services under a PSO's Medicare contract and that are provided to beneficiaries by health care providers that are not participating providers in the PSO's network of health care providers.

(11) "Parent of a sponsoring provider" means the public or private entity that owns or controls a controlling interest in the sponsoring provider or that has the power to appoint a controlling number of the governing board of a sponsoring provider or that has the power to direct the management policy and decisions of the sponsoring provider.

(12) "Provider" or "health care provider" means: (i) any individual that is engaged in the delivery of health care services and that is required by North Carolina law or regulation to be licensed to engage in the delivery of these health care services and is so licensed; (ii) any entity that is engaged in the delivery of health care services and that is required by North Carolina law or regulation to be licensed to engage in the delivery of these health care services and is so licensed; or (iii) any entity that is owned or controlled entirely by individuals or entities described in subparts (i) or (ii) of this definition.

(13) "Provider sponsored organization" or "PSO" means a public or private entity domiciled in this State, including a business corporation, a nonprofit corporation, a partnership, a limited liability company, a professional limited liability company, a professional corporation, a sole proprietorship, a public hospital, a hospital authority, a hospital

district, or a body politic: (i) that is established or organized by a health care provider or group of affiliated health care providers; (ii) in which physicians licensed pursuant to Article 1 of Chapter 90 of the General Statutes or to the laws of any state of the United States comprise no less than fifty percent (50%) of the governing board or body, unless otherwise prohibited by law; (iii) that provides a substantial proportion of the services under each Medicare contract directly through the provider or group of affiliated providers; and (iv) in which the provider or affiliated providers directly or indirectly share substantial financial risk and have at least a majority financial interest. The requirement in subpart (ii) of this definition shall not preclude a PSO that includes a tax-exempt hospital from adopting a bylaw provision that provides a veto for the tax-exempt hospital over actions of the PSO necessary to maintain the hospital's tax-exempt status. A PSO shall not be out of compliance with the requirement in subpart (ii) due to temporary vacancies on its governing board or body.

(14) "Secretary" means the Secretary of the Department of Health and Human Services.

(15) "Sponsoring providers" of a PSO means the health care provider domiciled in this State that assumes, or group of affiliated health care providers that directly or indirectly shares, substantial financial risk in the PSO and that has at least a majority financial interest in the PSO.

(16) "Substantial proportion of the services", as that term is used in G.S. 131E-276(n) and G.S. 131E-309(a), means at least seventy percent (70%), or sixty percent (60%) for PSOs whose beneficiaries reside primarily in rural areas, of the annual cost of health care services.

(17) A health care provider is affiliated with another provider if through contract, ownership, or otherwise, when: (i) one provider directly controls, is controlled by, or is under common control with the other provider; (ii) each provider participates in a lawful combination under which they share substantial financial risk for the

district, or a body politic: (i) that is established or organized by a health care provider or group of affiliated health care providers; (ii) in which physicians licensed pursuant to Article 1 of Chapter 90 of the General Statutes or to the laws of any state of the United States comprise no less than fifty percent (50%) of the governing board or body, unless otherwise prohibited by law; (iii) that provides a substantial proportion of the services under each Medicare contract directly through the provider or group of affiliated providers; and (iv) in which the provider or affiliated providers directly or indirectly share substantial financial risk and have at least a majority financial interest. The requirement in subpart (ii) of this definition shall not preclude a PSO that includes a tax-exempt hospital from adopting a bylaw provision that provides a veto for the tax-exempt hospital over actions of the PSO necessary to maintain the hospital's tax-exempt status. A PSO shall not be out of compliance with the requirement in subpart (ii) due to temporary vacancies on its governing board or body.

(14) "Secretary" means the Secretary of the Department of Health and Human Services.

(15) "Sponsoring providers" of a PSO means the health care provider domiciled in this State that assumes, or group of affiliated health care providers that directly or indirectly shares, substantial financial risk in the PSO and that has at least a majority financial interest in the PSO.

(16) "Substantial proportion of the services", as that term is used in G.S. 131E-276(n) and G.S. 131E-309(a), means at least seventy percent (70%), or sixty percent (60%) for PSOs whose beneficiaries reside primarily in rural areas, of the annual cost of health care services.

(17) A health care provider is affiliated with another provider if through contract, ownership, or otherwise, when: (i) one provider directly controls, is controlled by, or is under common control with the other provider; (ii) each provider participates in a lawful combination under which they share substantial financial risk for the

organization's operation; (iii) both providers are part of a controlled group of corporations as defined under section 1563 of the Internal Revenue Code of 1986; or (iv) both providers are part of an affiliated service group under section 414 of this Code. Control is presumed if one party directly or indirectly owns, controls, or holds the power to vote, or proxies for, at least fifty-one percent (51%) of the voting or governance rights of another.

"§ 131E-277. Direct or indirect sharing of substantial financial risk.

In order for sponsoring providers to directly or indirectly share substantial financial risk in the PSO, the PSO shall do one or more of the following:

(1) Provide services under its Medicare contract at a capitated rate;

(2) Provide designated services or classes of services under its Medicare contract for a predetermined percentage of premium or revenue from the Medicare program;

(3) Use significant financial incentives for its sponsoring providers, as a group to achieve specified cost-containment goals either by:

a. Withholding from all sponsoring providers a substantial amount of the compensation due to them, with distribution of that amount to the sponsoring providers based on performance of all sponsoring providers in meeting the cost-containment goals of the network as a whole; or

b. Establishing overall cost or utilization targets for the PSO, with the sponsoring providers subject to subsequent substantial financial rewards or penalties based on group performance in meeting the targets; or

(4) Agree to provide a complex or extended course of treatment that requires the substantial coordination of care by sponsoring providers in different specialties offering a complementary mix of services, for a fixed, predetermined payment, when the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's treatment or other factors; or

(5) Agree to any other arrangement that the Department determines to provide for the sharing of substantial financial risk by the sponsoring providers.

It is the intent of the General Assembly to encourage innovative methods by which sponsoring providers can directly or indirectly share substantial financial risk in the PSO in any lawful manner.

"**§ 131E-278. Applicability of other laws.**

(a) Unless otherwise required by federal law, provider sponsored organizations licensed pursuant to the terms of this Article are exempt from all regulation under Chapter 58 of the General Statutes. Plan contracts, provider contracts, and other arrangements related to the provision of covered services by these licensed networks or by health care providers of these PSOs when operating through these PSOs shall likewise be exempt from regulation under Chapter 58 of the General Statutes.

"**§ 131E-279. Approval.**

(a) Unless otherwise required by federal law, the Department shall be the agency of the State that shall license provider sponsored organizations that seek to contract with the federal government to provide health care services directly to Medicare beneficiaries under the Medicare+Choice program.

(b) Provider sponsored organizations which have been granted a waiver pursuant to 42 U.S.C. § 1395w-25(a)(2), or any successor thereof, and which otherwise meet the requirements of the PSO's Medicare contract shall be deemed by the State to be licensed under this Article for so long as the waiver or Medicare contract remains in effect. The foregoing shall not limit the Department's authority to regulate such PSOs and their respective sponsoring providers and affiliated providers as may be permitted in 42 U.S.C. § 1395w-25(a)(2)(G), or any successor thereof, or the PSO's Medicare contract.

(c) The Department shall license a PSO as a risk-bearing entity eligible to offer health benefits coverage in this State to Medicare beneficiaries if the PSO complies with the requirements of this Article. This license shall be granted or denied by the Department not longer than 90 days after the receipt of a substantially complete application for licensing. Within 45 days after the Department receives an application for licensing, the Department shall either notify the applicant that the application is substantially complete, or clearly and accurately specify in writing to the applicant all additional specific information required by the applicant to make the

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application a substantially completed application. This agency response shall set forth a date and time for a meeting within 30 days after it is sent to the applicant, at which a representative of the Department will explain with particularity the additional information required by the Department in the response to make the application substantially complete. The Department shall be bound by the response unless the Secretary determines that it must be modified in order to meet the purposes of this Article. The Secretary shall not delegate the authority to modify the response. If an applicant provides the additional information set forth in the response, the application shall be considered substantially complete. If the Department has not acted on an application within 90 days after it is deemed substantially complete, the Department shall immediately issue a license to the applicant, and the applicant shall be considered to have been licensed by the Department. Any reapplication which corrects the deficiencies which were specified by the Department in the response shall be approved by the Department.

(d) For purposes of determining, under 42 U.S.C. § 1395w-25(a)(2)B, or any successor thereof, the date of receipt by the State of a substantially complete application, the date the Department receives the applicant's written response to the agency response or an earlier date considered by the Department shall be considered to be that date. The foregoing shall not limit the Department's authority to consider an application not substantially complete under subsection (c) of this section if the applicant's response to the response does not provide substantially the information specified in the response.

(e) The standards in G.S. 131E-279 through G.S. 131E-288 and in G.S. 131E-290 through G.S. 131E-308 shall apply to PSOs, unless federal law specifies standards more favorable to PSOs or unless otherwise preempted by federal law.

(f) A license shall be denied only after the Department complies with the requirements of G.S. 131E-312.

"**§ 131E-280. Applicants for license.**

(a) Each application for licensing as a provider sponsored organization authorized to do business in North Carolina shall be certified by an officer or authorized representative of the applicant, shall be in a form prescribed by the Department, and shall be set forth or be accompanied by the following:

(1) A copy of the basic organizational document, if any, of the applicant and each sponsoring organization that holds greater than a five percent (5%) interest in the PSO, such as the articles of

incorporation, articles of organization, partnership agreement, trust agreement, or other applicable documents, and all amendments thereto;

(2) A copy of the respective bylaws, rules and regulations, or similar documents, if any, regulating the conduct of the internal affairs of the applicant and each sponsoring provider which holds greater than a five percent (5%) interest in the PSO;

(3) Copies of the document evidencing the arrangements between the applicant and each sponsoring provider that create the relationships and obligations described in G.S. 131E-276(n);

(4) A list of the names, addresses, and official positions of persons who are to be responsible for the conduct of the affairs of the applicant and of each sponsoring provider that holds greater than a five percent (5%) interest in the PSO, respectively, including all members of the respective boards of directors, boards of trustees, executive committees, or other governing boards or committees, the principal officers in the case of a corporation, and the partners or members in the case of a partnership or association;

(5) A copy of any contract form made or to be made between any class of providers and the PSO and a copy of any contract form made or to be made between third-party administrators, marketing consultants, or persons listed in subdivision (3) of this subsection and the PSO;

(6) A statement generally describing the provider sponsored organization, its sponsoring providers, its health care plan or plans, facilities, and personnel;

(7) A copy of the hospital license of each sponsoring provider that is a hospital, a copy of the license to practice medicine of each sponsoring provider or owner of a sponsoring provider that is a licensed physician, and a copy of the health care service or facility license held by any other licensed sponsoring provider;

(8) Financial statements showing the applicant's assets, liabilities, sources of financial support, and the financial statements of each sponsoring

incorporation, articles of organization, partnership agreement, trust agreement, or other applicable documents, and all amendments thereto;

(2) A copy of the respective bylaws, rules and regulations, or similar documents, if any, regulating the conduct of the internal affairs of the applicant and each sponsoring provider which holds greater than a five percent (5%) interest in the PSO;

(3) Copies of the document evidencing the arrangements between the applicant and each sponsoring provider that create the relationships and obligations described in G.S. 131E-276(n);

(4) A list of the names, addresses, and official positions of persons who are to be responsible for the conduct of the affairs of the applicant and of each sponsoring provider that holds greater than a five percent (5%) interest in the PSO, respectively, including all members of the respective boards of directors, boards of trustees, executive committees, or other governing boards or committees, the principal officers in the case of a corporation, and the partners or members in the case of a partnership or association;

(5) A copy of any contract form made or to be made between any class of providers and the PSO and a copy of any contract form made or to be made between third-party administrators, marketing consultants, or persons listed in subdivision (3) of this subsection and the PSO;

(6) A statement generally describing the provider sponsored organization, its sponsoring providers, its health care plan or plans, facilities, and personnel;

(7) A copy of the hospital license of each sponsoring provider that is a hospital, a copy of the license to practice medicine of each sponsoring provider or owner of a sponsoring provider that is a licensed physician, and a copy of the health care service or facility license held by any other licensed sponsoring provider;

(8) Financial statements showing the applicant's assets, liabilities, sources of financial support, and the financial statements of each sponsoring

provider that holds greater than a five percent (5%) interest in the PSO showing the sponsoring provider's assets, liabilities, and sources of support. If the applicant's or any such sponsoring provider's financial affairs are audited by independent certified public accountants, a copy of the applicant's or sponsoring provider's most recent regular certified financial statement shall be considered to satisfy this requirement unless the Department directs that additional or more recent financial information is required for the proper administration of this Article;

(9) If the applicant's obligations under G.S. 131E-282, 131E-283, 131E-297, 131E-298, or 131E-299 are guaranteed by one or more guarantors, financial statements showing each guarantor's assets, liabilities, and sources of financial support. If a guarantor's financial affairs are audited by independent certified public accountants, a copy of the guarantor's most recent regular audited financial statement shall be considered to satisfy this requirement unless the Department directs that additional or more recent financial information is required for the proper administration of this Article;

(10) A financial plan, satisfactory to the Department, covering the first 12 months of operation under the PSO's Medicare contract and which meets the requirements of G.S. 131E-283. If the financial plan projects losses, the financial plan must cover the period through 12 months beyond the projected breakeven;

(11) A statement reasonably describing the geographic area or areas to be served;

(12) A description of the procedures to be implemented to meet the protection against insolvency requirements of G.S. 131E-298; and

(13) Any other information the Department may require to make the determinations required in G.S. 131E-282.

(b) The Department may adopt rules exempting from the filing requirements of subsection (a) of this section those items it considered unnecessary.

"**§ 131E-281. Additional Information.**

(a) In addition to the information filed under G.S. 131E-280(a), each application shall include a description of the following:

(1) The program to be used to evaluate whether the applicant's network of sponsoring providers and contracted providers is sufficient, in numbers and types of providers, to assure that all health care services will be accessible without unreasonable delay;

(2) The program used to evaluate whether the sponsoring providers providers provide a substantial portion of services under each Medicare contract of the PSO;

(3) The program to be used for verifying provider credentials;

(4) The utilization review program for the review and control of health care services provided or paid for by the applicant;

(5) The quality management program to assure quality of care and health care services managed and provided through the health care plan; and

(6) The applicant's network of sponsoring providers and contracted providers and evidence of the ability of that network to provide all health care services other than out-of-network services and emergency services to the applicant's prospective beneficiaries.

(b) The department may promulgate rules and regulations exempting from the filing requirements of subdivision (a) those items it deems unnecessary.

"**§ 131E-282. Issuance of license.**

(a) Before issuing any such license, the Department may make such an examination or investigation as it deems expedient. The Department shall issue a license after receipt of a substantially complete application, upon the payment of the application fee prescribed in G.S. 131E-307and upon satisfaction of the following requirements:

(1) The applicant is duly organized as a provider sponsored organization as defined by the Article.

(2) That the PSO has initially a minimum net worth of one million five hundred thousand dollars ($1,500,000). In the event the PSO submits a financial plan that demonstrates that the PSO does not have to create but has or has available to it

(a) In addition to the information filed under G.S. 131E-280(a), each application shall include a description of the following:

(1) The program to be used to evaluate whether the applicant's network of sponsoring providers and contracted providers is sufficient, in numbers and types of providers, to assure that all health care services will be accessible without unreasonable delay;

(2) The program used to evaluate whether the sponsoring providers providers provide a substantial portion of services under each Medicare contract of the PSO;

(3) The program to be used for verifying provider credentials;

(4) The utilization review program for the review and control of health care services provided or paid for by the applicant;

(5) The quality management program to assure quality of care and health care services managed and provided through the health care plan; and

(6) The applicant's network of sponsoring providers and contracted providers and evidence of the ability of that network to provide all health care services other than out-of-network services and emergency services to the applicant's prospective beneficiaries.

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(1) The applicant is duly organized as a provider sponsored organization as defined by the Article.

(2) That the PSO has initially a minimum net worth of one million five hundred thousand dollars ($1,500,000). In the event the PSO submits a financial plan that demonstrates that the PSO does not have to create but has or has available to it

an administrative infrastructure that shall reduce the PSO's start-up costs, the Department may lower the initial minimum net worth required to one million dollars ($1,000,000) or to any lower amount as determined by the Department if the PSO operates primarily in rural areas.

(3) The PSO shall have at least seven hundred fifty thousand dollars ($750,000) in cash or equivalents on its balance sheet, except that the Department may permit a PSO operating primarily in rural areas to have a lesser amount held in cash or equivalents on its balance sheets.

(4) The applicant submits a financial plan satisfactory to the Department which covers the first 12 months of operation of the PSO's Medicare contract and which meets the requirements of G.S. 131E-283. If the plan projects losses, the financial plan shall cover the period through 12 months beyond projected break-even.

(5) The Department determines that the applicant has sufficient cash flow to meet its obligations as they become due. In making that determination, the Department shall consider the following:

a. The timeliness of payment;

b. The extent to which the current ratio is maintained at one to one, or whether there is a change in the current ratio over a period of time; and

c. The availability of outside financial resources.

(b) In calculating the net worth of a PSO, the Department shall admit the following:

(1) One hundred percent (100%) of the book value of health care delivery assets on the balance sheet of the applicant.

(2) One hundred percent (100%) of the value of cash and cash equivalents on the balance sheet of the applicant.

(3) If at least one million dollars ($1,000,000) of the initial minimum net worth requirement is met by cash or cash equivalents, then one hundred percent (100%) of the book value of the PSO's intangible assets up to twenty percent (20%) of the minimum net worth amount required. If less than one

million dollars ($1,000,000) of the initial minimum net worth requirement is met by cash or cash equivalents or if the Department has used its discretion to reduce the initial net worth requirement below one million five hundred thousand dollars ($1,500,000), then the Department shall admit one hundred percent (100%) of the book value of intangible assets of the PSO up to ten percent (10%) of the minimum net worth amount required.

(4) Standard accounting principles treatment shall be given to other assets of the PSO not used in the delivery of health care for the purposes of meeting the minimum net worth requirement.

(5) Deferred acquisition costs shall not be admitted.

"**§ 131E-283. Financial plan.**

(a) The financial plan shall include the following:

(1) A detailed marketing plan;

(2) Statements of revenue and expense on an accrual basis;

(3) Cash flow statements;

(4) Balance sheets; and

(5) The assumptions in support of the financial plan.

(b) In the financial plan, the PSO shall demonstrate that it has the resources available to meet the projected losses for the entire period to break even. Except for the use of guaranties as provided in subsection (c) of this section, letters of credit as provided in subsection (d) of this section, and other means as provided in subsection (e) of this section, the resources must be assets on the balance sheet of the PSO in a form that is either cash or convertible to cash in a timely manner, pursuant to the financial plan.

(c) Guaranties shall be acceptable as a resource to meet projected losses, under the following conditions:

(1) For the first year of the PSO's operation of the PSO's Medicare contract, the guarantor must provide the PSO with cash or cash equivalents to fund the projected losses, as follows:

a. Prior to the beginning of the first quarter, in the amount of the projected losses for the first two quarters;

b. Prior to the beginning of the second quarter, in the amount of the projected losses through the end of the third quarter; and

million dollars ($1,000,000) of the initial minimum net worth requirement is met by cash or cash equivalents or if the Department has used its discretion to reduce the initial net worth requirement below one million five hundred thousand dollars ($1,500,000), then the Department shall admit one hundred percent (100%) of the book value of intangible assets of the PSO up to ten percent (10%) of the minimum net worth amount required.

(4) Standard accounting principles treatment shall be given to other assets of the PSO not used in the delivery of health care for the purposes of meeting the minimum net worth requirement.

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(b) In the financial plan, the PSO shall demonstrate that it has the resources available to meet the projected losses for the entire period to break even. Except for the use of guaranties as provided in subsection (c) of this section, letters of credit as provided in subsection (d) of this section, and other means as provided in subsection (e) of this section, the resources must be assets on the balance sheet of the PSO in a form that is either cash or convertible to cash in a timely manner, pursuant to the financial plan.

(c) Guaranties shall be acceptable as a resource to meet projected losses, under the following conditions:

(1) For the first year of the PSO's operation of the PSO's Medicare contract, the guarantor must provide the PSO with cash or cash equivalents to fund the projected losses, as follows:

a. Prior to the beginning of the first quarter, in the amount of the projected losses for the first two quarters;

b. Prior to the beginning of the second quarter, in the amount of the projected losses through the end of the third quarter; and

c. Prior to the beginning of the third quarter, in the amount of the projected losses through the end of the fourth quarter.

(2) If the guarantor provides the cash or cash equivalents to the PSO in a timely manner on the above schedule, this funding shall be considered in compliance with the guarantor's commitment to the PSO. In the third quarter, the PSO shall notify the Department if the PSO intends to reduce the period of funding of projected losses. The Department shall notify the PSO within 60 days of receiving the PSO's notice if the reduction is not acceptable.

(3) If the above guaranty requirements are not met, the Department may take appropriate action, such as requiring funding of projected losses through means other than a guaranty. The Department retains discretion which shall be reasonably exercised to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(d) The Department may modify the conditions in subsection (c) of this section in order to clarify the acceptability of guaranty arrangements.

(e) An irrevocable, clean, unconditional letter of credit may be used in place of cash or cash equivalents if satisfactory to the Department.

(f) If approved by the Department, based on appropriate standards promulgated by the Department, PSOs may use the following to fund projected losses for periods after the first year: lines of credit from regulated financial institutions, legally binding agreements for capital contributions, or other legally binding contracts of a similar level of reliability.

(g) The exceptions in subsections (c), (d), and (e) of this section may be used in an appropriate combination or sequence.

"**§ 131E-284. Modifications.**

(a) A provider sponsored organization shall file a notice describing any significant change in the information required by the Department under G.S. 131E-280. Such notice shall be filed with the Department prior to the change. If the Department does not disapprove within 90 days after the filing, this modification shall be considered approved. Changes subject to the terms of this section include expansion of service area, addition or

deletion of sponsoring providers, changes in provider contract forms, and group contract forms when the distribution of risk is significantly changed, and any other changes that the Department describes in properly adopted rules. Every PSO shall report to the Department for the Department's information material changes in the network of sponsoring providers and affiliated providers of services to beneficiaries enrolled with the PSO, the addition or deletion of any Medicare contracts of the PSO or any other information the Department may require. This information shall be filed with the Department within 15 days after implementation of the reported changes. Every PSO shall file with the Department all subsequent changes in the information or forms that are required by this Article to be filed with the Department.

(b) The Department may adopt rules exempting from the filing requirements of subsection (a) of this section those items it considers unnecessary.

"§ 131E-285. Deposits.

(a) The Department shall require a deposit of one hundred thousand dollars ($100,000) for all provider sponsored organizations. Said deposits shall be included in the calculations of a PSO's or applicant's net worth.

(b) All deposits required by this section shall be administered in accordance with procedures established by the Department.

"§ 131E-286. Ongoing financial standards - net worth.

(a) Beginning the first day of operation of the PSO and except as otherwise provided in subsection (d) of this section, every PSO shall maintain a minimum net worth equal to the greater of the following amounts:

(1) One million dollars ($1,000,000);

(2) Two percent (2%) of annual premium revenues as reported on the most recent annual financial statement filed with the Department on the first one hundred fifty million dollars ($150,000,000) of premium and one percent (1%) of annual premium on the premium in excess of one hundred fifty million dollars ($150,000,000);

(3) An amount equal to the sum of three months uncovered health care expenditures as reported on the most recent financial statement filed with the Department;

(4) An amount equal to the sum of:

deletion of sponsoring providers, changes in provider contract forms, and group contract forms when the distribution of risk is significantly changed, and any other changes that the Department describes in properly adopted rules. Every PSO shall report to the Department for the Department's information material changes in the network of sponsoring providers and affiliated providers of services to beneficiaries enrolled with the PSO, the addition or deletion of any Medicare contracts of the PSO or any other information the Department may require. This information shall be filed with the Department within 15 days after implementation of the reported changes. Every PSO shall file with the Department all subsequent changes in the information or forms that are required by this Article to be filed with the Department.

(b) The Department may adopt rules exempting from the filing requirements of subsection (a) of this section those items it considers unnecessary.

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(b) All deposits required by this section shall be administered in accordance with procedures established by the Department.

"**§ 131E-286. Ongoing financial standards - net worth.**

(a) Beginning the first day of operation of the PSO and except as otherwise provided in subsection (d) of this section, every PSO shall maintain a minimum net worth equal to the greater of the following amounts:

(1) One million dollars ($1,000,000);

(2) Two percent (2%) of annual premium revenues as reported on the most recent annual financial statement filed with the Department on the first one hundred fifty million dollars ($150,000,000) of premium and one percent (1%) of annual premium on the premium in excess of one hundred fifty million dollars ($150,000,000);

(3) An amount equal to the sum of three months uncovered health care expenditures as reported on the most recent financial statement filed with the Department;

(4) An amount equal to the sum of:

a. Eight percent (8%) of annual health care expenditures paid on a noncapitated basis to nonaffiliated providers as reported on the most recent financial statement filed with the Department; and

b. Four percent (4%) of annual health care expenditures paid on a capitated basis to nonaffiliated providers plus annual health care expenditures paid on a noncapitated basis to affiliated providers; and

c. Zero percent (0%) of annual health care expenditures paid on a capitated basis to affiliated providers regardless of downstream arrangements from the affiliated provider.

(b) In calculating net worth, liabilities shall not include fully subordinated debt or subordinated liabilities. For purposes of this provision, subordinated liabilities are claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all creditors.

(c) In calculating net worth for purposes of this section, the items described in G.S. 131E-282(b) shall be admitted, except as follows:

(1) For intangible assets, if at least the greater of one million dollars ($1,000,000) or sixty-seven percent (67%) of the ongoing minimum net worth requirement is met by cash or cash equivalents, then the Department shall admit the book value of intangible assets up to twenty percent (20%) of the minimum net worth amount required. If less than the greater of one million dollars ($1,000,000) or sixty-seven percent (67%) of the ongoing minimum net worth requirement is met by cash or cash equivalents, then the Department shall admit the book value of intangible assets up to ten percent (10%) of the minimum net worth amount required; and

(2) Deferred acquisition costs shall not be admitted.

(d) The Department may lower the minimum ongoing net worth threshold for PSOs that operate primarily in rural areas.

(e) During the start-up phase of the PSO, the pre-break-even financial plan requirements shall apply. After the point of break-even, the financial plan requirement shall address cash needs and the financing required for the next three years.

(f) If a PSO, or the legal entity of which the PSO is a component, did not earn a net operating surplus during the most recent fiscal year, the PSO shall submit a financial plan, satisfactory to the Department, meeting all of the requirements established for the initial financial plan.

"§ 131E-287. Reporting.

The PSO shall file with the Department financial information relating to PSO solvency standards described in this Article, according to the following schedule:

(1) On a quarterly basis until break-even; and

(2) On an annual basis after break-even, if the PSO has a net operating surplus; or

(3) On a quarterly or monthly basis, as specified by the Department, after break-even, if the PSO does not have a net operating surplus.

"§ 131E-288. Liquidity.

(a) Each PSO shall have sufficient cash flow to meet its obligations as they become due. In determining the ability of a PSO to meet this requirement, the Department shall consider the following:

(1) The timeliness of payment;

(2) The extent to which the current ratio is maintained at one to one or whether there is a change in the current ratio over a period of time; and

(3) The availability of outside financial resources.

(b) The following corresponding remedies apply:

(1) If the PSO fails to pay obligations as they become due, the Department shall require the PSO to initiate corrective action to pay all overdue obligations.

(2) The Department may require the PSO to initiate corrective action if any of the following are evident: (i) the current ratio declines significantly; or (ii) a continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding requirements to restore the current ratio to one to one.

(3) If there is a change in the availability of the outside resources, the Department shall require the PSO to obtain funding from alternative financial resources.

(f) If a PSO, or the legal entity of which the PSO is a component, did not earn a net operating surplus during the most recent fiscal year, the PSO shall submit a financial plan, satisfactory to the Department, meeting all of the requirements established for the initial financial plan.

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(1) The timeliness of payment;

(2) The extent to which the current ratio is maintained at one to one or whether there is a change in the current ratio over a period of time; and

(3) The availability of outside financial resources.

(b) The following corresponding remedies apply:

(1) If the PSO fails to pay obligations as they become due, the Department shall require the PSO to initiate corrective action to pay all overdue obligations.

(2) The Department may require the PSO to initiate corrective action if any of the following are evident: (i) the current ratio declines significantly; or (ii) a continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding requirements to restore the current ratio to one to one.

(3) If there is a change in the availability of the outside resources, the Department shall require the PSO to obtain funding from alternative financial resources.

(c) Nothing in the foregoing liquidity requirements shall be interpreted to require the PSO to maintain a current ratio of one to one if the PSO can demonstrate to the Department that it is able to pay its obligations as they become due and the current ratio maintained by the PSO has neither declined significantly nor is on a continued downward trend.

"§ 131E-289. Minimum of net worth that must be in cash or cash equivalents.

(a) Except as otherwise provided in subsection (b) of this section, each PSO shall, on an ongoing basis, maintain a minimum net worth in cash or cash equivalents of the greater of:

(1) Seven hundred fifty thousand dollars ($750,000) cash or cash equivalents; or

(2) Forty percent (40%) of the minimum net worth required.

(b) The Department may lower the threshold for minimum net worth held in cash or cash equivalents by PSOs that operate primarily in rural areas.

(c) Cash or cash equivalents held to meet the net worth requirement shall be current assets of the PSO.

"§ 131E-290. Prohibited practice.

(a) No provider sponsored organization or sponsoring provider, unless licensed as an insurer under Chapter 58 of the General Statutes may use in its name, contracts, or literature any of the words 'insurance', 'casualty', 'surety', 'mutual', or any other words descriptive of the insurance, casualty, or surety business or deceptively similar to the name or description of any insurance or surety corporation doing business in this State.

(b) No provider sponsored organization or sponsoring provider shall engage in any activity or conduct which is prohibited by the terms of the PSO's Medicare contract.

"§ 131E-291. Collaboration with local health departments.

A provider sponsored organization and a local health department shall collaborate and cooperate within available resources regarding health promotion and disease prevention efforts that are necessary to protect the public health.

"§ 131E-292. Coverage.

(a) Provider sponsored organizations subject to this Article shall provide coverage for the medically appropriate and necessary services specified under the PSO's Medicare contract.

(b) In the event a PSO's Medicare contract or federal law, regulations, or rules governing coverage by the PSO of items or services to Medicare beneficiaries permits a PSO, sponsoring provider, or participating provider to object on moral or

religious grounds to providing an item or service to Medicare beneficiaries, it is the policy of this State to permit this objection and allow the participating provider to refuse to provide the item or service.

"**§ 131E-293. Rates.**

Rates charged by provider sponsored organizations to the Medicare program and charges by PSOs and sponsoring providers for items or services to beneficiaries shall be governed by the terms of the PSO's Medicare contract.

"**§ 131E-294. Consumer protection and quality standards.**

(a) Unless otherwise preempted by federal law or mandated by the Medicare program, the Department shall apply to provider sponsored organizations the same standards and requirements that the Department of Insurance applies to health maintenance organizations under Chapter 58 of the General Statutes with respect to the following consumer protection and quality matters:

(1) Quality management programs;
(2) Utilization review procedures;
(3) Unfair or deceptive trade practices;
(4) Antidiscrimination;
(5) Provider accessibility and availability; and
(6) Network provider credentialing.

"**§ 131E-295. Powers of insurers and medical service corporations.**

Notwithstanding any provision of the insurance and hospital or medical service corporation laws contained in Articles 1 through 66 of Chapter 58 of the General Statutes, an insurer or a hospital or medical service corporation may contract with a provider sponsored organization to provide insurance or similar protection against the cost of care provided through provider sponsored organizations and their sponsoring providers to beneficiaries and to provide coverage in the event of the failure of the provider sponsored organization or its sponsoring providers to meet its obligations under the PSO's Medicare contract. The beneficiaries of a provider sponsored organization constitute a permissible group under these laws. Among other things, under these contracts, the insurer or hospital or medical service corporation may make benefit payments to provider sponsored organizations for health care services rendered by providers pursuant to the health care plan.

"**§ 131E-296. Examinations.**

The Department may make an examination of the affairs of any provider sponsored organization and the contracts, agreements, or other arrangements pursuant to its health care plan as often as

religious grounds to providing an item or service to Medicare beneficiaries, it is the policy of this State to permit this objection and allow the participating provider to refuse to provide the item or service.

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"**§ 131E-296. Examinations.**

The Department may make an examination of the affairs of any provider sponsored organization and the contracts, agreements, or other arrangements pursuant to its health care plan as often as

the Department considers necessary for the protection of the interests of the people of this State but not less frequently than once every three years.

"**§ 131E-297. Hazardous financial condition.**

(a) Whenever the financial condition of any provider sponsored organization indicates a condition such that the continued operation of the provider sponsored organization might be hazardous to its beneficiaries, creditors, or the general public, then the Department may order the provider sponsored organization to take any action that may be reasonably necessary to rectify the existing condition, including one or more of the following steps:

(1) To reduce the total amount of present and potential liability for benefits by reinsurance;

(2) To reduce the volume of new business being accepted;

(3) To reduce the expenses by specified methods;

(4) To suspend or limit the writing of new business for a period of time;

(5) To require an increase to the provider sponsored organization's net worth by contribution;

(6) To add or delete sponsoring providers;

(7) To increase the amount of payments from the PSO which sponsoring providers agree to forego; or

(8) To require additional guaranties from sponsoring providers or from parents of sponsoring providers.

(b) If the Department determines that the liquidity standards in G.S. 131E-286, 131E-288, and 131E-289 do not provide sufficient early warning that the continued operation of any provider sponsored organization might be hazardous to its beneficiaries, creditors, or the general public, the Department may adopt rules to set uniform standards and criteria for such an early warning and to set standards for evaluating the financial condition of any provider sponsored organization, which standards shall be consistent with the purposes expressed in subsection (a) of this section.

"**§ 131E-298. Protection against insolvency.**

(a) The Department shall require deposits in accordance with the provisions of G.S. 131E-285.

(b) If a provider sponsored organization fails to comply with the net worth requirements of G.S. 131E-286, the Department may take appropriate action to assure that the continued operation of the provider sponsored organization will not be hazardous to the beneficiaries enrolled with the PSO.

(c) Every provider sponsored organization shall have and maintain at all times an adequate plan for protection against insolvency acceptable to the Department. In determining the adequacy of such a plan, the Department shall consider:

(1) A reinsurance agreement preapproved by the Department covering excess loss, stop-loss, or catastrophies. The agreement shall provide that the Department will be notified no less than 60 days prior to cancellation or reduction of coverage;

(2) A conversion policy or policies that will be offered by an insurer to the beneficiaries in the event of the provider sponsored organization's insolvency;

(3) Legally binding unconditional guaranties by adequately capitalized sponsoring provider or adequately capitalized sponsoring corporations of sponsoring providers;

(4) Legally binding obligations of sponsoring providers to forego payment for items or services provided by the sponsoring provider in order to avoid the financial insolvency of the PSO;

(5) Legally binding obligations of sponsoring providers or parents of sponsoring providers to make capital infusions to the PSO; and

(6) Any other arrangements offering protection against insolvency that the Department may require.

"**§ 131E-299. Hold harmless agreements or special deposit.**

(a) Unless the PSO maintains a special deposit in accordance with subsection (b) of this section, each contract between every PSO and a participating provider of health care services shall be in writing and shall set forth that in the event the PSO fails to pay for health care services as set forth in the contract, the Medicare subscriber or beneficiary shall not be liable to the provider for any sums owed by the PSO. No other provisions of such contracts shall, under any circumstances, change the effect of such a provision. No participating provider or agent, trustee, or assignee thereof may maintain any action at law against a subscriber or beneficiary to collect sums owed by the PSO.

(b) In the event that the participating provider contract has not been reduced to writing or that the contract fails to contain the required prohibition, the PSO shall maintain a special deposit in cash or cash equivalent as follows:

(c) Every provider sponsored organization shall have and maintain at all times an adequate plan for protection against insolvency acceptable to the Department. In determining the adequacy of such a plan, the Department shall consider:

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(b) In the event that the participating provider contract has not been reduced to writing or that the contract fails to contain the required prohibition, the PSO shall maintain a special deposit in cash or cash equivalent as follows:

(1) If at any time uncovered expenditures exceed ten percent (10%) of total health care expenditures the PSO shall either:

a. Place an uncovered expenditures insolvency deposit with the Department, or with any organization or trustee acceptable to the Department through which a custodial or controlled account is maintained, cash or securities that are acceptable to the Department. This deposit shall at all times have a fair market value in an amount of one hundred twenty percent (120%) of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred but not reported claims, and shall be calculated as of the first day of the month and maintained for the remainder of the month. If a PSO is not otherwise required to file a quarterly report, it shall file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section; or

b. Maintain adequate insurance or a guaranty arrangement approved in writing by the Department, to pay for any loss to beneficiaries claiming reimbursement due to the insolvency of the PSO. The Department shall approve a guaranty arrangement if the guarantying organization is a sponsoring provider, has been operating for at least 10 years and has a net worth, including organization-related land, buildings, and equipment of at least fifty million dollars ($50,000,000), unless the Department finds that the approval of this guaranty may be financially hazardous to beneficiaries.

(2) The deposit required under sub-subdivision a. of subdivision (1) of this section is an admitted asset of the PSO in the determination of net worth. All income from such deposits or trust accounts shall be assets of the PSO and may be withdrawn from such deposit or account quarterly with the approval of the Department;

(3) A PSO that has made a deposit may withdraw that deposit or any part of the deposit if (i) a substitute deposit of cash or securities of equal amount and value is made, (ii) the fair market value exceeds the amount of the required deposit, or (iii) the required deposit under this subsection is reduced or eliminated. Deposits, substitutions, or withdrawals may be made only with the prior written approval of the Department;

(4) The deposit required under sub-subdivision a. of subdivision (1) of this section is in trust and may be used only as provided under this section. The Department may use the deposit of an insolvent PSO for administrative costs associated with administering the deposit and payment of claims of enrollees of the PSO.

(c) Whenever the reimbursements described in this section exceed percent (%) of the PSO's total costs for health care services over the immediately preceding six months, the PSO shall file a written report with the Department containing the information necessary to determine compliance with sub-division a. of subdivision (1) of this section no later than 30 business days from the first day of the month. Upon an adequate showing by the PSO that the requirements of this section should be waived or reduced, the Department may waive or reduce these requirements to such an amount as it deems sufficient to protect beneficiaries of the PSO consistent with the intent and purpose of this Article.

"§ 131E-300. Continuation of benefits.

The Department shall require that each PSO have a plan for handling insolvency, which plan allows for continuation of benefits for the duration of the contract period for which premiums have been paid and continuation of benefits to beneficiaries who are confined in an inpatient facility until their discharge or expiration of benefits. In considering such a plan, the Department may require:

(1) Insurance to cover the expenses to be paid for benefits after an insolvency;

(2) Provisions in provider contracts that obligate the provider to provide services for the duration of the period after the PSO's insolvency for which premium payment has been made and until the beneficiaries' discharge from inpatient facilities;

(3) Insolvency reserves as the Department may require;

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(2) Provisions in provider contracts that obligate the provider to provide services for the duration of the period after the PSO's insolvency for which premium payment has been made and until the beneficiaries' discharge from inpatient facilities;

(3) Insolvency reserves as the Department may require;

(4) Letters of credit acceptable to the Department;
(5) Additional guaranties from a sponsoring provider of the PSO or from the parent of a sponsoring provider;
(6) Legally binding obligations of sponsoring providers to forego payment from the PSO for services provided to beneficiaries in order to avoid the insolvency of the PSO; and
(7) Any other arrangements to assure that benefits are continued as specified.

"**§ 131E-301. Insolvency.**

(a) In the event of an insolvency of a PSO upon order of the Department, all providers that were sponsoring providers of the PSO within the previous 12 months from the order of the Department shall, for 30 days after the order, offer all beneficiaries enrolled with the insolvent PSO covered services without charge other than for any applicable co-payments, deductibles, or coinsurance permitted to be charged to beneficiaries under the PSO's Medicare contract.

(b) If the Department determines that the sponsoring providers lack sufficient health care delivery resources to assure that health care services will be available and accessible to all of the beneficiaries of the insolvent PSO, then, in the event the Health Care Financing Administration of the United States Department of Health and Human Services fails to make such allocations in a timely manner, the Department shall allocate the insolvent PSO's contracts for these groups among all other PSOs that operate within a portion of the insolvent PSO's service area, taking into consideration the health care delivery resources of each PSO. Each PSO to which beneficiaries are so allocated by the Department shall offer such group or groups that PSO's existing coverage that is most similar to each beneficiary's coverage with the insolvent PSO at rates determined in accordance with the successor PSO's existing rating methodology.

(c) Taking into consideration the health care delivery resources of each such PSO, then in the event the Health Care Financing Administration of the U.S. Department of Health and Human Services fails to make such allocations in a timely manner, the Department shall also allocate among all PSOs that operate within a portion of the insolvent PSO's service area the insolvent PSO's beneficiaries who are unable to obtain other coverage. Each PSO to which beneficiaries are so allocated by the Department shall offer such beneficiaries that PSO's existing

coverage for individual or conversion coverage as determined by his type of coverage in the insolvent PSO at rates determined in accordance with the successor PSO's Medicare contract.

"**§ 131E-302. Replacement coverage.**

(a) Any carrier providing replacement coverage with respect to hospital, medical, or surgical expense or service benefits, within a period of 60 days from the date of discontinuance of a prior PSO contract or policy providing these hospital, medical, or surgical expense or service benefits, shall immediately cover all beneficiaries who were validly covered under the previous PSO contract or policy at the date of discontinuance and who would otherwise be eligible for coverage under the succeeding carrier's contract, regardless of any provisions of the contract relating to hospital confinement or pregnancy.

(b) Except to the extent benefits for the condition would have been reduced or excluded under the prior carrier's contract or policy, no provision in a succeeding carrier's contract of replacement coverage that would operate to reduce or exclude benefits on the basis that the condition giving rise to benefits preceded the effective date of the succeeding carrier's contract shall be applied with respect to those beneficiaries validly covered under the prior carrier's contract on the date of discontinuance.

"**§ 131E-303. Incurred but not reported claims.**

(a) Every PSO shall, when determining liability, include an amount estimated in the aggregate to provide for any unearned premium and for the payment of all claims for health care expenditures that have been incurred, whether reported or unreported, that are unpaid and for which such PSO is or may be liable; and to provide for the expense of adjustment or settlement of such claims.

(b) Such liabilities shall be computed in accordance with rules adopted by the Department upon reasonable consideration of the ascertained experience and character of the PSO.

"**§ 131E-304. Suspension or revocation of license.**

(a) The Department may suspend, revoke, or refuse to renew a PSO license if the Department finds that the PSO:

(1) Is operating significantly in contravention of its basic organizational document, or in a manner contrary to that described in and reasonably inferred from any other information submitted under G.S. 131E-280, unless amendments to these submissions have been filed with and approved by the Department;

coverage for individual or conversion coverage as determined by his type of coverage in the insolvent PSO at rates determined in accordance with the successor PSO's Medicare contract.

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(b) Except to the extent benefits for the condition would have been reduced or excluded under the prior carrier's contract or policy, no provision in a succeeding carrier's contract of replacement coverage that would operate to reduce or exclude benefits on the basis that the condition giving rise to benefits preceded the effective date of the succeeding carrier's contract shall be applied with respect to those beneficiaries validly covered under the prior carrier's contract on the date of discontinuance.

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(2) Issues evidences of coverage or uses a schedule of premiums for health care services that do not comply with Medicare or Medicaid program requirements as applicable;
(3) No longer maintains the financial reserve specified in G.S. 131E-286 or is no longer financially responsible and may reasonably be expected to be unable to meet its obligations to beneficiaries or prospective beneficiaries;
(4) Knowingly or repeatedly fails or refuses to comply with any law or rule applicable to the PSO or with any order issued by the Department after notice and opportunity for a hearing;
(5) Has knowingly made to the Department any false statement or report;
(6) Has sponsoring providers that fail to provide a substantial proportion of the services under any health plan during any 12-month period;
(7) Has itself or through any person on its behalf advertised or merchandised its items or services in an untrue, misrepresentative, misleading, or unfair manner;
(8) If continuing to operate would be hazardous to beneficiaries; or
(9) Has otherwise substantially failed to comply with this Article.

(b) A license shall be suspended or revoked only after compliance with G.S. 131E-305.

(c) When a PSO license is suspended, the PSO shall not, during the suspension, enroll any additional beneficiaries except newborn children or other newly acquired dependents of existing beneficiaries and shall not engage in any advertising or solicitation.

(d) When a PSO license is revoked, the PSO shall proceed, immediately following the effective date of the order of revocation, to wind up its affairs and shall conduct no further business except as may be essential to the orderly conclusion of the affairs of the PSO. The PSO shall engage in no advertising or solicitation. The Department may, by written order, permit any further operation of the PSO that the Department may find to be in the best interest of beneficiaries, to the end that beneficiaries will be afforded the greatest practical opportunity to obtain continuing health care coverage.

"**§ 131E-305. Administrative procedures.**

(a) When the Department has cause to believe that grounds for the denial of an application for a license exist, or that grounds for the suspension or revocation of a license exist, it shall notify the provider sponsored organization in writing specifically stating the grounds for denial, suspension, or revocation and fixing a time of at least 30 days thereafter for a hearing on the matter.

(b) After this hearing, or upon the failure of the provider sponsored organization to appear at this hearing, the Department shall take the action it considers advisable or make written findings that shall be mailed to the provider sponsored organization. The action of the Department shall be subject to review by the Superior Court of Wake County. The court may, in disposing of the issue before it, modify, affirm, or reverse the order of the Department in whole or in part.

(c) The provisions of Chapter 150B of the General Statutes apply to proceedings under this section to the extent that they are not in conflict with subsections (a) and (b) of this section.

"§ 131E-306. Department of Insurance.

At the request of the Department, the Department of Insurance shall evaluate a PSO's compliance with any or all of the solvency requirements set forth in this Article. Upon this request, the Department of Insurance shall undertake the evaluation in accordance with this Article and regulations adopted pursuant to it and shall report its evaluation to the Department in a timely manner. The Department of Insurance may collect from the applicant or PSO subject to the evaluation a fee not to exceed the fee that the Department of Insurance would be entitled to impose on a health maintenance organization for undergoing a similar evaluation. Nothing in this section limits the Department's final authority to license PSOs in accordance with this Article.

"§ 131E-307. Fees.

Every provider sponsored organization subject to this Article shall pay to the Department the following fees:

(1) For filing an application for a license, two hundred fifty dollars ($250.00); for each renewal thereof, five hundred dollars ($500.00); and

(2) For filing each quarterly report, one hundred dollars ($100.00).

"§ 131E-308. Penalties and enforcement.

(a) The provisions of G.S. 58-2-70, modified to replace the word 'Commissioner' by the word 'Department', applies to this Article. The Department may, in addition to or in lieu of

(a) When the Department has cause to believe that grounds for the denial of an application for a license exist, or that grounds for the suspension or revocation of a license exist, it shall notify the provider sponsored organization in writing specifically stating the grounds for denial, suspension, or revocation and fixing a time of at least 30 days thereafter for a hearing on the matter.

(b) After this hearing, or upon the failure of the provider sponsored organization to appear at this hearing, the Department shall take the action it considers advisable or make written findings that shall be mailed to the provider sponsored organization. The action of the Department shall be subject to review by the Superior Court of Wake County. The court may, in disposing of the issue before it, modify, affirm, or reverse the order of the Department in whole or in part.

(c) The provisions of Chapter 150B of the General Statutes apply to proceedings under this section to the extent that they are not in conflict with subsections (a) and (b) of this section.

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suspending or revoking a license under G.S. 131E-304, proceed under G.S. 58-2-70, as so modified, provided that the provider sponsored organization has a reasonable time within which to remedy the defect in its operations that gave rise to the procedure under G.S. 58-2-70.

(b) Any person who violates this Article shall be guilty of a Class 1 misdemeanor.

(c) If the Department shall for any reason have cause to believe that any violation of this Article has occurred or is threatened, the Department may give notice to the provider sponsored organization and to the representatives or other persons who appear to be involved in such suspected violation to arrange a conference with the alleged violators or their authorized representatives for the purpose of attempting to ascertain the facts relating to such suspected violation, and, in the event it appears that any violation has occurred or is threatened, to arrive at an adequate and effective means of correcting or preventing such violation.

Proceedings under this subsection shall not be governed by any formal procedural requirements and may be conducted in such manner as the Department may deem appropriate under the circumstances.

(d) The Department may issue an order directing a provider sponsored organization or a representative of a provider sponsored organization to cease and desist from engaging in any act or practice in violation of the provisions of this Article.

Within 30 days after service of the order of cease and desist, the respondent may request a hearing on the question of whether acts or practices in violation of this Article have occurred. These hearings shall be conducted pursuant to Chapter 150B of the General Statutes, and judicial review shall be available as provided by this Chapter.

(e) In the case of any violation of the provisions of this Article, if the Department elects not to issue a cease and desist order, or in the event of noncompliance with a cease and desist order issued pursuant to subsection (d) of this section, the Department may institute a proceeding to obtain injunctive relief, or seeking other appropriate relief, in the Superior Court of Wake County.

"§ 131E-309. Statutory construction and relationship to other laws.

(a) Except as otherwise provided in this Article, provisions of the insurance laws and provisions of hospital or medical service corporation laws shall not be applicable to any provider

sponsored organization granted a license under this Article or to its sponsoring providers when operating under such a license. This provision shall not apply to an insurer or hospital or medical service corporation licensed and regulated pursuant to the insurance laws or the hospital or medical service corporation laws of this State except with respect to its provider sponsored organization activities authorized and regulated pursuant to this Article.

(b) Solicitation of beneficiaries by a provider sponsored organization granted a license, or its representatives, shall not be construed to violate any provision of law relating to solicitation or advertising by health professionals or health care providers.

(c) Any provider sponsored organization licensed under this Article shall not be considered to be a provider of medicine or dentistry and shall be exempt from the provisions of Chapter 90 of the General Statutes relating to the practice of medicine and dentistry; provided, however, that this exemption does not apply to individual providers under contract with or employed by the provider sponsored organization or sponsoring providers or to the sponsoring providers.

"§ 131E-310. Filings and reports as public documents.

Except for information that constitutes a bona fide trade secret, proprietary information or competitively sensitive information of a sponsoring provider or parent of a sponsoring provider, all applications, filings, and reports required under this Article shall be treated as public documents.

"§ 131E-311. Confidentiality of medical information.

Any data or information pertaining to the diagnosis, treatment, or health of any beneficiary or applicant obtained from the person or from any provider by any provider sponsored organization or by any provider acting pursuant to its provider contract with a provider sponsored organization shall be held in confidence and shall not be disclosed to any person except to the extent that it may be necessary to carry out the purposes of this Article; or upon the express consent of the beneficiary or applicant; or pursuant to statute or court order for the production of evidence or the discovery thereof; or in the event of claim or litigation between such person and the provider sponsored organization wherein such data or information is pertinent. A provider sponsored organization shall be entitled to claim any statutory privileges against such disclosure which the provider who furnished such information to the provider sponsored organization is entitled to claim.

sponsored organization granted a license under this Article or to its sponsoring providers when operating under such a license. This provision shall not apply to an insurer or hospital or medical service corporation licensed and regulated pursuant to the insurance laws or the hospital or medical service corporation laws of this State except with respect to its provider sponsored organization activities authorized and regulated pursuant to this Article.

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Except for information that constitutes a bona fide trade secret, proprietary information or competitively sensitive information of a sponsoring provider or parent of a sponsoring provider, all applications, filings, and reports required under this Article shall be treated as public documents.

"§ 131E-311. Confidentiality of medical information.

Any data or information pertaining to the diagnosis, treatment, or health of any beneficiary or applicant obtained from the person or from any provider by any provider sponsored organization or by any provider acting pursuant to its provider contract with a provider sponsored organization shall be held in confidence and shall not be disclosed to any person except to the extent that it may be necessary to carry out the purposes of this Article; or upon the express consent of the beneficiary or applicant; or pursuant to statute or court order for the production of evidence or the discovery thereof; or in the event of claim or litigation between such person and the provider sponsored organization wherein such data or information is pertinent. A provider sponsored organization shall be entitled to claim any statutory privileges against such disclosure which the provider who furnished such information to the provider sponsored organization is entitled to claim.

adequate and timely basis those services to its enrolled members which it has contracted to furnish under the enrollment contract.

(3) This Article shall not apply to any employee benefit plan to the extent that the Federal Employee Retirement Income Security Act of 1974 preempts State regulation thereof.

(3a) This Article does not apply to any prepaid health service or capitation arrangement implemented or administered by the Department of Health and Human Services or its representatives, pursuant to 42 U.S.C. § 1396n or Chapter 108A of the General Statutes, a provider sponsored organization or other organization certified, qualified, or otherwise approved by the Department of Health and Human Services pursuant to Article 17 of Chapter 131E of the General Statutes, or to any provider of health care services participating in such a prepaid health service or capitation arrangement. Article; provided, however, that to the extent this Article applies to any such person acting as a subcontractor to a Health Maintenance Organization licensed in this State, that person shall be considered a single service Health Maintenance Organization for the purpose of G.S. 58-67-20(4), G.S. 58-67-25, and G.S. 58-67-110.

(4) Except as provided in paragraphs (1), (2), (3), and (3a) of this subsection, the persons to whom these paragraphs are applicable shall be required to comply with all provisions contained in this Article."

Section 3. There is appropriated from the General FUnd to the Department of Health and Human Services the sum of ------- for the 1998-99 fiscal year to implement this act.

Section 4. This act becomes effective July 1, 1998.

"§ 131E-312. Conflicts; severability.

To the extent that the provisions of this Article may be in conflict with any other provision of this Chapter, the provisions of this Article shall prevail and apply with respect to provider sponsored organizations. Notwithstanding the absence of adopted rules, the Department shall continue to process applications for provider sponsored organization licenses as described in this Article. If any section, term, or provision of this Article shall be adjudged invalid for any reason, these judgments shall not affect, impair, or invalidate any other section, term, or provision of this Article, but the remaining sections, terms, and provisions shall be and remain in full force and effect.

"§ 131E-313. Regulations.

This Article shall be self-implementing. No later than six months after the date of enactment of this Article, the Department may adopt rules consistent with this Article to authorize and regulate provider sponsored organizations to contract directly with the federal Medicare program to provide health care services to the beneficiaries of such programs. The Department shall issue permanent rules and, may issue temporary rules, to the extent these rules may be necessary. The Department shall limit its regulation of provider sponsored organizations to the licensing and regulating of these organizations as risk bearing entities contracting directly with the Medicare program and to the consumer protection and quality standards as provided in G.S. 131E-294, and shall not regulate any matters described in 42 U.S.C. § 1395W-26(b)(3), or any successor thereof."

Section 2. G.S. 58-67-10(b) reads as rewritten:

"(b) (1) It is specifically the intention of this section to permit such persons as were providing health services on a prepaid basis on July 1, 1977, or receiving federal funds under Section 254(c) of Title 42, U.S. Code, as a community health center, to continue to operate in the manner which they have heretofore operated.

(2) Notwithstanding anything contained in this Article to the contrary, any person can provide health services on a fee for service basis to individuals who are not enrollees of the organization, and to enrollees for services not covered by the contract, provided that the volume of services in this manner shall not be such as to affect the ability of the health maintenance organization to provide on an

adequate and timely basis those services to its enrolled members which it has contracted to furnish under the enrollment contract.

(3) This Article shall not apply to any employee benefit plan to the extent that the Federal Employee Retirement Income Security Act of 1974 preempts State regulation thereof.

(3a) This Article does not apply to any prepaid health service or capitation arrangement implemented or administered by the Department of Health and Human Services or its representatives, pursuant to 42 U.S.C. § 1396n or Chapter 108A of the General Statutes, a provider sponsored organization or other organization certified, qualified, or otherwise approved by the Department of Health and Human Services pursuant to Article 17 of Chapter 131E of the General Statutes, or to any provider of health care services participating in such a prepaid health service or capitation arrangement. Article; provided, however, that to the extent this Article applies to any such person acting as a subcontractor to a Health Maintenance Organization licensed in this State, that person shall be considered a single service Health Maintenance Organization for the purpose of G.S. 58-67-20(4), G.S. 58-67-25, and G.S. 58-67-110.

(4) Except as provided in paragraphs (1), (2), (3), and (3a) of this subsection, the persons to whom these paragraphs are applicable shall be required to comply with all provisions contained in this Article."

Section 3. There is appropriated from the General FUnd to the Department of Health and Human Services the sum of ------- for the 1998-99 fiscal year to implement this act.

Section 4. This act becomes effective July 1, 1998.

Section by Section Summary
PSO Medicare Licensing
98-LFZX-018(4.17)

G.S. Site	Summary of Provisions	Page & Line #
G.S. 131E-275	**General Provisions:** • Contains general declarations of legislative intent. • Provides a general overview of the federal statute permitting provider sponsored organizations (PSOs) to provide coverage to beneficiaries under the federal Medicare+Choice program. • Appoints the Department of Health and Human Resources, acting through the Medical Care Commission, as the agency which regulates PSOs and limits that regulation to the licensing and regulating PSOs as risk bearing entities contracting directly with the Medicare+Choice program. • Contains the general requirement that each PSO must obtain a license from the Department or be otherwise federally certified to meet solvency requirements prior to providing health care services to Medicare +Choice beneficiaries.	Page 1, lines 9-25. Page 2, lines 3-7. Page 2, lines 8-12.
G.S. 131E-276	**Provides the definitions for key terms.** • "Provider sponsored organization" mirrors the definition in the federal PSO statute (See Background information) **but adds a requirement that, unless otherwise prohibited by law, at least 50% of a PSO's governing body must be composed of licensed physicians.** • "Health care delivery assets" comes from the PSO solvency regulations which were negotiated between the Health Care Financing Administration and representatives of the health care and health insurance industries.	Page 3, lines 20-42 Page 4, lines 11-23 Page 2, lies 34-38

G.S. 131E-277	**Directly or indirectly share substantial financial risk.** • Defines what constitutes "directly or indirectly share substantial financial risk". The provision is modeled after federal antitrust guidelines for physician networks.	Page 4, lies 23-44 and page 5, lines 1-5.
G.S. 131E-278	**Applicability of other laws.** • Exempts licensed PSOs, their plan contracts, provider contracts, and other arrangements from regulation under Chapter 58 of the General Statutes, the North Carolina insurance laws.	Page 5, lies 9-15.
G.S. 131E-279	**Licensure Approval.** • Appoints the Medical Care Commission as the state licensing agency for Medicare PSOs and permits PSOs to be licensed as risk-bearing entities eligible to contract directly with Medicare if they either meet the requirements of the PSO statue or have received a federal waiver from sate requirements. (Federal Waiver does not waive state consumer protection and quality requirements). • Subsection (c) includes a specific time line and procedures for the processing of applications for State PSO license. Under the Federal PSO statute, state licensing requirements can be waived by the federal government so that PSO applicants can contract directly with Medicare in the event the state fails to act upon the application within 90 days after receipt of a substantially complete application. • Subsection (d) describes when an application is deemed substantially complete so that the federal time line can begin at a clearly defined time. • Subsection (e) allows federal standards to supersede state PSO standards if those standards are more favorable to the PSO or if state standards are otherwise preempted by federal law.	Page 5, lines 17-20. Page 5 lines 29-44 and Page 6, lines 1-6. Page 6, lines 7-14. Page 6, lines 15 -17.

G.S. 131E-280	**Requirements for Applicants.** • Describes the detailed information which PSOs and their sponsoring providers must provide in the licensing application. • Each application must be certified by officer, in form prescribed by Department, and must contain the following: 1) organizational document of the applicant and each sponsoring organization with > 5% interest in the PSO 2) bylaws, rules, regulations regulating internal affairs of the PSO and each sponsoring provider > 5% 3) document evidencing arrangements between PSO and each sponsoring provider which create the relationships and obligations described in 131E-276(n) (definition of PSO) 4) names and addresses of officers responsible for PSO and of each >5% sponsoring provider and members of boards 5) copy of contract form between PSO and any class of providers and copy of contract form between PSO and TPA, marketing consultants, and sponsoring providers 6) general statement describing the PSO, its sponsoring providers, healthcare plan, facilities and personnel 7) license of each licensed provider 8) financial statements showing PSOs assets, liabilities and sources of financial support; financial statement of each >5% sponsoring provider (information regarding sponsoring providers which hold an interest in the PSO of 5% or less would not be required to provide personal financial information) 9) if guarantees uses, financial from guarantors 10) financial plan covering the first 12 months of operation and which meets provisions of 131E-282 (requiring a financial plan). If losses are projected, plan must cover 12 months past break-even. 11) description of geographic areas to be served 12) description of the procedures to be implemented to meet protection against insolvency requirements of 131E-298.	Pages 6-7, and page 8, lines 1-4.

G.S. 131E-281	**Additional Information** • In addition to information filed under 131E-280(a) (above), each application must also include a description of: 1) program to ensure network sufficiency (services accessible without unreasonable delay) 2) program used to evaluate whether the sponsoring providers will provide a substantial portion of services 3) program to verify providers credentials 4) UR program 5) QM program 6) applicant's network of sponsoring and contracted providers and evidence that the network can provide all services except out of network and emergency (b) Department may promulgate rules exempting any of the above from being filed	Page 8, lines 8-26. Page 8, lines 27-28.
G.S. 131E-282	**Issuance of License.** • Describes the standards which PSOs must meet in order to receive their initial license. • Assets, binding commitments and sweat equity provided by sponsoring providers may be credited for a portion of the working capital requirements for PSOs. • Requires initial net worth of $1.5 million, reduced to $1.0 million if the PSO demonstrates that it has a sufficient administrative infrastructure in place. *(NC HMO Act = $1 million in working capital.)* • At least $750,000 of net worth must be in cash or cash equivalents; a portion of intangible value may be included in the net worth calculation.	Page 8, lines 30-43. Page 9, lines 37-43. Page 9, lines 3-7.

G.S. 131E-283	**Financial Plan** Section 131E-282 requires a PSO to submit a financial plan as part of its application. • The elements which must be included within the financial plan include: 1) detailed marketing plan 2) statements of revenue and expenses on an accrual basis 3) cash flow statements 4) balance sheets 5) assumptions in support of the plan. • A PSO must demonstrate that it has the resources available to meet the projected losses for the entire period to break-even. • Also describes the extent to which letters of credit and guarantees may be included as an acceptable resource. Standards on guarantees mirror the requirements under the federal PSO rule negotiated between HCFA and representatives of the health care and health insurance industries.	Page 10 and page 11, lines 1-5.
G.S. 131E-284	**Modifications.** • Describes the filing requirements for licensed PSOs when there are modifications to the PSO's initial application.	Page 11, lines 6-22.
G.S. 131E-285	**Deposits.** • Requires PSOs to make a deposit of $100,000. *(NC HMO Act = $ 500,000)*. The deposit will be included as part of the calculation of the PSO's net worth. • Department procedures govern administration of deposits	Page 11, lines 26-30.

G.S. 131E-286	**Ongoing Financial Standards.** • Establishes the net worth requirements which a PSO must meet once it is licensed and begins operations. 1. On an ongoing basis, PSOs are required to have a minimum net worth in the greater amount of: (a) $1 million; (*NC HMO Act = $1million*); (b) 2% of premiums on first $150 million and 1% thereafter; (c) an amount equal to three months uncovered health care expenditures; or (d) a specified percentage of annual health care expenditures. • These standards mirror the rule negotiated between HCFA and representatives of the health care and health insurance industries. • The Medical Care Commission has discretion to lower the financial threshold for PSOs operating primarily in rural areas.	Page 11, lines 31-44. Page 12, lines 31-32.
G.S. 131E-287	**Reporting.** • Requires PSOs to file quarterly reports on financial information relating to PSO solvency standards until break-even. • Then reports will be submitted annually if the PSO has a net operating surplus. • If the PSO does not have a net operating surplus, then reports will be either monthly or quarterly, as specified by the Medical Care Commission.	Page 12, lines 41-44.

G.S. 131E-288	**Liquidity.** • Requires each PSO to have sufficient cash flow to meet its obligations as they become due. • Maintenance of a current ratio of 1:1 is provided as an indicator of insufficient cash flow, but maintenance of such a ratio is not required unless imposed by the Medical Care Commission as a corrective action. • Corrective action may include a change in the distribution of assets, a reduction of liabilities or alternative arrangements to secure additional funding to restore the current ratio to 1:1 • If there is a change in the availability of outside resources, the Department shall require the PSO to obtain funding from alternative financial resources. • The liquidity provisions mirror the federal negotiated rule on solvency standards, but clarify the discretionary aspect of the guidance on a current ratio of 1:1.	Page 13, lines 5-32.
G.S. 131E-289	**Minimum Net Worth** • Requires an ongoing minimum net worth in cash or cash equivalents of either $750,000 or 40% of minimum net worth. *(NC HMO Act = $1 million).* • A lower amount may be allowed for PSOs operating primarily in rural areas. • Cash or cash equivalents held to meet the net worth requirement must be current assets of the PSO. These rules mirror the federal negotiated rule for PSO solvency.	Page 13, lines 33-43.
G.S. 131E-290	**Prohibited Practice.** • Prohibits PSOs and their sponsoring providers, not otherwise licensed under Chapter 58 (insurance laws) to describe themselves as being in the insurance casualty, or surety business. • Also prohibits them from engaging in conduct prohibited by the PSO's Medicare contract.	Page 14, lines 1-6, and 7-9.

G.S. 131E-291	**Collaboration with local health departments.** • Requires PSOs and their sponsoring providers to collaborate with local health departments in health promotion and disease prevention.	Page 14, lines 10-13.
G.S. 131E-292	**Coverage Requirements.** • PSOs are required to meet the coverage requirements of their Medicare contract. • If Medicare allows PSOs or their participating providers to object on moral or religious grounds to providing items or services to a Medicare beneficiary, the PSO/provider may make such objection. (includes advanced directives)	Page 14, lines 15-17 lines 18-23.
G.S. 131E-293	**Reimbursement Rates.** • Rates under PSO's Medicare contracts are governed by the terms of that contract.	Page 14, lines 25-27.
G.S. 131E-294	**Consumer Protection and Quality Standards.** • Applies to PSOs the same standards and requirements that the Department of Insurance applies to health maintenance organizations under Chapter 58 with respect to: 1. consumer protection and quality management programs, 2. utilization review procedures, 3. unfair or deceptive trade practices, 4. antidiscrimination, 5. provider accessibility and availability, 6. and network provider credentialing. • May be superseded by federal law or mandated by the Medicare program. • 42 U.S.C. Sec. 1395w-25(a)(2)(G) provides that PSOs which have received federal waivers from state insolvency requirements must still comply with state laws regarding consumer protection and quality standards imposed upon PSOs, unless those laws are superseded by federal law.	Page 14, lines 28-39.

G.S. 131E-295	**Powers of Insurers and Medical Service Providers.** • Permits an insurer or a hospital or medical service corporation to contract with a PSO to provide insurance and to provide coverage in the event of the failure of the provider sponsored organization or its sponsoring providers to meet its obligations.	Page 14, lines 41-44, page 15, lines 1-8.
G.S. 131E-296	**Examinations.** • Requires the Medical Care Commission to perform examinations of PSOs at least once every three (3) years or more often as it deems necessary for the protection of the interests of the people of this State.	Page 15, lines 10-14.
G.S. 131E-297	**Hazardous Financial Conditions.** • Provides the Medical Care Commission to take action if the it believes that the PSO is in a hazardous financial condition. For example: 1) reduce total amount of present and potential liability for benefits by reinsurance 2) reduce volume of new business accepted 3) reduce expenses by specified methods 4) suspend or limit the writing of new business for a period of time 5) require an increase in the PSOs net worth by contribution 6) add or delete sponsoring providers 7)increase the amount of payments from the PSO which sponsoring providers agree to forego, or 8) require additional guaranties from sponsors or their parents • Permits the Medical Care Commission to adopt rules to set uniform standards and criteria for early warning for financial problems and to set standards for evaluating the financial condition of any PSO if the liquidity standards do not provide sufficient early warning of hazardous conditions of PSOs.	Page 15, lines 16-34. Page 15, lines 35-42.

G.S. 131E-298	**Protection Against Insolvency.** • Requires that each PSO maintains at all times an adequate plan for protection against insolvency acceptable to the Department. • Describes the elements of an acceptable plan of protection, including the existence of the following: 1) reinsurance agreement preapproved by Department and providing 60 day notice to department in event of cancellation or reduction of coverage 2) conversion policy offered by an insurer in the event of PSO's insolvency 3) legally binding unconditional guaranties 4) legally binding obligations of sponsoring providers to forego payment in order to avoid insolvency	Page 16, lines 1-26.
G.S. 131E-299	**Hold Harmless Agreements or Special Deposits.** • Requires that PSO's include in their contracts with participating providers the requirement that the provider hold the Medicare subscriber or beneficiary harmless if the PSO fails to pay the provider. • If there is no participating provider contract, then the PSO must keep special deposits in cash or cash equivalents or through reinsurance in uncovered health care expenditures reach a specified threshold. • The special deposit provision tracks the federal negotiated rule for PSO solvency. • The Department may waive or reduce requirements of this section.	Page 16, lines 28-44 and page 17. Page 18, lines 1-5.
G.S. 131E-300	**Continuation of Benefits.** • Requires each PSO to have a plan, in the event of insolvency, for continuing benefits for the duration of the contract period for which premiums have been paid and for the continuation of benefits to beneficiaries who are confined in an inpatient facility until their discharge or expiration of benefits.	Page 18, lines 6-26.

G.S. 131E-301	**In the Event of Insolvency.** • All providers which were sponsoring providers of an insolvent PSO within the previous 12 months are required to offer all beneficiaries enrolled with the insolvent PSO covered services without charge for thirty (30) days. • In addition, requires the Medical Care Commission to allocate the insolvent PSO's contracts to other PSOs operating in the area and to allocate the insolvent PSO's beneficiaries who are unable to obtain other coverage.	Page 18, lines 27-43. Page 19, lines 3-11.
G.S. 131E-302	**Replacement Coverage.** • Requires immediate coverage of beneficiaries by carriers providing replacement coverage within a period of 60 days of discontinuance of prior PSO contract or policy providing and without reducing benefits otherwise available under the prior PSO contract or policy.	Page 19, lines 12-27.
G.S. 131E-303	**Incurred But Not Reported Claims.** • Requires PSOs to make estimates of their liability for incurred by not reported claims.	Page 19, lines 29-36.
G.S. 131E-304	**Suspension or Revocation of License.** • Permits the Medical Care Commission to suspend, revoke, or refuse to renew a PSO license in certain events, such as: 1. the PSO operates significantly in contravention of its basic organizational document or 2. if it substantially fails the liquidity targets and no longer maintains the financial reserve requirements or 3. if the continued operation of the PSO would be hazardous to beneficiaries.	Page 19, lines 37-44, and page 18, lines 1-34.
G.S. 131E-305	**Administrative Procedures.** • Requires the Medical Care Commission to notify PSOs if their applications are denied or if their licenses are revoked or suspended and provides them with rights to a hearing on the denial, suspension or revocation.	Page 20, lines 35-44.

G.S. 131E-306	**Department of Insurance.** • Permits the Medical Care Commission to request that the Department of Insurance evaluate a PSO's compliance with any or all of the solvency requirements set forth in this Article. • Upon such a request, the Department of Insurance is required to undertake the evaluation in accordance with this Article and regulations issued thereunder and report its evaluation to the Medical Care Commission in a timely manner. • The Department of Insurance is entitled to collect from the PSO subject to the evaluation a fee not to exceed the fee that the Department of Insurance would be entitled to impose on an health maintenance organization for undergoing a similar evaluation. • The Medical Care Commission retains final authority to license PSOs in accordance with the PSO Act.	Page 21, lines 6-16.
G.S. 131E-307	**Fees.** • Requires PSOs to pay fees for applications, license renewal and filing of annual reports.	Page 21, lines 17-25.
G.S. 131E-308	**Penalties and Enforcement.** • Imposes penalties (Class 1 misdemeanor) if the provisions of this Article are violated or threatened to be violated • authorizes the Medical Care Commission to institute proceedings for cease and desist orders or injunctive relief. • Authorizes the Department to institute a proceeding in the Superior Court of Wake County to obtain injunctive or other appropriate relief.	Page 21, lines 26-44. Page 22, lines 1-14.

G.S. 131E-309	**Statutory Construction and Relationship to Other Laws.** • Provides that, unless specified, insurance laws and provisions of hospital or medical service corporation laws are not be applicable to any provider sponsored organization granted a license under this Article or to its sponsoring providers when operating under such a license. • Licensed PSOs are not deemed to be practicing medicine or dentistry. • PSO solicitation shall not be construed to violate professional prohibitions on solicitation.	Page 22, lines 15-32.
G.S. 131E-310	**Filings and Reports are Public Records.** • Exempts PSO and sponsoring provider trade secrets and competitively sensitive information from public record rules.	Page 22, lines 34-37.
G.S. 131E-311	**Confidentiality of Medical Information.** • Medical information given to PSO or its providers is confidential, but may be released under limited circumstances specified in statute. • PSO may claim provider privileges against disclosure.	Page 22, lines 38-44 and page 23, lines 1-6.
G.S. 131E-312	**Conflicts and Severability.** • The provisions of the PSO Act prevail when there is a conflict with other provisions of Chapter 131E of the General Statutes. • Requires the Medical Care Commission to process PSO applications in the absence of promulgated regulations. • Severs any section of the Article which is determined to be invalid.	Page 23,lines 7-15.

G.S. 131E-313	**Regulations.** • The Article is self-implementing • No later than six (6) months after the date of enactment of the PSO Act, the Medical Care Commission may promulgate rules and regulations consistent with the PSO Act to authorize and regulate provider sponsored organizations to contract directly with the federal Medicare program to provide health care services to the beneficiaries of such programs.	Page 23,lines 16-27.
Section 2	Makes PSOs statute effective June 1, 1998.	

SECTION III

EXHIBITS

ARTICLE 12M.
Joint Legislative Health Care Oversight Committee.

§ 120-70.110. Creation and membership of Joint Legislative Health Care Oversight Committee.

There is established the Joint Legislative Health Care Oversight Committee. The Committee consists of 14 members as follows:

(1) Seven members of the Senate appointed by the President Pro Tempore of the Senate, at least three of whom are members of the minority party; and

(2) Seven members of the House of Representatives appointed by the Speaker of the House of Representatives, at least three of whom are members of the minority party.

Terms on the Committee are for two years and begin on the convening of the General Assembly in each odd-numbered year, except the terms of the initial members, which begin on appointment. Members may complete a term of service on the Committee even if they do not seek reelection or are not reelected to the General Assembly, but resignation or removal from service in the General Assembly constitutes resignation or removal from service on the Committee.

A member continues to serve until the member's successor is appointed. A vacancy shall be filled within 30 days by the officer who made the original appointment.

(1997-443, s. 22.1(b).)

Editor's Note. - Session Laws 1997-443, s. 35.5, made this Article effective July 1, 1997.

Session Laws 1997-443, s. 1.1, provides: "This act shall be known as 'The Current Operations and Capital Improvements Appropriations Act of 1997'".

Session Laws 1997-443, s. 35.4, is a severability clause.

This section was enacted as § 120-70.96 by Session Laws 1997-443, s. 22.1. It has been recodified at the direction of the Revisor of Statutes.

§ 120-70.111. Purpose and powers of Committee.

(a) The Joint Legislative Health Care Oversight Committee shall review, on a continuing basis, the provision of health care and health care coverage to the citizens of this State, in order to make ongoing recommendations to the General Assembly on ways to improve health care for North Carolinas. To this end, the Committee shall study the delivery, availability, and cost of health care in North Carolina. The Committee may also study other matters related to health care and health care coverage in this State.

(b) The Committee may make interim reports to the General Assembly on matters for which it may report to a regular session of the General Assembly. A report to the General Assembly may contain any legislation needed to implement a recommendation of the Committee.

(1997-443, s. 22.1(b).)

Editor's Note. - This section was enacted as § 120-70.97 by Session Laws 1997-443, s. 22.1. It has been recodified at the direction of the Revisor of Statutes.

§ 120-70.112. Organization of Committee.

(a) The President Pro Tempore of the Senate and the Speaker of the House of Representatives shall each designate a cochair of the Joint Legislative Health Care Oversight Committee. The Committee shall meet at least once a quarter and may meet at other times upon the joint call of the cochairs.

(b) A quorum of the Committee is eight members. No action may be taken except by a majority vote at a meeting at which a quorum is present. While in the discharge of its official duties, the Committee has the powers of a joint committee under G.S. 120-19 and G.S. 120-19.1 through G.S. 120-19.4.

(c) Members of the Committee receive subsistence and travel expenses as provided in G.S. 120-3.1. The Committee may contract for consultants or hire employees in accordance with G.S. 120-32.02. The Legislative Services Commission, through the Legislative Services Officer, shall assign professional staff to assist the Committee in its work. Upon the direction of the Legislative Services Commission, the Supervisors of Clerks of the Senate and of the House of Representatives shall assign clerical staff to the Committee. The expenses for clerical employees shall be borne by the Committee.

(1997-443, s. 22.1(b).)

Editor's Note. - This section was enacted as § 120-70.98 by Session Laws 1997-443, s. 22.1. It has been recodified at the direction of the Revisor of Statutes.

EXHIBIT B

North Carolina General Assembly
Legislative Services Office

George R. Hall, Legislative Services Officer
(919) 733-7044

Elaine W. Robinson, Director
Administrative Division
Room 5, Legislative Building
16 W. Jones Street
Raleigh, NC 27603-5925
(919) 733-7500

Gerry F. Cohen, Director
Bill Drafting Division
Suite 401, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-6660

Thomas L. Covington, Director
Fiscal Research Division
Suite 619, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-4910

Tony C. Goldman, Director
Information Systems Division
Suite 400, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-6834

Terrence D. Sullivan, Director
Research Division
Suite 545, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-2578

TO: Members,
Joint Legislative Health Care Oversight Committee

FROM: Representative James Crawford, Chairman
Pharmacy Issues Subcommittee

RE: Final Report on Activities and Recommendations

DATE: May 18, 1998

Membership:

Representative Jim Crawford, Chair
Representative Edd Nye
Representative Thomas Wright
Senator Jim Forrester
Senator Wib Gulley
Senator Beverly Perdue

Scope Of Study:

The Pharmacy Issues Subcommittee was appointed by the Co-Chairmen of the Joint Legislative Health Care Oversight Committee on February 10, 1998. The subcommittee was directed to study the proposed amendments to the Pharmacy Practice Act and Senate Bill 866, Third Edition, concerning managed care, prescription drug reimbursements and market competition in the retail drug industry. The subcommittee was asked to report any legislative recommendations to the full Committee prior to the beginning of the 1998 General Session.

Activities:

The subcommittee met five times. At the first meeting on March 10, representatives from the Pharmacy Association and the Board of Pharmacy presented a series of proposed changes to the Pharmacy Practice Act. The industry draft proposal was thoroughly discussed. Numerous questions were raised and staff was directed to draft a bill to incorporate the amendments as well as other provisions at the suggestion of members and others attending the meeting.

The next meeting was held on March 17. The focus of this meeting was Senate Bill 866 (Third Edition). Mike James, representing the NC Retail Pharmacy Association, spoke in favor of SB 866. Brad Adcock, representing Blue Cross Blue Shield spoke against the bill. The subcommittee members present and other interested parties were invited to submit to the Chair amendments to the bill for subcommittee discussion, but none were submitted.

The next meeting was held on April 20. The subcommittee voted to endorse SB 866, Third Edition, without amendments. The draft proposal to amend the Pharmacy Practice Act was reviewed and several suggestions for further revisions were made.

The next meeting was held on May 7 to review the draft proposal to amend the Pharmacy Practice Act. The subcommittee was informed by several individuals in attendance that the did not have the unanimous support of all affected parties. The subcommittee acknowledged this fact, but voted to recommend the draft bill, with a minor amendment, to the Joint Legislative Health Care Oversight Committee.

Representative Crawford offered the subcommittee's recommendation to the Joint Legislative Health Care Oversight Committee at its May 7, 1998 meeting. The Committee, however, recommended that the subcommittee review the submitted draft again to determine whether it could be further amended to include only those provisions that were supported by all interested parties. The subcommittee met again on May 18, 1998. A pared down version of the previous draft was reviewed and voted out by the subcommittee.

Recommendation and Endorsement:

The subcommittee endorses SB 866 (Third Edition) and recommends AN ACT TO AMEND THE PHARMACY PRACTICE ACT for introduction to the 1998 General Session.

North Carolina General Assembly
Legislative Services Office

George R. Hall, Legislative Services Officer
(919) 733-7044

Elaine W. Robinson, Director
Administrative Division
Room 5, Legislative Building
16 W. Jones Street
Raleigh, NC 27603-5925
(919) 733-7500

Gerry F. Cohen, Director
Bill Drafting Division
Suite 401, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-6660

Thomas L. Covington, Director
Fiscal Research Division
Suite 619, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-4910

Tony C. Goldman, Director
Information Systems Division
Suite 400, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-6834

Terrence D. Sullivan, Director
Research Division
Suite 545, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-2578

TO: Members,
Joint Legislative Health Care Oversight Committee

FROM: Senator Wib Gulley, Chairman

RE: Health Care Information Privacy Subcommittee
Subcommittee's Report on Activities and Recommendation

DATE: May 18, 1998

Membership:

Senator Wib Gulley, Chairman
Senator Leslie Winner
Senator Fletcher Hartsell
Representative Ed Nye
Representative Theresa Esposito
Representative Joanne Bowie

Scope of Study:

The Health Care Information Privacy Subcommittee was appointed by the Co-Chairs of the Joint Legislative Health Care Oversight Committee on February 10, 1998 and was directed to study emerging issues related to the integrity and privacy of health information that is increasingly being stored in computers and transmitted exchanged electronically over wide networks. The Subcommittee was asked to report its findings concerning the adequacy of North Carolina law to protect the privacy of health information and any legislative recommendation for the 1998 General Session.

Activities:

The subcommittee met twice. The subcommittee's deliberations focused on: how technology is currently being used to improve health care; why clear and comprehensive rules regarding the collection, use, storage and disclosure of computerized health information is crucial; the need for State legislation; and federal proposals to protect the privacy of health information and federal preemption of State legislation.

The subcommittee heard testimony and presentations from several individuals who are experts in health information management and privacy issues including: Bill Cox, Director, Division of Information Resource Management, NC Department of Health and Human Services; William D. Mattern, MD, Associate Dean Academic Affairs, UNC School of Medicine; Jean T. Foster, RRA, NC Health Information Management Association, Pitt County Memorial Hospital, and James Belliard, MD, President of the NC Psychiatric Association.

Barbara B. Garlock, Kilpatrick, Stockton LLP, and Walter E. Daniels, Daniels and Daniels, PA provided the subcommittee with a detailed overview of proposed legislation initiated and drafted by the North Carolina Healthcare Information and Communications Alliance, Inc.

Findings:

Legislation is needed in North Carolina that will ensure that health information is: 1) secure, private, accurate, and reliable; 2) properly disclosed or modified; and 3) accessible only to those with a legitimate need for the information.

Recommendation:

The subcommittee recommends AN ACT TO PROTECT THE PRIVACY OF HEALTH INFORMATION for introduction to the 1998 General Session.

SECTION IV

ENDORSEMENTS

North Carolina General Assembly
Legislative Services Office

George R. Hall, Legislative Services Officer
(919) 733-7044

Elaine W. Robinson, Director
Administrative Division
Room 5, Legislative Building
16 W. Jones Street
Raleigh, NC 27603-5925
(919) 733-7500

Gerry F. Cohen, Director
Bill Drafting Division
Suite 401, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-6660

Thomas L. Covington, Director
Fiscal Research Division
Suite 619, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-4910

Donald W. Fulford, Director
Information Systems Division
Suite 400, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-6834

Terrence D. Sullivan, Director
Research Division
Suite 545, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-2578

May 18, 1998

The Honorable Daniel F. McComas, Chairman
House Insurance Subcommittee on Health
Room 2123
Legislative Building
Raleigh, North Carolina 27611

Dear Representative McComas:

The Legislative Research Commission authorized the Joint Legislative Health Care Oversight Committee to study issues related to prescription drug competition in the interim period between the 1997 and 1998 Regular Sessions. [Sec. 2.7, S.L. 483 (SB 32)]. As authorized, the Committee conducted a thorough study of Senate Bill 866 (3rd Edition), "Prescription Drugs/Competition." SB 866 passed 3rd reading in the Senate on April 30, 1997, and was referred to the House Insurance subcommittee on Health on May 27, 1997. It is currently pending in that committee.

The Joint Legislative Health Care Oversight Committee carefully considered the impact SB 866 is expected to have on the financial stability of independent pharmacies, health care costs, prescription drug market competition, managed care and the public's health. The Committee heard from health care providers, payers, consumers, retail pharmacists and other interested parties. As a result of its review, the Committee decided to endorse the bill, in its current version.

The Committee requests that your Subcommittee consider giving SB 866 (Third Edition) a favorable report during the 1998 Regular Session.

Sincerely,

Copy to: Chair, Senate Commerce
Chair, Senate Rules
Chair, House Rules
Speaker Harold Brubaker
President Pro Tem Marc Basnight

DRAFT

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1997

S 3

SENATE BILL 866*
Commerce Committee Substitute Adopted 4/29/97
Third Edition Engrossed 4/30/97

Short Title: Prescription Drugs/Competition. (Public)

Sponsors:

Referred to:

April 15, 1997

A BILL TO BE ENTITLED

AN ACT TO PROMOTE COMPETITION, CHOICE, AND AVAILABILITY IN THE PURCHASE OF PRESCRIPTION DRUGS AND PHARMACEUTICAL SERVICES.

The General Assembly of North Carolina enacts:

Section 1. Article 51 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-51-37A. Prescription drugs and pharmaceutical services benefits.**

(a) This section applies only to health benefit plans that provide benefits for prescription drugs and pharmaceutical services.

(b) The purposes of this section are:

(1) To promote competition among and continued availability of retail pharmacies that redeem benefits for prescription drugs and pharmaceutical services provided to consumers by a health benefit plan or insurance certificate.

(2) To prohibit anticompetitive restrictions in pharmacy provider contracts between a pharmacy and a health benefit plan, insurer, or third-party administrator.

(3) To enable a pharmacy to establish without restriction its prices for both prescription drugs and pharmaceutical services, as well as to control its hours of operation.

(4) To further ensure that consumers may redeem prescription drugs and pharmaceutical services benefits allowed by a health benefit plan or an insurer at the pharmacy of the beneficiary's choice.

(5) To continue to enable a health benefit plan, insurer, or third-party administrator to establish prescription drug and pharmaceutical services benefits it provides to its beneficiaries or insureds, so long as in so doing it does not interfere with the right of the pharmacy to establish its own price or charge for the drug or service.

(c) As used in this section:

(1) 'Benefit' or 'benefits' means a benefit for either prescription drugs or pharmaceutical services, or both, provided by a health benefit plan or an insurer.

(2) 'Drug' or 'prescription drug' means any substance subject to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395, as amended.

(3) 'Health benefit plan' means an accident and health insurance policy or certificate; a nonprofit service corporation contract; a health maintenance organization subscriber contract; a plan provided by a multiple employer welfare arrangement; coverage provided by an employer under G.S. 97-93; or a plan provided by another benefit arrangement, to the extent permitted by the Employee Retirement Income Security Act of 1974, as amended, or by any waiver of or other exception to the act provided under federal law or regulation. 'Health benefit plan' does not mean accident only insurance, or credit insurance, or disability income insurance.

(4) 'Insurer' means any entity that provides or offers a health benefit plan, including, but not limited to, an entity subject to Article 49, Article 65, or Article 67 of this Chapter.

(5) 'Pharmacy' means a pharmacy required by Article 4A of Chapter 90 of the General Statutes to be registered with the North Carolina Board of Pharmacy. Unless otherwise expressly provided in this section, the term 'pharmacy' also means a pharmacy that redeems benefits under a health benefit plan, insurer, or third-party administrator through a pharmacy provider contract or otherwise.

(6) 'Pharmacy provider contract' means a contract or agreement between a pharmacy and a health benefit plan, an insurer, or a third-party administrator under which the pharmacy agrees to redeem prescription drugs and pharmaceutical services benefits provided by a health benefit plan or insurer to the subscribers or beneficiaries of the plan or health insurance certificate.

(7) 'Third-party administrator' means a person who directly or indirectly solicits or effects coverage of, underwrites, collects

(4) To further ensure that consumers may redeem prescription drugs and pharmaceutical services benefits allowed by a health benefit plan or an insurer at the pharmacy of the beneficiary's choice.

(5) To continue to enable a health benefit plan, insurer, or third-party administrator to establish prescription drug and pharmaceutical services benefits it provides to its beneficiaries or insureds, so long as in so doing it does not interfere with the right of the pharmacy to establish its own price or charge for the drug or service.

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(6) 'Pharmacy provider contract' means a contract or agreement between a pharmacy and a health benefit plan, an insurer, or a third-party administrator under which the pharmacy agrees to redeem prescription drugs and pharmaceutical services benefits provided by a health benefit plan or insurer to the subscribers or beneficiaries of the plan or health insurance certificate.

(7) 'Third-party administrator' means a person who directly or indirectly solicits or effects coverage of, underwrites, collects

charges or premiums, or adjusts or denies claims in connection with a health benefit plan.

(d) Notwithstanding G.S. 58-51-37, a health benefit plan, insurer, third-party administrator, or other entity shall not, directly or indirectly, restrict or prohibit a pharmacy that is not a party to a pharmacy provider contract from establishing its charge or price for prescription drugs and pharmaceutical services, or both, or its hours of operation.

(e) Subject to the provisions of this section, a benefit for prescription drugs or pharmaceutical services or both may be redeemed by the beneficiary at any pharmacy of the beneficiary's choice. The health benefit plan, insurer, third-party administrator, or other person or entity providing benefits shall redeem benefits for prescription drugs or pharmaceutical services provided by a pharmacy that is not a party to a pharmacy provider contract at the same rate and in the same manner as it redeems the benefits for the drugs or services provided by a pharmacy under a pharmacy provider contract.

(f) A health benefit plan, insurer, third-party administrator, or other person or entity providing benefits may not, directly or indirectly, restrict or financially coerce the beneficiary's choice of pharmacy.

(g) Notwithstanding G.S. 58-51-37, if the charge or price established by the pharmacy for a prescription drug or pharmaceutical service, or both, is greater than the benefit allowed by the health benefit plan or insurer for the drug or service, then the beneficiary is responsible for paying the pharmacy the difference between the benefit and the charge or price of the pharmacy for the prescription drug or pharmaceutical service, or both. Prior to filling the prescription, if the beneficiary requests the information and the pharmacist has the information, the pharmacist shall inform the beneficiary what the price difference will be.

(h) A health benefit plan, insurer, or third-party administrator shall not restrict or prohibit, directly or indirectly, a pharmacy that is not a party to a pharmacy provider contract from charging the beneficiary for services rendered by the pharmacy that are in addition to charges for the drug, for dispensing the drug, or for patient counseling.

(i) The health benefit plan or the insurer shall inform all beneficiaries under the plan that benefits may be redeemed at any pharmacy which the beneficiary chooses. This information shall be communicated through reasonable means on a timely basis and at regular intervals. The health benefit plan, insurer, or third party administrator shall not express an opinion or judgment as to what a pharmacy's charge or price should be or what a beneficiary's co-payment difference should be. This information shall also be included in the written summary or description of the health benefit plan or insurance, as well as other written communications furnished to beneficiaries where benefits are mentioned. Nothing in this section shall prevent a health benefit plan or insurer from notifying its enrollees or participants of which pharmacies have agreed to fill prescriptions without any additional charges.

(j) A pharmacy eligible to redeem benefits under a health benefit plan may announce and advertise that eligibility in a commercially reasonable manner.

(k) Penalties:

(1) The Commissioner of Insurance shall not approve any health benefit plan or policy providing prescription drugs or pharmaceutical services benefits that does not conform to the provisions of this section.

(2) Any provision of a health benefit plan that is executed, delivered, or renewed or otherwise contracted for in this State that is in conflict with any provision of this section shall be void, to the extent of the conflict.

(3) Any provision of a pharmacy provider contract between a health benefit plan, or insurer, or third-party administrator, or other person subject to the provisions of this section and a pharmacy, or pharmacist licensed under Article 4A of Chapter 90 of the General Statutes, that is in conflict with this section is void to the extent of the conflict.

(4) The Commissioner of Insurance shall investigate and sanction any person, health benefit plan, insurer, third-party administrator, or other person that violates the provisions of this section, pursuant to Chapter 58 and other applicable law.

(5) A health benefit plan or insurer, or third-party administrator, or other person that violates this section shall be subject to the provisions of G.S. 58-2-70 concerning civil penalties, restitution, and summary suspension of license or certificate; provided, however, if pursuant to G.S. 58-2-70(d), monetary civil penalties are directed by the Commissioner, for the purposes of this section, these penalties shall not be less than one thousand dollars ($1,000) per day, nor more than ten thousand dollars ($10,000) per day.

(6) If the Commissioner has reason to believe that a health benefit plan, insurer, third-party administrator, or other person or entity has failed to comply with this section, the Commissioner shall issue and serve upon the person or entity a statement of the charges in that respect and a notice of hearing to be held at the time and place fixed in the notice, which shall not be less than 10 days after the date of service of the notice. If, after hearing, the Commissioner finds that the person or entity is in violation of this section, the Commissioner shall reduce the finding to writing and issue and serve upon the person or entity an order requiring the person or entity to cease and desist from engaging in the violation. A person or entity required to cease and desist pursuant to this section may obtain a review of the cease and desist order in accordance with the procedures set forth in G.S. 58-63-35. A person or entity found to be in violation of this section shall be subject to civil monetary penalties for violations committed on and after the date the person or entity received the statement of charges and notice of hearing from the Commissioner.

(1) The Commissioner of Insurance shall not approve any health benefit plan or policy providing prescription drugs or pharmaceutical services benefits that does not conform to the provisions of this section.

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(7) The Commissioner of Insurance shall have the authority granted by this Chapter to enforce violations of this section, including additional authority provided in this section.

(8) The Attorney General shall bring such actions as are necessary to enforce or prevent violations of this section, either through representation of the Commissioner of Insurance or otherwise."

Section 2. If any provision of this act or the application of this act to any person or circumstance is held invalid, the other provisions or applications of this act shall be given effect without the invalid provisions or applications.

Section 3. This act applies to every health benefit plan as defined in Section 1 of this act that is delivered, issued for delivery, or renewed on or after October 1, 1997. For purposes of this act, renewal of a health benefit plan is presumed to occur on each anniversary of the date on which coverage was first effective on the person or persons covered by the health benefit plan.

Section 4. This act becomes effective October 1, 1997.

North Carolina General Assembly
Legislative Services Office

DRAFT

George R. Hall, Legislative Services Officer
(919) 733-7044

Elaine W. Robinson, Director
Administrative Division
Room 5, Legislative Building
16 W. Jones Street
Raleigh, NC 27603-5925
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Terrence D. Sullivan, Director
Research Division
Suite 545, LOB
300 N. Salisbury St.
Raleigh, NC 27603-5925
(919) 733-2578

April 30, 1998

MEMORANDUM

TO: Members of the Joint Legislative Health Care Oversight Subcommittee on Pharmacy Issues

FROM: Linda Attarian, Staff Counsel

RE: Bill Summary of Senate Bill 866, Third Edition: Prescription Drugs/Competition

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Background:

Under current law, an insurer who provides pharmaceutical benefits to its enrollees must contract with any pharmacy willing to agree to the terms offered by the insurer. This policy was implemented to provide all pharmacies the choice to participate in any health benefit plan and thereby continue to serve its long-time customers, and to avoid having its customers "contracted" away to other pharmacies.

Some contracts offered to pharmacies by insurers (typically HMOs) require the pharmacy to agree not to charge the beneficiary anything more than a set co-payment. Under such an agreement, the insurer reimburses the balance of the pharmacy's cost of providing the prescription drug and any associated pharmaceutical services provided to the beneficiary. Some retail pharmacists have found that the reimbursements are insufficient to provide a competitive profit margin. The bill seeks to remedy this problem.

Summary of the bill:

The bill will apply to contracts between pharmacies and insurers and will affect all insurance companies, health maintenance organizations and other types of managed care organizations that provide or administer benefits for pharmaceutical services to any resident of North Carolina.

The bill provides the following duties and powers:

1. An insurer must allow the beneficiary to redeem their prescription drug benefits at any pharmacy the beneficiary chooses, at the same rate and in the same manner as a contracting pharmacy, even if the pharmacy the beneficiary chooses does not agree to participate in the health benefit plan according to the terms offered by the insurer. [See Page 3, lines 8-15].

2. An insurer may not do anything that would directly or indirectly restrict or financially coerce the beneficiary's choice of pharmacy. [See Page 3, lines 16-18.

3. Notwithstanding the pharmacy of choice law, an insurer is prohibited from doing anything that will directly or indirectly restrict a pharmacy that has not agreed to participate in the health benefit plan from setting its own prices for prescription drugs, pharmaceutical services, or its hours of operation. [See Page 3, lines 3-7].

4. An insurer is prohibited from directly or indirectly restricting a pharmacy that has not agreed to participate in the health benefit plan from charging the beneficiary for services rendered by the pharmacy that are in addition to dispensing fees and patient counseling fees. An example of an additional fee that could be charged is a fee for home delivery. [See Page 3, lines 27-30].

5. A pharmacy that has not agreed to participate in the health benefit plan may charge the beneficiary the difference between the pharmacy's set price for the drug or service and the total of the beneficiary's co-payment and the insurer's reimbursement allowed under the plan. For example:
   - If the plan allows a co-payment of $5.00 and a reimbursement of $25.00 for a particular prescription drug that the pharmacy has set the price at $40.00, the pharmacy could charge the beneficiary $10.00 in addition to the $5.00 co-payment to cover the pharmacy's price of the drug.; or
   - If the pharmacy sets a $10.00 counseling charge on each prescription and the beneficiary's health benefit plan only reimburses the pharmacy $5.00 for counseling on each prescription the pharmacy could charge the beneficiary an additional $5.00 to cover this cost. [See Page 3, lines 12-24].

6. In the situation in number 5, above, the pharmacist must inform the beneficiary of any price differentials prior to the transaction if:
   - the beneficiary asks if an additional charge will be due and if so, how much; and
   - if the pharmacist has the information prior to the transaction. [See Page 3, lines 24-26].

7. The insurer must provide written information to all its enrollees on a timely basis and at regular intervals, informing them that they may fill their prescriptions at any pharmacy they choose and their benefit will be the same even if the pharmacy of choice does not participate in the health benefit plan. [See Page 3, lines 31-34]].

8. The insurer may not express an opinion or judgment as to what a reasonable price for a particular drug or pharmaceutical service should be or what the beneficiary's co-payment should be. [See Page 3, lines 34-37].

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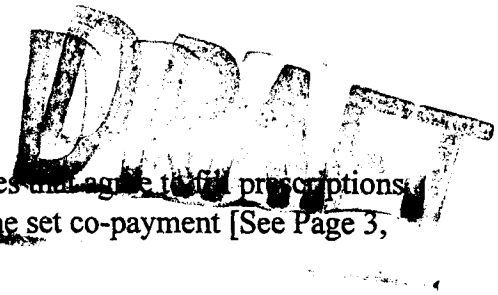

9. The insure may provide its enrollees with a listing pharmacies that agree to fill prescriptions for beneficiaries without any additional charges other than the set co-payment [See Page 3, lines 39-41].

Penalties:

An insurer who violates this section will be subject to the provisions of G.S. 58-2-70 concerning civil penalties, restitution, and summary suspension of its license or certificate. If any monetary civil penalties are imposed, they shall not be less than $1,000 per day and not more than $10,000 per day. [See Page 4, lines 19-26]. Further, the Commissioner of Insurance is authorized to issue and serve a cease and desist order. [See Page 4, lines 27-44].

The act becomes effective October 1, 1997. (This would be changed presumably to October 1, 1998).