GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 2001

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SENATE BILL 199

Insurance and Consumer Protection Committee Substitute Adopted 4/25/01

Short Title: Managed Care Patients' Bill of Rights.	(Public)
Sponsors:	
Referred to:	

February 22, 2001

A BILL TO BE ENTITLED

AN ACT TO IMPROVE ACCESS TO HEALTH CARE ADVICE, INFORMATION, AND SERVICES TO COVERED PERSONS UNDER HEALTH BENEFIT PLANS; ESTABLISH STANDARDS FOR HEALTH PLAN DISCLOSURES TO CONSUMERS; ESTABLISH A PATIENTS' ASSISTANCE PROGRAM; REQUIRE COVERAGE FOR CLINICAL TRIALS AND NEWBORN HEARING SCREENING; PROVIDE STANDARDS FOR INDEPENDENT REVIEW OF NONCERTIFICATIONS BY AN INSURER OR MANAGED CARE PLAN, AND TO HOLD MANAGED CARE ENTITIES LIABLE FOR HARM CAUSED TO INSUREDS OR ENROLLEES BY THE FAILURE TO EXERCISE ORDINARY CARE IN MAKING TREATMENT DECISIONS.

The General Assembly of North Carolina enacts:

PART I. PATIENT ACCESS TO MEDICAL ADVICE AND CARE

Subpart A. Continuity of Care in HMOs

SECTION 1. Article 67 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-67-88. Continuity of care.**

(a) Definitions. – As used in this section:

(1) 'Ongoing special condition' means:

a. In the case of an acute illness, a condition that is serious enough to require medical care or treatment to avoid a reasonable possibility of death or permanent harm.

b. In the case of a chronic illness or condition, or a disease or condition that is life-threatening, degenerative, or disabling, and requires medical care or treatment over a prolonged period of time.

c. Pregnancy, from the start of the second trimester.
d. Terminal illness.

(2) 'Terminal illness' means an individual has a medical prognosis that the individual's life expectancy is six months or less.

(3) 'Terminated or termination'. – Includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by an HMO for failure to meet applicable quality standards or for fraud.

(b) Termination of Provider. – If a contract between an HMO benefit plan that is not a point-of-service plan and a health care provider is terminated by the provider or by the HMO, or benefits or coverage provided by the HMO are terminated because of a change in the terms of provider participation in a health benefit plan of an HMO that is not a point-of-service plan, and an individual is covered by the plan and is terminally ill or undergoing treatment from the provider for an ongoing special condition at the time of the termination, then, the HMO shall:

(1) Upon termination of the contract by the HMO or upon receipt by the HMO of written notification of termination by the provider, notify the individual on a timely basis of the termination and of the right to elect continuation of coverage of treatment by the provider under this section.

(2) Subject to subsection (h) of this section, permit the individual to elect to continue to be covered with respect to the terminal illness or treatment by the provider of the ongoing special condition during a transitional period provided under this section.

(c) Newly Covered Insured. – Each health benefit plan offered by an HMO that is not a point-of-service plan shall provide transition coverage to individuals who are newly covered under the health benefit plan because the individual's employer has changed health benefit plans, and the HMO shall:

(1) Notify the individual at the time of enrollment of the right to elect continuation of coverage of treatment by the provider under this section.

(2) Subject to subsection (h) of this section, permit the individual to elect to continue to be covered with respect to the terminal illness or treatment by the provider of the ongoing special condition during a transitional period provided under this section.

(d) Transitional Period: In General. – Except as otherwise provided in subsections (e), (f), and (g) of this section, the transitional period under this subsection shall extend up to 90 days, as determined by the treating health care provider, after the date of the notice to the individual described in subdivision (b)(1) of this section or the enrollment in a new plan described in subdivision (c)(1) of this section.

(e) Transitional Period: Scheduled Surgery, Organ Transplantation, or Institutional Care. – If surgery, organ transplantation, or other inpatient care was scheduled for an individual before the date of the notice required under subdivision

(b)(1) of this section, or the enrollment in a new plan described in subdivision (c)(1) of this section or if the individual on that date was on an established waiting list or otherwise scheduled to have the surgery, transplantation, or other inpatient care, the transitional period under this subsection with respect to the surgery, transplantation, or other inpatient care shall extend beyond the period under subsection (d) of this section through the date of discharge of the individual after completion of the surgery, transplantation, or other inpatient care, and through postdischarge follow-up care related to the surgery, transplantation, or other inpatient care occurring within 90 days after the date of discharge.

(f) Transitional Period: Pregnancy. – If an insured has entered the second trimester of pregnancy on the date of the announcement of the termination of the provider status under subdivision (b)(1) of this section, or the enrollment in a new plan described in subdivision (c)(1) of this section, and the provider was treating the pregnancy before the date of the announcement of the termination, or the enrollment in the new plan, the transitional period with respect to the provider's treatment of the pregnancy shall extend through the provision of 60 days of postpartum care.

(g) Transitional Period: Terminal Illness. – If an insured was determined to be terminally ill at the time of a provider's termination of participation, or at the time of enrollment in the new plan, and the provider was treating the terminal illness before the date of termination or enrollment in the new plan, the transitional period shall extend for the remainder of the individual's life with respect to care directly related to the treatment of the terminal illness or its medical manifestations.

(h) Permissable Terms and Conditions. – An HMO may condition coverage of continued treatment by a provider under subdivision (b)(2) or (c)(2) of this section upon the following terms and conditions:

(1) The provider agrees to accept reimbursement from the HMO and individual involved, with respect to cost-sharing, at the rates applicable before the start of the transitional period as payment in full.

(2) The provider agrees to adhere to the quality assurance standards of the HMO responsible for payment under subdivision (1) of this subsection and to provide to the HMO necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to the HMO's established policies and procedures for participating providers, including procedures regarding referrals and obtaining prior authorization, providing services pursuant to a treatment plan, if any, approved by the HMO, and member hold harmless provisions.

(4) The insured notifies the HMO within 45 days of the date of the notice described in subdivision (b)(1) of this section or the new enrollment described in subdivision (c)(1) of this section.

(5) The provider agrees to discontinue providing services and refer the enrollee to a network provider by the end of the transition period.

(i) Construction. – Nothing in this section:

(1) Requires the coverage of benefits that would not have been covered if the provider involved remained a participating provider.

(2) Requires an HMO to offer a transitional period when the HMO terminates a provider's contract for reasons relating to quality of care or fraud; and refusal to offer a transitional period under these circumstances is not subject to the grievance review provisions of G.S. 58-50-62.

(3) Prohibits an HMO from extending any transitional period beyond that specified in this section.

(4) Prohibits an HMO from terminating the continuing services of a provider as described in this section when the HMO has determined that the provider's continued provision of services may result in, or is resulting in, a serious danger to the health or safety of the enrollee. Such terminations shall be in accordance with the contract provisions that the provider would otherwise be subject to if the provider's contract were still in effect.

(j) Disclosure of Right to Transitional Period. – Each HMO shall include a clear description of an insured's rights under this section in its evidence of coverage and summary plan description."

Subpart B. Extended or Standing Referral to Specialist

SECTION 1.2. G.S. 58-3-223 reads as rewritten:

"**§ 58-3-223. Managed care access to specialist care.**

(a) Each insurer offering a health benefit plan that does not allow direct access to all in-plan specialists shall develop and maintain written policies and procedures by which an insured may receive an extended or standing referral to an in-plan specialist. The ~~procedure~~insurer shall provide for an extended or standing referral to a specialist if the insured has a serious or chronic degenerative, disabling, or life-threatening disease or condition, which in the opinion of the insured's primary care physician, in consultation with the specialist, requires ongoing specialty care. The extended or standing referral shall be for a period not to exceed 12 months and shall be made under a treatment plan coordinated with the insurer in consultation with the primary care physician, the specialist, and the insured or the insured's designee.

(b) As used in this section:

(1) 'Health benefit plan' has the meaning applied in G.S. 58-3-167.~~means an accident and health insurance policy or certificate; a nonprofit hospital or medical service corporation contract; a health maintenance organization subscriber contract; a plan provided by a multiple employer welfare arrangement; 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 that Act provided under federal law or regulation. 'Health~~

~~benefit plan' does not mean any plan implemented or administered by the North Carolina Department of Health and Human Services or the United States Department of Health and Human Services, or any successor agency, or its representatives. 'Health benefit plan' also does not mean any of the following kinds of insurance:~~

~~a. Accident.~~

~~b. Credit.~~

~~c. Disability income.~~

~~d. Long-term care or nursing home care.~~

~~e. Medicare supplement.~~

~~f. Specified disease.~~

~~g. Dental or vision.~~

~~h. Coverage issued as a supplement to liability insurance.~~

~~i. Workers' compensation.~~

~~j. Medical payments under automobile or homeowners.~~

~~k. Hospital income or indemnity.~~

~~l. Insurance under which benefits are payable with or without regard to fault and that are statutorily required to be contained in any liability policy or equivalent self-insurance.~~

(2) 'Insurer' ~~means an entity that writes a health benefit plan and that is an insurance company subject to this Chapter, a service corporation under Article 65 of this Chapter, or a health maintenance organization under Article 67 of this Chapter, or a multiple employer welfare arrangement under Article 49 of this Chapter.~~has the meaning applied in G.S. 58-3-167.

(3) 'Serious or chronic degenerative, disabling, or life-threatening disease or condition' means a disease or condition, which in the opinion of the patient's treating primary care physician and specialist, requires frequent and periodic monitoring and consultation with the specialist on an ongoing basis.

(4) 'Specialist' includes a subspecialist."

SECTION 1.2A. G.S. 58-3-200(d) reads as rewritten:

"(d) Services Outside Provider Networks. – No insurer shall penalize an insured or subject an insured to the out-of-network benefit levels offered under the insured's approved health benefit ~~plan~~ plan, including an insured receiving an extended or standing referral under G.S. 58-3-223, unless contracting health care providers able to meet health needs of the insured are reasonably available to the insured without unreasonable delay."

Subpart C. Selection of Specialist as Primary Care Physician

SECTION 1.3. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-230. Selection of specialist as primary care provider.**

(a) Each insurer shall have a procedure by which an insured diagnosed with a serious or chronic degenerative, disabling, or life-threatening disease or condition, either of which requires specialized medical care may select as his or her primary care physician a specialist with expertise in treating the disease or condition who shall be responsible for and capable of providing and coordinating the insured's primary and specialty care. If the insurer determines that the insured's care would not be appropriately coordinated by that specialist, the insurer may deny access to that specialist as a primary care provider.

(b) The selection of the specialist shall be made under a treatment plan approved by the insurer, in consultation with the specialist and the insured or the insured's designee and after notice to the insured's primary care provider, if any. The specialist may provide ongoing care to the insured and may authorize such referrals, procedures, tests, and other medical services as the insured's primary care provider would otherwise be allowed to provide or authorize, subject to the terms of the treatment plan. Services provided by a specialist who is providing and coordinating primary and specialty care remain subject to utilization review and other requirements of the insurer, including its requirements for primary care providers."

Subpart D. Direct Access to Pediatrician

SECTION 1.4. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-240. Direct access to pediatrician for minors.**

Each insurer offering a health benefit plan that uses a network of contracting health care providers shall allow an insured to choose a contracting pediatrician in the network as the primary care provider for the insured's children who are under the age of 18."

Subpart E. Access to Prescription Drugs

SECTION 1.5. G.S. 58-3-221 reads as rewritten:

"**§ 58-3-221. Access to nonformulary and restricted access prescription drugs.**

(a) If an insurer maintains one or more closed formularies for or restricts access to covered prescription drugs or devices, then the insurer shall do all of the following:

(1) Develop the formulary or formularies and any restrictions on access to covered prescription drugs or devices in consultation with and with the approval of a pharmacy and therapeutics committee, which shall include participating ~~providers~~ physicians who are licensed to ~~prescribe prescription drugs or devices.~~ practice medicine in this State.

(2) Make available to participating ~~providers and pharmacists~~ providers, pharmacists, and enrollees the complete drugs or devices formulary or formularies maintained by the insurer including a list of the devices and prescription drugs on the formulary by major therapeutic category

that specifies whether a particular drug or device is preferred over other drugs or devices.

(3) Establish and maintain an expeditious process or procedure that allows an enrollee or a physician acting on behalf of an enrollee to obtain, without penalty or additional cost-sharing beyond that provided for in the health benefit plan, coverage for a specific nonformulary drug or device determined to be medically necessary and appropriate by the participating physician without prior approval from the insurer, after the participating physician notifies the insurer that:

a. Either (i) the formulary alternatives have been ineffective in the treatment of the enrollee's disease or condition, or (ii) the formulary alternatives cause or are reasonably expected by the physician to cause a harmful or adverse clinical reaction in the enrollee; and

b. Either (i) the drug is prescribed in accordance with any applicable clinical protocol of the insurer for the prescribing of the drug, or (ii) the drug has been approved as an exception to the clinical protocol pursuant to the insurer's exception procedure.

(4) Provide coverage for a restricted access drug or device to an enrollee without requiring prior approval if an enrollee's physician certifies in writing that the enrollee has previously used an alternative nonrestricted access drug or device and the alternative drug or device has been ineffective or detrimental to the enrollee's health.

(b) An insurer may not void a contract or refuse to renew a contract between the insurer and a prescribing provider because the prescribing provider has prescribed a medically necessary and appropriate nonformulary or restricted access drug or device as provided in this section.

(c) As used in this section:

(1) 'Closed formulary' means a list of prescription drugs and devices reimbursed by the insurer that excludes coverage for drugs and devices not listed.

(1a) 'Health benefit plan' has definition provided in G.S. 58-3-167. ~~means an accident and health insurance policy or certificate; a nonprofit hospital or medical service corporation contract; a health maintenance organization subscriber contract; a plan provided by a multiple employer welfare arrangement; 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 that Act provided under federal law or regulation. 'Health benefit plan' does not mean any plan implemented or administered by the North Carolina Department of Health and Human Services or the United States Department of Health and Human Services, or any~~

~~successor agency, or its representatives. 'Health benefit plan' also does not mean any of the following kinds of insurance:~~

~~a. Accident.~~

~~b. Credit.~~

~~c. Disability income.~~

~~d. Long-term care or nursing home care.~~

~~e. Medicare supplement.~~

~~f. Specified disease.~~

~~g. Dental or vision.~~

~~h. Coverage issued as a supplement to liability insurance.~~

~~i. Workers' compensation.~~

~~j. Medical payments under automobile or homeowners.~~

~~k. Hospital income or indemnity.~~

~~l. Insurance under which benefits are payable with or without regard to fault and that are statutorily required to be contained in any liability policy or equivalent self-insurance.~~

(2) 'Insurer' has the meaning provided in G.S. 58-3-167. ~~means an entity that writes a health benefit plan and that is an insurance company subject to this Chapter, a service corporation organized under Article 65 of this Chapter, a health maintenance organization organized under Article 67 of this Chapter, or a multiple employer welfare arrangement under Article 49 of this Chapter~~.

(3) 'Restricted access drug or device' means those covered prescription drugs or devices for which reimbursement by the insurer is conditioned on the insurer's prior approval to prescribe the drug or device or on the provider prescribing one or more alternative drugs or devices before prescribing the drug or device in question.

(d) Nothing in this section requires an insurer to pay for drugs or devices or classes of drugs or devices related to a benefit that is specifically excluded from coverage by the insurer."

Subpart F. Managed Care Patients' Assistance Program

SECTION 1.6. Article _____ of Chapter _____ of the General Statutes is amended by adding the following new section to read:

"**§ _____. Managed Care Patients' Assistance Program.**

(a) The Office of Managed Care Patients' Assistance Program is hereby established. The Director of the Office of Managed Care Patients' Assistance Program shall be appointed by the Governor.

(b) The Managed Care Patients' Assistance Program shall provide information and assistance to individuals enrolled in managed care plans. The Managed Care Patients' Assistance Program shall have expertise and experience in both health care and

advocacy and will assume the specific duties and responsibilities set forth in subsection (c) of this section.

(c) The duties and responsibilities of the Managed Care Patients' Assistance Program are as follows:

(1) Develop and distribute educational and informational materials for consumers, explaining their rights and responsibilities as managed care plan enrollees.

(2) Answer inquiries posed by consumers and refer inquiries of a regulatory nature to staff within the Department of Insurance.

(3) Advise managed care plan enrollees about the utilization review process.

(4) Assist enrollees with the grievance, appeal, and external review procedures established by Article 50 of Chapter 58 of the General Statutes.

(5) Publicize the Office of the Managed Care Patients' Assistance Program.

(6) Compile data on the activities of the Office and evaluate such data to make recommendations as to the needed activities of the Office.

(d) The Director of the Managed Care Patients' Assistance Program shall annually report the activities of the Managed Care Patients' Assistance Program, including the types of appeals, grievances, and complaints received and the outcome of these cases. The report shall be submitted to the General Assembly, upon its convening or reconvening, and shall make recommendations as to efforts that could be implemented to assist managed care consumers."

PART II. HEALTH PLAN DISCLOSURES

Subpart A. Managed Care Reporting and Disclosure Requirements

SECTION 2.1. G.S. 58-3-191(b) reads as rewritten:

"(b) Disclosure requirements. – Each health benefit plan shall provide the following applicable information to plan participants and bona fide prospective participants upon request:

(1) The evidence of coverage (G.S. 58-67-50), subscriber contract (G.S. 58-65-60, 58-65-140), health insurance policy (G.S. 58-51-80, 58-50-125, 58-50-55), or the contract and benefit summary of any other type of health benefit plan;

(2) An explanation of the utilization review criteria and treatment protocol under which treatments are provided for conditions specified by the prospective participant. This explanation shall be in writing if so requested;

(3) If denied a recommended treatment, written reasons for the denial and an explanation of the utilization review criteria or treatment protocol upon which the denial was based;

(4) The plan's ~~restrictive formularies~~ closed formularies, restricted access drugs or devices, or prior approval requirements for obtaining prescription drugs, whether a particular drug or therapeutic class of drugs is excluded from its formulary, and the circumstances under which a nonformulary drug may be covered; and

(5) The plan's procedures and medically based criteria for determining whether a specified procedure, test, or treatment is experimental."

Subpart B. Provider Directory Information

SECTION 2.2. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-245. Provider directories.**

(a) Every health benefit plan utilizing a provider network shall make a listing of network providers available to insureds and shall update the listing no less frequently than once a year. In addition, every health benefit plan shall maintain a telephone system and may maintain an electronic or on-line system through which insureds can access up-to-date network information. If the health benefit plan produces printed directories, the directories shall contain language disclosing the date of publication, frequency of updates, that the directory may not contain the latest network information, and contact information for accessing up-to-date network information.

(b) Each listing shall include:

(1) The provider's name, address, telephone number, and, if applicable, area of specialty.

(2) Whether the provider may be selected as a primary care provider.

(3) To the extent known to the health benefit plan, an indication of whether the provider:

a. Is or is not currently accepting new patients.

b. Has any other restrictions that would limit an insured's access to that provider.

(c) The listing shall include all of the types of participating providers. Upon a participating provider's written request, the insurer shall also list in the directory, as part of the participating provider's listing, the names of any allied health professionals who provide primary care services under the supervision of the participating provider and whose services are covered by virtue of the carrier's contract with the supervising participating provider and whose credentials have been verified by the supervising participating provider. These allied health professionals shall be listed as a part of the directory listing for the participating provider upon receipt of a certification by the supervising participating provider that the credentials of the allied health professional have been verified."

Subpart C. Disclosure of Payment Obligations

SECTION 2.3. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-250. Payment obligations for covered services.**

(a) If an insurer calculates a benefit amount for a covered service under a health benefit plan through a method other than a fixed dollar co-payment, the insurer shall clearly explain in its evidence of coverage and plan summaries how it determines its payment obligations and the payment obligations of the insured. The explanation shall include:

(1) An example of the steps the insurer would take in calculating the benefit amount and the payment obligations of each party.

(2) Whether the insurer has obtained the agreement of health care providers not to bill an insured for any amounts by which a provider's charge exceeds the insurer's recognized charge for a covered service and whether the insured may be liable for paying any excess amount.

(3) Which party is responsible for filing a claim or bill with the insurer.

(b) If an insured is liable for an amount that differs from a stated fixed dollar co-payment or may differ from a stated coinsurance percentage because the coinsurance amount is based on a (plan allowance or other such amount rather than the actual charges and providers are permitted to balance bill the insured, the evidence of coverage, plan summaries, and marketing and advertising materials that include information on benefit levels shall contain the following statement: 'NOTICE: Your actual expenses for covered services may exceed the stated [coinsurance percentage or co-payment amount] because actual provider charges may not be used to determine [plan/insurer or similar term] and [insured/member/enrollee or similar term] payment obligations.' "

PART III. MANDATED BENEFITS

Subpart A. Clinical Trials

SECTION 3.1. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-255. Coverage of clinical trials.**

(a) As used in this section:

(1) 'Covered clinical trials' means phase III and phase IV patient research studies designed to evaluate new treatments, including prescription drugs and that: (i) involve the treatment of life-threatening medical conditions, (ii) are medically indicated and preferable for that patient compared to available noninvestigational treatment alternatives, and (iii) have clinical and preclinical data that shows the trial will likely be

more effective for that patient than available noninvestigational alternatives. Covered clinical trials must also meet the following requirements:

a. Must involve determinations by treating physicians, relevant scientific data, and opinions of experts in relevant medical specialties.

b. Must be trials approved by centers or cooperative groups that are funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense, or the Department of Veterans Affairs. The health benefit plan may also cover clinical trials sponsored by other entities.

c. Must be conducted in a setting and by personnel that maintain a high level of expertise because of their training, experience, and volume of patients.

(2) 'Health benefit plan' is defined by G.S. 58-3-167.

(3) 'Insurer' is defined by G.S. 58-3-167.

(b) Each health benefit plan shall provide coverage for participation in phase III and phase IV covered clinical trials by its insureds or enrollees who meet protocol requirements of the trials and provide informed consent.

(c) Only medically necessary costs of health care services, as defined in G.S. 58-50-61, associated with participation in a covered clinical trial, including those related to health care services typically provided absent a clinical trial, the diagnosis and treatment of complications, and medically necessary monitoring, are required to be covered by the health benefit plan and only to the extent that such costs have not been or are not funded by national agencies, commercial manufacturers, distributors, or other research sponsors of participants in clinical trials.

(d) Clinical trial costs not required to be covered by a health benefit plan include the costs of services that are not health care services, those provided solely to satisfy data collection and analysis needs, those related to investigational drugs and devices, and those that are not provided for the direct clinical management of the patient. In the event a claim contains charges related to services for which coverage is required under this section, and those charges have not been or cannot be separated from costs related to services for which coverage is not required under this section, the health benefit plan may deny the claim."

Subpart B. Newborn Hearing Screening

SECTION 3.2. Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-260. Insurance coverage for newborn hearing screening mandated.**

(a) As used in this section, the terms 'health benefit plan' and 'insurer' have the meanings applied under G.S. 58-3-167.

(b) Each health benefit plan shall provide coverage for newborn hearing screening ordered by the attending physician pursuant to G.S. 130A-125. The same deductibles, coinsurance, reimbursement methodologies, and other limitations and administrative procedures as apply to similar services covered under the health benefit plan shall apply to coverage for newborn hearing screening."

PART IV. EXTERNAL REVIEW AND MANAGED CARE ENTITY LIABILITY

Subpart A. Independent, External Review Process

SECTION 4.1. The title of Article 50 of Chapter 58 of the General Statutes reads as rewritten:

"Article 50.

General Accident and Health Insurance Regulations."

SECTION 4.2. Article 50 of Chapter 58 of the General Statutes is amended as follows:

(1) By designating G.S. 58-50-1 through G.S. 58-50-45 as Part 1 with the heading "Miscellaneous Provisions."

(2) By designating G.S. 58-50-50 through G.S. 58-50-64 as Part 2 with the heading "PPOs, Utilization Review and Grievances."

(3) By designating G.S. 58-50-65 through G.S. 58-50-70 as Part 3 with the heading "Scope and Sanctions."

(4) By designating G.S. 58-50-75 through G.S. 58-50-95 as Part 4 with the heading "Health Benefit Plan External Review."

(5) By designating G.S. 58-50-100 through G.S. 58-50-156 as Part 5 with the heading "Small Employer Group Health Insurance Reform."

SECTION 4.3. G.S. 58-50-151 is recodified as G.S. 58-51-116.

SECTION 4.4. The prefatory language of G.S. 58-50-61(a) reads as rewritten:

"(a) Definitions. – As used in this ~~section and~~ section, in G.S. 58-50-62, and in Part 4 of this Article, the term:".

SECTION 4.5. Article 50 of Chapter 58 of the General Statutes is amended by adding a new Part to read:

"Part 4. Health Benefit Plan External Review.

"**§ 58-50-75. Purpose, scope, and definitions.**

(a) The purpose of this Part is to provide standards for the establishment and maintenance of external review procedures to assure that covered persons have the opportunity for an independent review of an appeal decision upholding a noncertification or a second-level grievance review decision upholding a noncertification, as defined in this Part.

(b) This Part applies to all persons that provide or perform utilization review. With respect to second-level grievance review decisions, this Part applies only to second-level grievance review decisions involving noncertification decisions.

(c) In addition to the definitions in G.S. 58-50-61(a), as used in this Part:

(1) 'Covered benefits' or 'benefits' means those benefits consisting of medical care, provided directly through insurance or otherwise and including items and services paid for as medical care, under the terms of a health benefit plan.

(2) 'Covered person' means a policyholder, subscriber, enrollee, or other individual covered by a health benefit plan. 'Covered person' includes another person, including the covered person's health care provider, acting on behalf of the covered person.

(3) 'Independent review organization' or 'organization' means an entity that conducts independent external reviews of appeals of noncertifications and second-level grievance review decisions.

"**§ 58-50-76:** Reserved.

"**§ 58-50-77. Notice of right to external review.**

(a) An insurer shall notify the covered person in writing of the covered person's right to request an external review and include the appropriate statements and information set forth in this section at the time the insurer sends written notice of:

(1) An appeal decision under G.S. 58-50-61 upholding a noncertification; and

(2) A second-level grievance review decision under G.S. 58-50-62 upholding the original noncertification.

(b) The insurer shall include in the notice required under subsection (a) of this section for a notice related to an appeal decision under G.S. 58-50-61, a statement informing the covered person that:

(1) If the covered person has a medical condition where the time frame for completion of an expedited review of a grievance involving an appeal decision under G.S. 58-50-61 would reasonably be expected to seriously jeopardize the life or health of the covered person or jeopardize the covered person's ability to regain maximum function, the covered person may file a request for an expedited external review under G.S. 58-50-82 at the same time the covered person files a request for an expedited review of a grievance involving an appeal decision under G.S. 58-50-61 and G.S. 58-50-62, but that the organization assigned to conduct the expedited external review will determine whether the covered person shall be required to complete the expedited review of the grievance before conducting the expedited external review.

(2) If the insurer has not issued a written decision to the covered person within 45 days after the date the covered person files the grievance with the insurer pursuant to G.S. 58-50-62 and the covered person has

not requested or agreed to a delay, the covered person may file a request for external review under G.S. 58-50-80 of this section and shall be considered to have exhausted the insurer's internal grievance process for purposes of G.S. 58-50-79.

(c) The insurer shall include in the notice required under subsection (a) of this section for a notice related to a final second-level grievance review decision under G.S. 58-50-62, a statement informing the covered person that:

(1) If the covered person has a medical condition where the time frame for completion of a standard external review under G.S. 58-50-80 would reasonably be expected to seriously jeopardize the life or health of the covered person or jeopardize the covered person's ability to regain maximum function, the covered person may file a request for an expedited external review under G.S. 58-50-82; or

(2) If the second-level grievance review decision concerns an admission, availability of care, continued stay, or health care service for which the covered person received emergency services but has not been discharged from a facility, the covered person may request an expedited external review under G.S. 58-50-82.

(d) In addition to the information to be provided under subsections (b) and (c) of this section, the insurer shall include a copy of the description of both the standard and expedited external review procedures the insurer is required to provide under G.S. 58-50-93, including the provisions in the external review procedures that give the covered person the opportunity to submit additional information.

"**§ 58-50-78:** Reserved.

"**§ 58-50-79. Exhaustion of internal grievance process.**

(a) Except as provided in subsections (d) and (e) of this section, a request for an external review under G.S. 58-50-80 or G.S. 58-50-82 shall not be made until the covered person has exhausted the insurer's internal grievance process under G.S. 58-50-62.

(b) A covered person shall be considered to have exhausted the insurer's internal grievance process for purposes of this section, if the covered person:

(1) Has filed a second-level grievance involving a noncertification appeal decision under G.S. 58-50-61 and G.S. 58-50-62.

(2) Except to the extent the covered person requested or agreed to a delay, has not received a written decision on the grievance from the insurer within 45 days since the date the covered person filed the grievance with the insurer.

(c) Notwithstanding subsection (b) of this section, a covered person may not make a request for an external review of a noncertification involving a retrospective review determination made under G.S. 58-50-61 until the covered person has exhausted the insurer's internal grievance process.

(d) At the same time a covered person files a request for an expedited appeal involving a noncertification as set forth in G.S. 58-50-61(l), the covered person may file

a request for an expedited external review of the noncertification under G.S. 58-50-82 if the covered person has a medical condition where the time frame for completion of an expedited review of the appeal involving a noncertification set forth in G.S. 58-50-61(l) would be reasonably expected to seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function. An insurer may waive its right to conduct an expedited review of an appeal and allow the covered person to proceed with an expedited external review of the noncertification.

(e) Upon receipt of a request for an expedited external review under subsection (d) of this section, the organization conducting the external review in accordance with the provisions of G.S. 58-50-82 shall immediately determine whether the covered person shall be required to complete the expedited review process set forth in G.S. 58-50-61(l) before it conducts the expedited external review, unless the insurer has waived its right to conduct an expedited review of the appeal decision.

(f) Upon a determination made under subsection (e) of this section that the covered person must first complete the expedited appeal process under G.S. 58-50-61(l), the organization immediately shall notify the covered person and the insurer of this determination and that it will not proceed with the expedited external review under G.S. 58-50-82 until completion of the expedited appeal process and the covered person's grievance at the completion of the expedited appeal process remains unresolved.

(g) A request for an external review of a noncertification may be made before the covered person has exhausted the insurer's internal grievance procedures under G.S. 58-50-61 and G.S. 58-50-62 whenever the insurer agrees to waive the exhaustion requirement. If the requirement to exhaust the insurer's internal grievance procedures is waived, the covered person may file a request in writing for a standard external review as set forth in G.S. 58-50-80 or may make a request for an expedited external review as set forth in G.S. 58-50-82.

"**§ 58-50-80. Standard external review.**

(a) Within 60 days after the date of receipt of a notice of a noncertification appeal decision or a second-level grievance review decision under G.S. 58-50-77, a covered person may file a request for an external review with the Commissioner.

(b) Upon receipt of a request for an external review under subsection (a) of this section, the Commissioner immediately shall notify and send a copy of the request to the insurer that made the decision which is the subject of the request. The insurer shall immediately submit to the Commissioner the information required for the preliminary review under subsection (c) of this section.

(c) Within five business days after the date of receipt of a request for an external review, the Commissioner shall complete a preliminary review of the request to determine whether:

(1) The individual is or was a covered person in the health benefit plan at the time the health care service was requested or, in the case of a retrospective review, was a covered person in the health benefit plan at the time the health care service was provided.

(2) The health care service that is the subject of the noncertification appeal decision or the second-level grievance review decision upholding a noncertification reasonably appears to be a covered service under the covered person's health benefit plan.

(3) The covered person has exhausted the insurer's internal appeal and grievance processes under G.S. 58-50-61 and G.S. 58-50-62 unless the covered person is not required to exhaust the insurer's internal appeal or grievance process under G.S. 58-50-79.

(4) The covered person has provided all the information and forms required by the Commissioner that are necessary to process an external review.

(d) Upon completion of the preliminary review under subsection (c) of this section, the Commissioner immediately shall notify the covered person in writing whether the request is complete and whether the request has been accepted for external review. If the request is not complete, the Commissioner shall request from the covered person the information or materials needed to make the request complete. The covered person shall furnish the Commissioner with the requested information or materials within 90 days after the date of the insurer's decision for which external review is requested. If the request is not accepted for external review, the Commissioner shall inform the covered person and the insurer in writing of the reasons for its nonacceptance.

(e) If the request is accepted for external review, the Commissioner shall:

(1) Include in the notice provided under subsection (d) of this section a statement that the covered person may submit to the Commissioner in writing within seven days after the date of the notice additional information and supporting documentation relevant to the initial denial that the organization shall consider when conducting the external review.

(2) Immediately notify the insurer in writing of the acceptance of the request for external review.

The Commissioner shall maintain an alphabetical listing of independent review organizations approved under G.S. 58-50-85 and shall systematically assign on a rotating basis the next independent review organization on that list capable of performing the review to conduct the external review. After the last organization on the list has been assigned a review, the commissioner shall return to the top of the list to continue assigning reviews.

(f) The Commissioner shall forward to the review organization that was assigned by the Commissioner any documents that were received relating to the request for external review. At the same time the Commissioner forwards the information to the review organization, the Commissioner shall forward the information to the insurer.

(g) Within seven days after the date of receipt of the notice provided under subsection (d) of this section, the insurer or its designee utilization review organization shall provide to the assigned organization the documents and any information

considered in making the noncertification appeal decision or the second-level grievance review decision. Except as provided in subsection (h) of this section, failure by the insurer or its designee utilization review organization to provide the documents and information within the time specified in this subsection shall not delay the conduct of the external review.

(h) If the insurer or its utilization review organization fails to provide the documents and information within the time specified in subsection (g) of this section, the assigned organization may terminate the external review and make a decision to reverse the noncertification appeal decision or the second-level grievance review decision. Immediately upon making the decision under this subsection, the organization shall notify the covered person, the insurer, and the Commissioner.

(i) Upon receipt of the information required to be forwarded under subsection (f) of this section, the insurer may reconsider its noncertification appeal decision or second-level grievance review decision that is the subject of the external review. Reconsideration by the insurer of its noncertification appeal decision or second-level grievance review decision under this subsection shall not delay or terminate the external review. The external review shall be terminated if the insurer decides, upon completion of its reconsideration, to reverse its noncertification appeal decision or second-level grievance review decision and provide coverage or payment for the requested health care service that is the subject of the noncertification appeal decision or second-level grievance review decision.

(j) Immediately upon making the decision to reverse its noncertification appeal decision or second-level grievance review decision under subsection (i) of this section, the insurer shall notify the covered person, the organization, and the Commissioner in writing of its decision. The organization shall terminate the external review upon receipt of the notice from the insurer sent under this subsection.

(k) The assigned organization shall review all of the information and documents received under subsections (f) and (g) of this section that have been forwarded to the organization by the Commissioner and the insurer, including the most recent updated information available. In addition, the assigned review organization, to the extent the documents or information are available and the review organization considers them appropriate, shall consider the following in reaching a decision:

(1) The covered person's medical records.

(2) The attending health care provider's recommendation.

(3) Consulting reports from appropriate health care providers and other documents submitted by the insurer, covered person, or the covered person's treating provider.

(4) The most appropriate practice guidelines that are based on sound clinical evidence and that are periodically evaluated to assure ongoing efficacy.

(5) Any applicable clinical review criteria developed and used by the insurer or its designee utilization review organization.

(6) Medical necessity, as defined in G.S. 58-3-200(b).

(7) Any documentation supporting the medical necessity and appropriateness of the provider's recommendation.

The assigned organization shall review the terms of coverage under the covered person's health benefit plan with the insurer to ensure that the organization's decision shall not be contrary to the terms of coverage under the covered person's health benefit plan with the insurer.

The assigned organization's determination shall be based on the covered person's medical condition at the time of the initial noncertification decision.

(l) Within 45 days after the date of receipt by the Commissioner of the request for external review, the assigned organization shall provide written notice of its decision to uphold or reverse the noncertification appeal decision or second-level grievance review decision to the covered person, the insurer, and the Commissioner. In reaching a decision, the assigned review organization is not bound by any decisions or conclusions reached during the insurer's utilization review process or the insurer's internal grievance process under G.S. 58-50-61 and G.S 58-50-62.

(m) The organization shall include in the notice sent under subsection (l) of this section:

(1) A general description of the reason for the request for external review.

(2) The date the organization received the assignment from the Commissioner to conduct the external review.

(3) The date the organization received information and documents submitted by the covered person and by the insurer.

(4) The date the external review was conducted.

(5) The date of its decision.

(6) The principal reason or reasons for its decision.

(7) The clinical rationale for its decision.

(8) References to the evidence or documentation, including the practice guidelines, considered in reaching its decision.

(9) The professional qualifications and licensure of the clinical peer reviewers.

(10) Notice to the covered person that he or she is not liable for the cost of the external review.

(n) Upon receipt of a notice of a decision under subsection (m) of this section reversing the noncertification appeal decision or second-level grievance review decision, the insurer shall immediately reverse the noncertification appeal decision or second-level grievance review decision that was the subject of the review and shall process the claim accordingly. In the event the covered person is no longer enrolled in the health benefit plan when the insurer receives notice of a decision under subsection (m) of this section reversing the noncertification appeal decision or second-level grievance review decision at the time the decision is rendered, the insurer shall be responsible under this section only for the costs of those services or supplies the covered person would have received prior to disenrollment.

"**§ 58-50-81:** Reserved.

"**§ 58-50-82. Expedited external review.**

(a) Except as provided in subsection (h) of this section, a covered person may make a written or oral request for an expedited external review with the Commissioner at the time the covered person receives:

(1) An appeal decision under G.S. 58-50-61(k) or (l) upholding a noncertification if:

a. The noncertification appeal decision involves a medical condition of the covered person for which the time frame for completion of an expedited second-level grievance review of a noncertification set forth in G.S. 58-50-62(i) would reasonably be expected to seriously jeopardize the life or health of the covered person or jeopardize the covered person's ability to regain maximum function; and

b. The covered person has filed a request for an expedited second-level review of a noncertification as set forth in G.S. 58-50-61(i); or

(2) A second-level grievance review decision under G.S. 58-60-62(h) or (i) upholding a noncertification:

a. If the covered person has a medical condition where the time frame for completion of a standard external review under G.S. 58-50-80 would reasonably be expected to seriously jeopardize the life or health of the covered person or jeopardize the covered person's ability to regain maximum function; or

b. If the second-level grievance concerns a noncertification of an admission, availability of care, continued stay, or health care service for which the covered person received emergency services, but has not been discharged from a facility.

(b) At the time the Commissioner receives a request for an expedited external review, the Commissioner immediately shall:

(1) Notify and provide a copy of the request to the insurer that made the noncertification appeal decision or second-level grievance review decision which is the subject of the request.

(2) For a request that the Commissioner has determined meets the reviewability requirements set forth in G.S. 58-50-80(c), the Commissioner shall immediately determine, based on medical advice from a medical professional who is not affiliated with the organization that will be assigned to conduct the external review of the request, whether the request should be reviewed on an expedited basis because the time frame for completion of a standard external review under G.S. 58-50-80 would reasonably be expected to seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function. The Commissioner shall then inform the covered person and the insurer whether the review will

be conducted using an expedited or standard time frame, and shall, in accordance with G.S. 58-50-80, assign an organization to conduct the review within the appropriate time frame.

(c) In reaching a decision, the assigned organization is not bound by any decisions or conclusions reached during the insurer's utilization review process or internal grievance process under G.S. 58-50-61 and G.S. 58-50-62.

(d) At the time the insurer receives the notice under subsection (b) of this section, the insurer or its designee utilization review organization shall immediately provide or transmit all documents and information considered in making the noncertification appeal decision or the second-level grievance review decision to the assigned review organization electronically or by telephone or facsimile or any other available expeditious method.

(e) In addition to the documents and information provided or transmitted under subsection (d) of this section, the assigned organization, to the extent the information or documents are available and the organization considers them appropriate, shall consider the following in reaching a decision:

(1) The covered person's pertinent medical records.

(2) The attending health care provider's recommendation.

(3) Consulting reports from appropriate health care providers and other documents submitted by the insurer, covered person, or the covered person's treating provider.

(4) The most appropriate practice guidelines that are based on sound clinical evidence and that are periodically evaluated to assure ongoing efficacy.

(5) Any applicable clinical review criteria developed and used by the insurer or its designee utilization review organization in making noncertification decisions.

(6) Medical necessity, as defined in G.S. 58-3-200(b).

(7) Any documentation supporting the medical necessity and appropriateness of the provider's recommendation.

The assigned organization shall review the terms of coverage under the covered person's health benefit plan to ensure that the organization's decision shall not be contrary to the terms of coverage under the covered person's health benefit plan.

The assigned organization's determination shall be based on the covered person's medical condition at the time of the initial noncertification decision.

(f) As expeditiously as the covered person's medical condition or circumstances require, but not more than four days after the date of receipt of the request for an expedited external review, the assigned organization shall make a decision to uphold or reverse the noncertification appeal decision or second-level grievance review decision and notify the covered person, the insurer, and the Commissioner of the decision.

(g) If the notice provided under subsection (f) of this section was not in writing, within two days after the date of providing that notice, the assigned organization shall provide written confirmation of the decision to the covered person, the insurer, and the

Commissioner and include the information set forth in G.S. 58-50-80(o). Upon receipt of the notice, a decision under subsection (f) of this section reversing the noncertification appeal decision or second-level grievance review decision, the insurer shall immediately reverse the noncertification appeal decision or second-level grievance review decision that was the subject of the review and shall process the claim accordingly.

(h) An expedited external review shall not be provided for retrospective noncertifications.

"**§ 58-50-83:** Reserved.

"**§ 58-50-84. Binding nature of external review decision.**

(a) An external review decision is binding on the insurer.

(b) An external review decision is binding on the covered person except to the extent the covered person has other remedies available under applicable federal or State law.

(c) A covered person may not file a subsequent request for external review involving the same noncertification appeal decision or second-level grievance review decision for which the covered person has already received an external review decision under this Part.

"**§ 58-50-85. Approval of independent review organizations.**

(a) The Commissioner shall approve independent review organizations eligible to be assigned to conduct external reviews under this Part to ensure that an organization satisfies the minimum qualifications established under G.S. 58-50-87. The Commissioner shall develop an application form for initially approving and for reapproving organizations to conduct external reviews.

(b) Any organization wishing to be approved to conduct external reviews under this Part shall submit the application form and include with the form all documentation and information necessary for the Commissioner to determine if the organization satisfies the minimum qualifications established under G.S. 58-50-87. Applicants must submit pricing information sufficient to demonstrate that if selected, the applicant's total fee per review will not exceed commercially reasonable fees charged for similar services in the industry. The Commissioner shall not approve any independent review organization that either fails to provide sufficient pricing information or has fees that do not meet the guidelines established under this subsection.

(c) The Commissioner may, in his discretion, determine that accreditation by a nationally recognized private accrediting entity with established and maintained standards for independent review organizations that meet the minimum qualifications established under G.S. 58-50-87 will cause an independent review organization to be deemed to have met, in whole or in part, the requirements of this section and G.S. 58-50-87. A decision by the Commissioner to recognize an accreditation program for the purpose of granting deemed status may be made only after reviewing the accreditation standards and program information submitted by the accrediting body. An independent review organization seeking deemed status due to its accreditation shall submit original documentation issued by the accrediting body to demonstrate its accreditation.

(d) An approval is effective for two years, unless the Commissioner determines before expiration of the approval that the independent review organization is not satisfying the minimum qualifications established under G.S. 58-50-87.

(e) Whenever the Commissioner determines that an independent review organization no longer satisfies the minimum requirements established under G.S. 58-50-87, the Commissioner shall terminate the approval of the independent review organization.

"**§ 58-50-86:** Reserved.

"**§ 58-50-87. Minimum qualifications for independent review organizations.**

(a) As a condition of approval under G.S. 58-50-85 to conduct external reviews, an independent review organization shall have and maintain written policies and procedures that govern all aspects of both the standard external review process and the expedited external review process set forth in G.S. 58-50-80 and G.S. 58-50-82 that include, at a minimum:

(1) A quality assurance mechanism in place that ensures:

a. That external reviews are conducted within the specified time frames and required notices are provided in a timely manner.

b. The selection of qualified and impartial clinical peer reviewers to conduct external reviews on behalf of the independent review organization and suitable matching of reviewers to specific cases.

c. The confidentiality of medical and treatment records and clinical review criteria.

d. That any person employed by or under contract with the independent review organization adheres to the requirements of this Part.

e. The independence and impartiality of the independent review organization and the external review process and limits the ability of any person to improperly influence the external review decision.

(2) A toll-free telephone service to receive information on a 24-hour-day, seven-day-a-week basis related to external reviews that is capable of accepting, recording, or providing appropriate instruction to incoming telephone callers during other than normal business hours.

(3) Agree to maintain and provide to the Commissioner the information set out in G.S. 58-50-90.

(4) A program for credentialing clinical peer reviewers.

(5) Agree to contractual terms or written requirements established by the Commissioner regarding the procedures for handling a review.

(6) The independent review organization shall consult with a medical doctor licensed to practice in North Carolina to advise the independent review organization on issues related to the standard of practice,

technology, and training of North Carolina physicians with respect to the organization's North Carolina business.

(b) All clinical peer reviewers assigned by an independent review organization to conduct external reviews shall be medical doctors or other appropriate health care providers who meet the following minimum qualifications:

(1) Be an expert in the treatment of the covered person's injury, illness, or medical condition that is the subject of the external review.

(2) Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar injury, illness, or medical condition of the covered person.

(3) If the covered person's treating provider is a medical doctor, hold a nonrestricted license, and, if a specialist medical doctor, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review.

(4) If the covered person's treating provider is not a medical doctor, hold a nonrestricted license, registration, or certification in the same allied health occupation as the covered person's treating provider.

(5) Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical peer reviewer's physical, mental, or professional competence or moral character.

(c) In addition to the requirements set forth in subsection (a) of this section, an independent review organization may not own or control, be a subsidiary of, or in any way be owned or controlled by, or exercise control with a health benefit plan, a national, State, or local trade association of health benefit plans, or a national, State, or local trade association of health care providers.

(d) In addition to the requirements set forth in subsections (a), (b), and (c) of this section, to be approved under G.S. 58-50-85 to conduct an external review of a specified case, neither the independent review organization selected to conduct the external review nor any clinical peer reviewer assigned by the independent organization to conduct the external review may have a material professional, familial, or financial conflict of interest with any of the following:

(1) The insurer that is the subject of the external review.

(2) The covered person whose treatment is the subject of the external review or the covered person's authorized representative.

(3) Any officer, director, or management employee of the insurer that is the subject of the external review.

(4) The health care provider, the health care provider's medical group, or independent practice association recommending the health care service or treatment that is the subject of the external review.

(5) The facility at which the recommended health care service or treatment would be provided.

(6) The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person whose treatment is the subject of the external review.

(e) In determining whether an independent review organization or a clinical peer reviewer of the independent review organization has a material professional, familial, or financial conflict of interest for purposes of subsection (d) of this section, the Commissioner shall take into consideration situations where the independent review organization to be assigned to conduct an external review of a specified case or a clinical peer reviewer to be assigned by the independent review organization to conduct an external review of a specified case may have an apparent professional, familial, or financial relationship or connection with a person described in subsection (d) of this section, but that the characteristics of that relationship or connection are such that they are not a material professional, familial, or financial conflict of interest that results in the disapproval of the independent review organization or the clinical peer reviewer from conducting the external review.

"**§ 58-50-88:** Reserved.

"**§ 58-50-89. Hold harmless for Commissioner and independent review organizations.**

The Commissioner or an independent review organization or clinical peer reviewer working on behalf of an organization shall not be liable for damages to any person for any opinions rendered during or upon completion of an external review conducted under this Part, unless the opinion was rendered in bad faith or involved gross negligence.

"**§ 58-50-90. External review reporting requirements.**

(a) An organization assigned under G.S. 58-50-80 or G.S. 58-50-82 to conduct an external review shall maintain written records in the aggregate and by insurer on all requests for external review for which it conducted an external review during a calendar year and submit a report to the Commissioner, as required under subsection (b) of this section.

(b) Each organization required to maintain written records on all requests for external review under subsection (a) of this section for which it was assigned to conduct an external review shall submit to the Commissioner, at least annually, a report in the format specified by the Commissioner.

(c) The report shall include in the aggregate and for each insurer:

(1) The total number of requests for external review.

(2) The number of requests for external review resolved and, of those resolved, the number resolved upholding the noncertification appeal decision or second-level grievance review decision and the number resolved reversing the noncertification appeal decision or second-level grievance review decision.

(3) The average length of time for resolution.

(4) A summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the Commissioner.

(5) The number of external reviews under G.S. 58-50-80(k) and (l) that were terminated as the result of a reconsideration by the insurer of its noncertification appeal decision or second-level grievance review decision after the receipt of additional information from the covered person.

(6) Any other information the Commissioner may request or require.

(d) The organization shall retain the written records required under this section for at least three years.

(e) Each insurer shall maintain written records in the aggregate and for each type of health benefit plan offered by the insurer on all requests for external review of which the insurer receives notice from the Commissioner under this Part. The insurer shall retain the written records required under this section for at least three years.

"**§ 58-50-91:** Reserved.

"**§ 58-50-92. Funding of external review.**

The insurer against which a request for a standard external review or an expedited external review is filed shall reimburse the Department of Insurance for the fees charged by the organization in conducting the external review.

"**§ 58-50-93. Disclosure requirements.**

(a) Each insurer shall include a description of the external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to covered persons.

(b) The description required under subsection (a) of this section shall include a statement that informs the covered person of the right of the covered person to file a request for an external review of a noncertification appeal decision or a second-level grievance review decision upholding a noncertification with the Commissioner. The statement shall include the telephone number and address of the Commissioner.

(c) In addition to subsection (b) of this section, the statement shall inform the covered person that, when filing a request for an external review, the covered person will be required to authorize the release of any medical records of the covered person that may be required to be reviewed for the purpose of reaching a decision on the external review.

"**§ 58-50-94. Competitive selection of independent review organizations.**

(a) The Commissioner shall prepare and publish requests for proposals from independent review organizations that want to be approved under G.S. 58-50-85. All proposals shall be sealed. The Commissioner shall open all proposals in public.

(b) After the public opening, the Commissioner shall review the proposals, examining the costs and quality of the services offered by the independent review organizations, the reputation and capabilities of the independent review organizations submitting the proposals, and the provisions in G.S. 58-50-85 and G.S. 58-50-87. The Commissioner shall determine which proposal or proposals would satisfy the provisions

of this Part. The Commissioner shall make his determination in consultation with an evaluation committee whose membership includes representatives of insurers subject to Part 4 of Article 50 of Chapter 58 of the General Statutes, health care providers, and insureds. In selecting the review organizations, in addition to considering cost, quality, and adherence to the requirements of the request for proposals, the Commissioner shall consider the desirability and feasibility of contracting with multiple review organizations in order to allow insureds a choice of review organizations and shall ensure that at least one review organization is available to and capable of reviewing cases involving highly specialized services and treatments of any nature. The Commissioner may reject any or all proposals.

(c) An independent review organization may seek to modify or withdraw a proposal only after the public opening and only on the basis that the proposal contains an unintentional clerical error as opposed to an error in judgment. An independent review organization seeking to modify or withdraw a proposal shall submit to the Commissioner a written request, with facts and evidence in support of its position, before the determination made by the Commissioner under subsection (b) of this section, but not later than two days after the public opening of the proposals. The Commissioner shall promptly review the request, examine the nature of the error, and determine whether to permit or deny the request.

(d) The provisions of Article 3C of Chapter 143 of the General Statutes do not apply to this Part.

"**§ 58-50-95. Report by Commissioner.**

The Commissioner shall report semiannually to the Joint Legislative Health Care Oversight Committee regarding the nature and appropriateness of reviews conducted under this Part. The report, which shall be provided to the public upon request, should include the number of reviews, underlying issues in dispute, character of the reviews, dollar amounts in question, whether the review was decided in favor of the covered person or the health benefit plan, the cost of review, and any other information relevant to the evaluation of the effectiveness of this Part."

SECTION 4.6. G.S. 58-50-62(h)(7) reads as rewritten:

"(7) A statement that the decision is the insurer's final determination in the matter. In cases where the review concerned a noncertification and the insurer's decision on the second-level grievance review is to uphold its initial noncertification, a statement advising the covered person of his or her right to request an external review and a description of the procedure for submitting a request for external review to the Commissioner of Insurance."

Subpart B. Health Plan Liability

SECTION 4.7. Chapter 90 of the General Statutes is amended by adding a new Article to read:

"Article lG.

"Health Care Liability.

"**§ 90-21.50. Definitions.**

As used in this Article, unless the context clearly indicates otherwise, the term:

(1) 'Health benefit plan' means an accident and health insurance policy or certificate; a nonprofit hospital or medical service corporation contract; a health maintenance organization subscriber contract; a plan provided by a multiple employer welfare arrangement. 'Health benefit plan' does not mean any plan implemented or administered through the Department of Health and Human Services or its representatives. 'Health benefit plan' also does not mean any of the following kinds of insurance:

a. Accident;
b. Credit;
c. Disability income;
d. Long-term or nursing home care;
e. Medicare supplement;
f. Specified disease;
g. Dental or vision;
h. Coverage issued as a supplement to liability insurance;
i. Workers' compensation;
j. Medical payments under automobile or homeowners;
k. Insurance under which benefits are payable with or without regard to fault and that are statutorily required to be contained in any liability policy or equivalent self-insurance; and
l. Hospital income or indemnity.

(2) 'Health care provider' means:

a. An individual who is licensed, certified, or otherwise authorized under this Chapter to provide health care services in the ordinary course of business or practice of a profession or in an approved education or training program; or
b. A health care facility, licensed under Chapters 131E or 122C of the General Statutes, where health care services are provided to patients;

'Health care provider' includes:

1. An agent or employee of a health care facility that is licensed, certified, or otherwise authorized to provide health care services;
2. The officers and directors of a health care facility; and
3. An agent or employee of a health care provider who is licensed, certified, or otherwise authorized to provide health care services.

(3) 'Health care service' means a health or medical procedure or service rendered by a health care provider that:

a. Provides testing, diagnosis, or treatment of a human disease or dysfunction; or

b. Dispenses drugs, medical devices, medical appliances, or medical goods for the treatment of a human disease or dysfunction.

(4) 'Health care decision' means a determination by a managed care entity which is subject to external review under Part 4 of Article 50 of the General Statutes and is also a determination that:

a. A prospective or concurrent request for approval of coverage is denied or reduced because it is not medically necessary or appropriate or because it is experimental or investigational; provided, however, that a health care decision does not include a decision based solely on the application of a specific exclusion under the health benefit plan; and

b. Affects the quality of the diagnosis, care, or treatment provided under the health benefit plan to an enrollee or insured of the health benefit plan.

(5) 'Insured or enrollee' means a person that is insured by or enrolled in a health benefit plan under a policy, plan, certificate, or contract issued or delivered in this State by an insurer.

(6) 'Insurer' means an entity that writes a health benefit plan and that is an insurance company subject to Chapter 58 of the General Statutes, a service corporation organized under Article 65 of Chapter 58 of the General Statutes, a health maintenance organization organized under Article 67 of Chapter 58 of the General Statutes, or a multiple employer welfare arrangement subject to Article 49 of Chapter 58 of the General Statutes.

(7) 'Managed care entity' means an insurer that:

a. Delivers, administers, or undertakes to provide for, arrange for, or reimburse for health care services, or assumes the risk for the delivery of health care services; and

b. Has a system or technique to control or influence the quality, accessibility, utilization, or costs and prices of health care services delivered or to be delivered to a defined enrollee population.

'Managed care entity' does not include: (i) an employer purchasing coverage or acting on behalf of its employees or the employees of one or more subsidiaries or affiliated corporations of the employer, or (ii) a health care provider.

(8) 'Ordinary care' means that degree of care prevailing at the time the managed care entity made the health care decision that a managed care entity of ordinary prudence would use under the same or similar circumstances.

(9) 'Physician' means:
a. An individual licensed to practice medicine in this State;
b. A professional association or corporation organized under Chapter 55B of the General Statutes; or
c. A person or entity wholly owned by physicians.
(10) 'Successor external review process' means an external review process equivalent in all respects to G.S. 58-50-75 through G.S. 58-50-95 approved by the Department and implemented by a health benefit plan in the event that G.S. 58-50-75 through G.S. 58-50-95 are found by a court of competent jurisdiction to be void, unenforceable, or preempted by federal law, in whole or in part.

"**§ 90-21.51. Duty to exercise ordinary care; liability for damages for harm.**

(a) Each managed care entity for a health benefit plan has the duty to exercise ordinary care when making health care treatment decisions and is liable for damages for harm to an insured or enrollee proximately caused by its failure to exercise ordinary care.

(b) In addition to the duty imposed under subsection (a) of this section, each managed care entity for a health benefit plan is liable for damages for harm to an insured or enrollee proximately caused by the health care treatment decisions made by:
(1) Its agents or employees; or
(2) Representatives that are acting on its behalf and over whom it has exercised sufficient influence or control to reasonably effect the actual care and treatment of the insured or enrollee which results in the failure to exercise ordinary care.

(c) It shall be a defense to any action brought under this section against a managed care entity for a health benefit plan that:
(1) Neither the managed care entity nor an agent or employee or representative for whom the managed care entity is liable under subsection (b) of this section controlled, influenced, or participated in the health care treatment decision; and
(2) The managed care entity did not deny or delay payment for any health care service or treatment prescribed or recommended by a physician or health care provider to the insured or enrollee.

(d) In an action brought under this Article against a managed care entity, a finding that a physician or health care provider is an agent or employee of the managed care entity may not be based solely on proof that the physician or health care provider appears in a listing of approved physicians or health care providers made available to insureds or enrollees under the managed care entity's health benefit plan.

(e) An action brought under this Article is not a medical malpractice action as defined in Article 1B of this Chapter. A managed care entity may not use as a defense in an action brought under this Article any law that prohibits the corporate practice of medicine.

(f) A managed care entity shall not be liable for the independent actions of a health care provider, who is not an agent or employee of the managed care entity, when that health care provider fails to exercise the standard of care required by G.S. 90-21.12. A health care provider shall not be liable for the independent actions of a managed care entity when the managed care entity fails to exercise the standard of care required by this Article.

(g) Nothing in this Article shall be construed to create an obligation on the part of a managed care entity to provide to an insured or enrollee a health care service or treatment that is not covered under its health benefit plan.

(h) A managed care entity may not enter into a contract with a health care provider, or with an employer or employer group organization, that includes an indemnification or hold harmless clause for the acts or conduct of the managed care entity. Any such indemnification or hold harmless clause is void and unenforceable to the extent of the restriction.

"**§ 90-21.52. No liability under this Article on the part of an employer or employer group organization that purchases coverage or assumes risk on behalf of its employees or a physician or health care provider.**

(a) This Article does not create any liability on the part of an employer or employer group purchasing organization that purchases health care coverage or assumes risk on behalf of its employees.

(b) This Article does not create any liability on the part of a physician or health care provider in addition to that otherwise imposed under existing law. No managed care entity held liable under this Article shall be entitled to contribution under Chapter 1B of the General Statutes from a physician or health care provider.

"**§ 90-21.53. Separate trial required.**

Upon motion of any party in an action that includes a claim brought pursuant to this Article involving a managed care entity, the court shall order separate discovery and a separate trial of any claim, cross-claim, counterclaim, or third-party claim against any physician or other health care provider.

"**§ 90-21.54. Punitive damages; exhaustion of administrative remedies and appeals; evidence.**

(a) An action brought under this Article is subject to the provisions and limitations of Chapter 1D of the General Statutes for recovery of punitive damages.

(b) No action may be commenced under this Article until the plaintiff has exhausted all administrative remedies and appeals, including those internal remedies and appeals established under G.S. 58-50-61 through G.S. 58-50-62, and G.S. 58-50-75 through G.S. 58-50-95, and including those established under any successor external review process.

(c) Any information, documents, or other records or materials considered by the Independent Review Organization in conducting its review shall be admissible in any action commenced under this article in accordance with the North Carolina Rules of Evidence.

"**§ 90-21.55. External review decision.**

Either the insured or enrollee or their personal representative or the managed care entity may use an external review decision made in accordance with G.S. 58-50-75 through G.S. 58-50-95, or made in accordance with any successor external review process, as evidence in any cause of action which includes an action brought under this Part, provided that an adequate foundation is laid for the introduction of the external review decision into evidence and the testimony is subject to cross-examination."

SECTION 4.8. G.S. 1A-1, Rule 42, reads as rewritten:

"**Rule 42. Consolidation; separate trials.**

(a) Consolidation. – ~~When~~ Except as provided in subdivision (b)(2) of this section, when actions involving a common question of law or fact are pending in one division of the court, the judge may order a joint hearing or trial of any or all the matters in issue in the actions; he may order all the actions consolidated; and he may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay. When actions involving a common question of law or fact are pending in both the superior and the district court of the same county, a judge of the superior court in which the action is pending may order all the actions consolidated, and he may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.

(b) Separate trials. –

(1) The court may in furtherance of convenience or to avoid prejudice and shall for considerations of venue upon timely motion order a separate trial of any claim, ~~crossclaims~~ cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, ~~crossclaims,~~ cross-claims, counterclaims, third-party claims, or issues.

(2) Upon motion of any party in an action that includes a claim commenced under Article 1G of Chapter 90 of the General Statutes involving a managed care entity as defined in G.S. 90-21.50, the court shall order separate discovery and a separate trial of any claim, cross-claim, counterclaim, or third-party claim against a physician or other medical provider."

SECTION 5.(a) G.S. 58-2-105 reads as rewritten:

"**§ 58-2-105. Confidentiality of medical records.**

(a) All patient medical records in the possession of the Department are confidential and are not public records pursuant to G.S. 58-2-100 or G.S. 132-1. As used in this section, "patient medical records" includes personal information that relates to an individual's physical or mental condition, medical history, or medical treatment, and that has been obtained from the individual patient, a health care provider, or from the patient's spouse, parent, or legal guardian.

(b) Under Part 4 of Article 50 of this Chapter, the Department may disclose patient medical records to an independent review organization, and the organization shall maintain the confidentiality of those records as required by this section, except as allowed by G.S. 58-30-75."

SECTION 5.(b) G.S. 58-3-200(b) reads as rewritten:

"(b) Medical Necessity. – An insurer that limits its health benefit plan coverage to medically necessary services and supplies shall define "medically necessary services or supplies" in its health benefit plan as those covered services or supplies that are:

(1) Provided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease; ~~and~~ and, except as allowed under G.S. 58-3-255, not for experimental, investigational, or cosmetic purposes.

(2) Necessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, disease, or its symptoms.

(3) Within generally accepted standards of medical care in the community.

(4) Not solely for the convenience of the insured, the insured's family, or the provider.

For medically necessary services, nothing in this subsection precludes an insurer from comparing the cost-effectiveness of alternative services or supplies when determining which of the services or supplies will be covered."

SECTION 5.(c) G.S. 58-50-61(a)(12) reads as rewritten:

"(12) "Medically necessary services or supplies" means those covered services or supplies that are:

a. Provided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease.

b. Except as allowed under G.S. 58-3-255, ~~Not~~ not for experimental, investigational, or cosmetic purposes.

c. Necessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, disease, or its symptoms.

d. Within generally accepted standards of medical care in the community.

e. Not solely for the convenience of the insured, the insured's family, or the provider.

For medically necessary services, nothing in this subdivision precludes an insurer from comparing the cost-effectiveness of alternative services or supplies when determining which of the services or supplies will be covered."

SECTION 6. If any section or provision of this act is declared unconstitutional or invalid by the courts, it does not affect the validity of the act as a whole or any part other than the part so declared to be unconstitutional or invalid.

SECTION 7. Section 1.6 of this act becomes effective January 1, 2002. Sections 3.1 and 3.2 of this act become effective December 1, 2001, and apply to health benefit plans that are delivered, issued for delivery, or renewed on or after that date. Sections 4.1 through 4.8 of this act become effective March 1, 2002. The remainder of this act is effective when it becomes law and applies to health benefit plans that are delivered, issued for delivery, or renewed on or after January 1, 2002. Nothing in this act obligates the General Assembly to appropriate funds to implement this act.