GENERAL ASSEMBLY OF NORTH CAROLINA **SESSION 2001**

 \mathbf{S} 1 **SENATE BILL 199**

Short Title:	Managed Care Patients' Bill of Rights. (Public)	
Sponsors:	Senators Wellons, Purcell, Forrester; Albertson, Allran, Ballance Carpenter, Carter, Cunningham, Dalton, Garrou, Garwood, Gulley Harris, Kinnaird, Lee, Lucas, Martin of Guilford, Metcalf, Miller, Odom Rand, Robinson, Rucho, Shaw of Cumberland, Shaw of Guilford, Soles Swindell, Thomas, Warren, and Weinstein.	,
Referred to:	Insurance and Consumer Protection.	

February 22, 2001

1	A BILL TO BE ENTITLED
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2	AN ACT TO IMPROVE ACCESS TO HEALTH CARE ADVICE, INFORMATION,
3	AND SERVICES TO COVERED PERSONS UNDER HEALTH BENEFIT
4	PLANS; ESTABLISH STANDARDS FOR HEALTH PLAN DISCLOSURES TO
5	CONSUMERS; ESTABLISH A MANAGED CARE OMBUDSMAN PROGRAM;
6	REQUIRE COVERAGE FOR CLINICAL TRIALS AND NEWBORN HEARING
7	SCREENING; PROVIDE STANDARDS FOR INDEPENDENT REVIEW OF
8	NONCERTIFICATIONS BY AN INSURER OR MANAGED CARE PLAN, AND
9	TO HOLD MANAGED CARE ENTITIES LIABLE FOR HARM CAUSED TO
10	INSUREDS OR ENROLLEES BY THE FAILURE TO EXERCISE ORDINARY
11	CARE IN MAKING TREATMENT DECISIONS.
12	The General Assembly of North Carolina enacts:

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.

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- Definitions. As used in this section: (a)
 - 'Ongoing special condition' means: <u>(1)</u>

1		<u>a.</u>	In the case of an acute illness, a condition that is serious enough
2			to require medical care or treatment to avoid a reasonable
3			possibility of death or permanent harm.
4		<u>b.</u>	In the case of a chronic illness or condition, a disease or
5			condition that is life-threatening, degenerative, disabling, and
6			requires medical care or treatment over a prolonged period of
7			time.
8		<u>c.</u>	Pregnancy.
9		<u>d.</u>	Terminal illness.
10	<u>(2)</u>	<u>'Tern</u>	ninal illness' means an individual has a medical prognosis that the
11		indiv	idual's life expectancy is six months or less.
12	<u>(3)</u>	<u>'Tern</u>	ninated or termination' Includes, with respect to a contract, the
13			ration or nonrenewal of the contract, but does not include a
14		termi	ination of the contract by an HMO for failure to meet applicable
15			ty standards or for fraud.
16	(b) Term	_	of Provider. – If a contract between an HMO that is not a point-
17	of-service plan	and	a health care provider is terminated, or benefits or coverage
18	provided by a l	nealth (care provider are terminated because of a change in the terms of
19	provider partici	pation	in a health benefit plan of an HMO that is not a point-of-service
20	plan, and an i	ndividu	ual is covered by the plan and is terminally ill or undergoing
21	treatment from	the p	provider for an ongoing special condition at the time of the
22	termination, the	n, the	HMO shall:
23	<u>(1)</u>	Notif	fy the individual on a timely basis of the termination and of the
24		right	to elect continuation of coverage of treatment by the provider
25		unde	r this section.
26	<u>(2)</u>	Subje	ect to subsection (g) of this section, permit the individual to elect
27		to co	ntinue to be covered with respect to treatment by the provider of
28			ondition during a transitional period provided under this section.
29	(c) New		ered Insured. – Each health benefit plan offered by an HMO that
30	is not a point-o	f-servi	ce plan shall provide transition coverage to individuals who are
31	_		a new or existing group contract because of an involuntary change
32	in health plans,		·
33	(1)		fy the individual at the time of enrollment of the right to elect
34			nuation of coverage of treatment by the provider under this
35		section	· · · · · · · · · · · · · · · · · · ·
36	<u>(2)</u>	Subje	ect to subsection (h) of this section, permit the individual to elect
37		-	entinue to be covered with respect to treatment by the provider of
38			ondition during a transitional period provided under this section.
39	(d) Trans		Period: In General. – Except as otherwise provided in
40			nd (g) of this section, the transitional period under this subsection
41			days, as determined by the treating health care provider, after the
42			cribed in subdivision (b)(1) of this section or the enrollment in a
43			subdivision (c)(1) of this section.

- (e) Transitional Period: Scheduled Surgery, Organ Transplantation, or Institutional Care. If surgery, organ transplantation, or institutional 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 institutional care, the transitional period under this subsection with respect to the surgery, transplantation, or institutional 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 institutional care, and through post discharge follow-up care related to the surgery, transplantation, or institutional 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 postpartum care directly related to the delivery.
- (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 individual notifying the plan of the election of continued coverage and upon the provider agreeing to 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.

- (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. 58-60-62.
 - (3) Prohibits an HMO from extending any transitional period beyond that specified in this section.
- (j) <u>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."</u>

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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' 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.

Disability income. 1 c. 2 d. Long-term care or nursing home care. 3 Medicare supplement. e. Specified disease. 4 f. 5 Dental or vision. g. 6 h. Coverage issued as a supplement to liability insurance. 7 i. Workers' compensation. j. Medical payments under automobile or homeowners. 8 9 k. Hospital income or indemnity. Insurance under which benefits are payable with or without 10 1. regard to fault and that are statutorily required to be contained 11 12 in any liability policy or equivalent self-insurance. 'Insurer' means an entity that writes a health benefit plan and that is an 13 (2) 14 insurance company subject to this Chapter, a service corporation under 15 Article 65 of this Chapter, or a health maintenance organization under Article 67 of this Chapter, or a multiple employer welfare arrangement 16 17 under Article 49 of this Chapter. 18 (3) 'Serious or chronic degenerative, disabling, or life-threatening disease or condition' means a disease or condition, which in the opinion of the 19 20 patient's treating primary care physician and specialist, requires 21 frequent and periodic monitoring and consultation with the specialist on an ongoing basis. 22 23 If a child under age 18 requires the services of a specialist for the treatment of (c) 24 a serious or chronic degenerative, disabling, or life-threatening disease or condition, the insurer shall permit the insured to receive a standing referral to a specialist who has 25 subspecialty training in pediatrics. 26 If an in-plan specialist able to meet the health needs of the insured is not 27 (d) available, or is not reasonably available to the insured without unreasonable delay, then 28 29 the insurer shall permit the insured to receive an extended or standing referral described under subsections (b) and (c) of this section to an out-of-network specialist, and the 30 insurer shall not penalize the insured or subject an insured to the out-of-network benefit 31 32 levels offered under the insured's health benefit plan." 33 34 Subpart C. Selection of Specialist as Primary Care Physician 35

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 a new insured, upon being covered by a health benefit plan, or an existing insured diagnosed with a serious or chronic degenerative, disabling, or life-threatening disease or condition, either of which requires specialized medical care over a prolonged period of time, may select as his or her primary care physician a specialist with expertise in treating the life-threatening or degenerative and disabling condition or disease who shall be responsible for and

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capable of providing and coordinating the insured's primary and specialty care. If the insurer determines that the insured's care would most appropriately be coordinated by that specialist, the insurer shall permit access to that specialist.

- (b) The referral to the specialist shall be made under a treatment plan approved by the insurer, in consultation with the primary care provider, the specialist, and the insured or the insured's designee. The specialist may provide ongoing care to the insured upon a single referral from the insurer or the insured's primary care provider 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.
- (c) This section does not require an insurer to allow an insured to have a nonparticipating specialist unless a participating specialist, capable of providing the services necessary under the treatment plan, is available, or reasonably available to the insured without unreasonable delay, taking into account the medical factors of an individual case.
- (d) If an insurer makes or allows a referral under this section to a nonparticipating specialist because a participating specialist capable of providing the services necessary under the treatment plan is not available, or reasonably available to the insured without unreasonable delay, the services provided under the approved treatment plan shall be allowed at no additional cost to the insured beyond what the insured would otherwise pay for services received from a participating specialist."

26 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 any 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 <u>for-or restricts access</u> <u>to covered</u> prescription drugs or devices, then the insurer shall do all of the following:
 - (1) Develop the formulary or formularies <u>or restrictions on access</u> in consultation with and with the approval of a pharmacy and

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- therapeutics committee, which shall include participating providers who are licensed to prescribe prescription drugs or devices.
- (2) Make available to participating providers and pharmacists 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 to obtain, without penalty or additional cost-sharing beyond that provided for in the health benefit plan, coverage for a specific nonformulary or restricted access 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:
 - 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.
- An insurer may not void a contract or refuse to renew a contract between the (b) 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:
 - 'Closed formulary' means a list of prescription drugs and devices (1) reimbursed by the insurer that excludes coverage for drugs and devices not listed.
 - 'Health benefit plan' means an accident and health insurance policy or (1a) 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.

1		'Health benefit plan' also does not mean any of the following kinds of
2		insurance:
3		a. Accident.
4		b. Credit.
5		c. Disability income.
6		d. Long-term care or nursing home care.
7		e. Medicare supplement.
8		f. Specified disease.
9		g. Dental or vision.
10		h. Coverage issued as a supplement to liability insurance.
11		i. Workers' compensation.
12		j. Medical payments under automobile or homeowners.
13		k. Hospital income or indemnity.
14		1. Insurance under which benefits are payable with or without
15		regard to fault and that are statutorily required to be contained
16		in any liability policy or equivalent self-insurance.
17	(2)	'Insurer' means an entity that writes a health benefit plan and that is an
18	` ,	insurance company subject to this Chapter, a service corporation
19		organized under Article 65 of this Chapter, a health maintenance
20		organization organized under Article 67 of this Chapter, or a multiple
21		employer welfare arrangement under Article 49 of this Chapter.
22	<u>(3)</u>	'Restricted access drug or device' means those covered prescription
23		drugs or devices for which reimbursement by the insurer is
24		conditioned on the insurer's prior approval to prescribe the drug or
25		device or on the provider prescribing one or more alternative drugs or
26		devices before prescribing the drug or device in question.
27		g in this section requires an insurer to pay for drugs or devices or
28	_	or devices related to a benefit that is specifically excluded from
29	coverage by the i	nsurer."
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31	Subpart F. Man	aged Care Ombudsman Program
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33		ION 1.6. Article of Chapter of the General Statutes is
34	•	ng the following new section to read:
35		anaged Care Ombudsman.
36		ffice of the Managed Care Ombudsman is hereby established. The
37		mbudsman shall be appointed by the Governor.
38		anaged Care Ombudsman shall provide information and assistance to
39		led in managed care plans. The Managed Care Ombudsman shall have
40		perience in both health care and advocacy and will assume the specific
41	-	asibilities set forth in subsection (c) of this section.
42		uties and responsibilities of the Managed Care Ombudsman are as
43	<u>follows:</u>	

Develop and distribute educational and informational materials for (1) 1 consumers, explaining their rights and responsibilities as managed care 2 3 plan enrollees. Answer inquiries posed by consumers, and refer inquiries of a 4 (2) 5 regulatory nature to staff within the Department of Insurance. 6 Assist managed care plan enrollees with the utilization review process. (3) 7 Assist enrollees with the grievance and appeal procedures established (4) 8 by Article 50 of Chapter 58 of the General Statutes. 9 (5) Publicize the Office of the Managed Care Ombudsman. 10 (6) Compile data on the activities of the Office and evaluate such data to make recommendations as to the needed activities of the Office. 11 12 (d) The Managed Care Ombudsman shall annually report the activities of the Managed Care Ombudsman, including the types of appeals, grievances, and complaints 13 14 received and the outcome of these cases. The report shall be submitted to the General 15 Assembly, upon its convening or reconvening, and shall make recommendations as to efforts that could be implemented to assist managed care consumers. 16 17 Administrative and financial support for the Office of Managed Care 18 Ombudsman shall be provided from fees collected by the Commissioner as authorized 19 by law." 20 21 PART II. HEALTH PLAN DISCLOSURES 22 23 Subpart A. Managed Care Reporting and Disclosure Requirements 24 25 **SECTION 2.1.** G.S. 58-3-191(b) reads as rewritten: Disclosure requirements. - Each health benefit plan shall provide the 26 27 following applicable information to plan participants and bona fide prospective participants upon request: 28 29 The evidence of coverage (G.S. 58-67-50), subscriber contract (G.S. (1) 30 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 31 32 other type of health benefit plan; 33 An explanation of the utilization review criteria and treatment protocol (2) under which treatments are provided for conditions specified by the 34 prospective participant. This explanation shall be in writing if so 35 requested; 36 37 If denied a recommended treatment, written reasons for the denial and (3) an explanation of the utilization review criteria or treatment protocol 38 39 upon which the denial was based; The plan's restrictive formularies closed formularies, restricted access 40 (4) drugs or devices, or prior approval requirements for obtaining 41 42 prescription drugs, whether a particular drug or therapeutic class of drugs is excluded from its formulary, and the circumstances under 43

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.

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

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, plan summaries, and explanation of benefits, how it determines its payment obligations and the payment obligations of the insured. The explanation shall include and clearly indicate:
 - (1) The steps the insurer has taken in calculating the benefit amount and the payment obligations of each party.
 - 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.
 - Which party is responsible for filing a claim or bill with the insurer.
 - (4) Whether the insured may be liable for paying any excess amount.
- (b) If an insured is liable for an amount that differs from a stated fixed dollar copayment or from a stated coinsurance percentage because the coinsurance amount is based on a plan allowance or other such amount rather than the actual charges, 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 are not 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 patient research studies designed to evaluate new treatments, including prescription drugs and that: (i) involve the treatment of life-threatening medical conditions, (ii) are clearly superior to available noninvestigational treatment alternatives, and (iii) have clinical and preclinical data that shows the trial will be at least as effective as noninvestigational alternatives. Covered clinical trials must also meet the following requirements:
 - <u>a.</u> <u>Must involve determinations by treating physicians, relevant scientific data, and opinions of experts in relevant fields of medicine.</u>
 - b. Must be approved by the National Institutes of Health, a National Institutes of Health cooperative group or center, the U.S. Food and Drug Administrative, the U.S. Department of Defense, or the U.S. Department of Veterans Affairs. The health benefit plan may also cover clinical trials sponsored by other entities.
 - <u>c.</u> <u>Must be approved by applicable qualified institutional review</u> boards.
 - d. Must be conducted in and by facilities and 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 covered clinical trials by its insureds or enrollees who meet substantially all protocol requirements of the trials and exercise informed consent in the trials. The health benefit plan shall provide coverage for participation in covered clinical trial phases III and IV. The health benefit plan may also approve coverage for participation in covered clinical trial phase II.
- (c) Only medically necessary costs of health care services involved in treatments provided to patients for the purpose of the trials are required to be covered by the health benefit plan to the extent that such costs are not customarily funded by national agencies, commercial manufacturers, distributors, or other such providers.
- (d) Clinical trial costs not required to be covered by a health benefit plan include, but are not limited to, the costs of services that are not health care services and costs associated with managing research in the trials.

1 2	(e) Health benefit plans shall not exclude benefit plans shall not exclude benefits for covered clinical trials if the proposed treatment is the only appropriate protocol for		
3	the condition being treated."		
4	the condition being treated.		
5	Subpart B. Newborn Hearing Screening		
6	SECTION 2.2 Article 2 of Chapter 50 of the Consul Statutes is amonded		
7	SECTION 3.2. Article 3 of Chapter 58 of the General Statutes is amended		
8	by adding a new section to read:		
9	"§ 58-3-260. Insurance coverage for newborn hearing screening mandated.		
10	(a) As used in this section, the terms 'health benefit' plan and 'insurer' have the		
11	meanings applied under G.S. 58-3-167.		
12	(b) Each health benefit plan shall provide coverage for newborn hearing		
13	screening ordered by the attending physician pursuant to G.S. 130A-125."		
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15	PART IV. EXTERNAL REVIEW AND MANAGED CARE ENTITY LIABILITY		
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17	Subpart A. Independent, External Review Process		
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19	SECTION 4.1. The title of Article 50 of Chapter 58 of the General Statutes		
20	reads as rewritten:		
21	"Article 50.		
22	"General Accident and Health Insurance Regulations."		
23	SECTION 4.2. Article 50 of Chapter 58 of the General Statutes is amended		
24	as follows:		
25	(1) By designating G.S. 58-50-1 through G.S. 58-50-45 as Part 1 with the		
26	heading "Miscellaneous Provisions."		
27	(2) By designating G.S. 58-50-50 through G.S. 58-50-64 as Part 2 with the		
28	heading "PPOs, Utilization Review and Grievances."		
29	(3) By designating G.S. 58-50-65 through G.S. 58-50-70 as Part 3 with the		
30	heading "Scope and Sanctions."		
31	(4) By designating G.S. 58-50-75 through G.S. 58-50-95 as Part 4 with the		
32	heading "Health Benefit Plan External Review."		
33	(5) By designating G.S. 58-50-100 through G.S. 58-50-156 as Part 5 with		
34	the heading "Small Employer Group Health Insurance Reform."		
35	SECTION 4.3. G.S. 58-50-151 is recodified as G.S. 58-51-116.		
36	SECTION 4.4. The prefatory language of G.S. 58-50-61(a) reads as		
37	rewritten:		
38	"(a) Definitions. – As used in this section and section, in G.S. 58-50-62, and in		
39	Part 4 of this Article, the term:".		
40	SECTION 4.5. Article 50 of Chapter 58 of the General Statutes is amended		
41	by adding a new Part to read:		
42	"Part 4. Health Benefit Plan External Review.		
43	"§ 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) 'Disclose' means to release, transfer, or otherwise divulge protected health information to any person other than the individual who is the subject of the protected health information or his or her legal guardian, including the custodial parent(s) of a minor child.
 - (3) 'Health information' means information or data, whether oral or recorded in any form or medium, and personal facts or information about events or relationships that relates to: the past, present, or future physical, mental, or behavioral health or condition of an individual or a member of the individual's family; the provision of health care services to an individual; or payment for the provision of health care services to an individual.
 - (4) <u>'Independent review organization' or 'organization' means an entity that conducts independent external reviews of appeals of noncertifications and second-level grievance review decisions.</u>
 - (5) 'Protected health information' means health information that identifies an individual who is the subject of the information; or with respect to which there is a reasonable basis to believe that the information could be used to identify an individual.

"<u>§ 58-50-76</u>: 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:

- If the covered person has a medical condition where the time frame for (1) 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.
 - (e) An insurer that has collected protected health information under a valid authorization under this Part may use and disclose the protected health information to a person acting on behalf of or at the direction of the insurer for the performance of the insurer's insurance functions: claims administration, claims adjustment and management, fraud investigation, underwriting, loss control, rate-making functions,

- reinsurance, risk management, case management, disease management, quality assessment, quality improvement, provider credentialing verification, utilization review, peer review activities, appeal and grievance procedures, policyholder service functions, internal administration of compliance, managerial, and information systems; compliance with the external review process under G.S. 58-50-80 and G.S. 58-50-82; and responding to legal action involving a noncertification by the insurer. Additional insurance functions may be allowed for the purpose of this subsection with the prior approval of the Commissioner. The protected health information shall not be used or disclosed for any purpose other than in those described in this subsection, except with the prior written consent of the covered person or his or her legal guardian, including custodial parent.
 - (f) Except for a request for an expedited external review under G.S. 58-50-82, all requests for external review shall be made in writing to the Commissioner.
 - "§ **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(j) 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(j), 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.
 - (h) If the requirement to exhaust the insurer's internal grievance procedures is waived under subsection (g) of this section, 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 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, including the authorization form provided under G.S. 58-50-77(e).

- (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.
 - (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 that the organization shall consider when conducting the external review.
 - (2) <u>Immediately notify the insurer in writing of the acceptance of the request for external review.</u>
 - (3) Provide the covered person and the covered person's provider with a list of organizations approved under G.S. 58-50-85.
 - (4) Inform the covered person that the covered person has the right to select the organization of his or her choice and notify the Commissioner within five days after receipt of the notice, and that if the covered person does not select an organization and inform the Commissioner of the selection within five days after receipt of the notice, the Commissioner will assign an organization to conduct the external review.
- (f) 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.
- (g) If the insured does not select an organization of his or her choice and notify the Commissioner of the selection within five days after receipt of the Commissioner's notice under subsection (e) of this section, the Commissioner shall systematically assign an appropriate independent review organization that has been approved under G.S. 58-50-85 to conduct the external review. In reaching a decision, the assigned 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.
- (h) Within seven days after the date of receipt of the notice provided under subsection (e) 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 (i) 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.

- (i) If the insurer or its utilization review organization fails to provide the documents and information within the time specified in subsection (h) 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.
- (j) The assigned organization shall review all of the information and documents received under subsections (h) and (i) of this section and any other information submitted in writing by the covered person under subsection (e) of this section that has been forwarded to the organization by the Commissioner. Upon receipt of any information submitted by the covered person under subsection (e) of this section, at the same time the Commissioner forwards the information to the organization, the Commissioner shall forward the information to the insurer.
- (k) Upon receipt of the information required to be forwarded under subsection (j) 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.
- (1) Immediately upon making the decision to reverse its noncertification appeal decision or second-level grievance review decision under subsection (k) 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.
- (m) In addition to the documents and information provided under subsections (h) and (i) of this section, the assigned organization, to the extent the documents or information are available and the 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 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.
 - (5) The most appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, or any other practice guidelines developed by the federal government,

1		national or professional medical societies, boards, and associations.
2		Local practice guidelines may be used when appropriate.
3	<u>(6)</u>	Any applicable clinical review criteria developed and used by the
4		insurer or its designee utilization review organization.
5	<u>(7)</u>	Medical necessity, as defined in G.S. 58-3-200(b).
6	(n) Withi	in 45 days after the date of receipt by the Commissioner of the request
7		lew, the assigned organization shall provide written notice of its decision
8		everse the noncertification appeal decision or second-level grievance
9		to the covered person, the insurer, and the Commissioner.
10		organization shall include in the notice sent under subsection (n) of this
11	section:	
12	<u>(1)</u>	A general description of the reason for the request for external review.
13	<u>(2)</u>	The date the organization received the assignment from the
14	(2)	Commissioner to conduct the external review.
15	<u>(3)</u>	The date the organization received information and documents
16	(4)	submitted by the covered person and by the insurer.
17	<u>(4)</u>	The date the external review was conducted.
18	<u>(5)</u>	The date of its decision.
19	<u>(6)</u>	The principal reason or reasons for its decision.
20	<u>(7)</u>	The clinical rationale for its decision. References to the evidence or documentation including the practice.
21	<u>(8)</u>	References to the evidence or documentation, including the practice
22 23	(0)	guidelines, considered in reaching its decision. The professional qualifications and licensure of the clinical peer
23 24	<u>(9)</u>	reviewers.
25	(10)	Notice to the covered person that he or she is not liable for the cost of
26	(10)	the external review.
27	(p) Upon	receipt of a notice of a decision under subsection (n) of this section
28		noncertification appeal decision or second-level grievance review
29	_	surer immediately shall approve the coverage that was the subject of the
30		appeal decision or second-level grievance review decision.
31	"§ 58-50-81 : R	
32	" <u>§ 58-50-82.</u> E	xpedited external review.
33		ot as provided in subsection (h) of this section, a covered person may
34	make a request	for an expedited external review with the Commissioner at the time the
35	covered person	receives:
36	<u>(1)</u>	An appeal decision under G.S. 58-50-61(k) or (l) upholding a
37		noncertification if:
38		<u>a.</u> The noncertification appeal decision involves a medical
39		condition of the covered person for which the time frame for
40		completion of an expedited second-level grievance review of a
41		noncertification set forth in G.S. 58-50-62(i) would reasonably
42		be expected to seriously jeopardize the life or health of the
43		covered person or jeopardize the covered person's ability to
44		regain maximum function; and

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

 4 (2) A second-level grievance review decision under G.S. 58-60-62(h) 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.
 - For a request that the Commissioner has determined meets the reviewability requirements set forth in G.S. 58-50-80(c), assign an organization that has been approved under G.S. 58-50-87. The organization shall immediately determine 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 organization shall then inform the covered person, insurer, and Commissioner of its determination and conduct a review and make a decision on 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 necessary documents and information considered in making the final noncertification decision to the assigned 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.

- 1 (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 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.
 - (5) The most appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, or any other practice guidelines developed by the federal government, national or professional medical societies, boards, and associations. Local practice guidelines may be used when appropriate.
 - (6) Any applicable clinical review criteria developed and used by the insurer or its designee utilization review organization in making noncertification decisions.
 - (7) Medical necessity, as defined in G.S. 58-3-200(b).
 - (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 immediately shall approve the coverage that was the subject of the noncertification.
 - (h) An expedited external review may not be provided for retrospective noncertifications.
 - "<u>§ 58-50-83:</u> 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.
 - (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) The Commissioner may charge an application fee that independent review organizations shall submit to the Commissioner with an application for approval and reapproval.
 - (e) 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.
 - (f) 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 and remove the independent review organization from the list of independent review organizations approved to conduct external reviews under this Part that is maintained by the Commissioner under subsection (g) of this section.
 - (g) The Commissioner shall maintain and periodically update a list of approved independent review organizations.
 - "§ **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

1				organization and suitable matching of reviewers to specific
2				cases.
3			<u>c.</u>	The confidentiality of medical and treatment records and
4				clinical review criteria.
5			<u>d.</u>	That any person employed by or under contract with the
6				independent review organization adheres to the requirements of
7				this Part.
8		<u>(2)</u>	A toll	-free telephone service to receive information on a 24-hour-day,
9			seven	-day-a-week basis related to external reviews that is capable of
10			accep	ting, recording, or providing appropriate instruction to incoming
11			<u>teleph</u>	one callers during other than normal business hours.
12		<u>(3)</u>	Agree	e to maintain and provide to the Commissioner the information
13			set ou	t in G.S. 58-50-90.
14		<u>(4)</u>	A pro	gram for credentialing clinical peer reviewers.
15		(5)	Agree	e to contractual terms or written requirements established by the
16			_	nissioner regarding the procedures for handling a review.
17	<u>(b)</u>	All cl		peer reviewers assigned by an independent review organization to
18			_	ews shall be medical doctors or other appropriate health care
19				e following minimum qualifications:
20	*	(1)		expert in the treatment of the covered person's injury, illness, or
21				cal condition that is the subject of the external review.
22		<u>(2)</u>		nowledgeable about the recommended health care service or
23				nent through recent or current actual clinical experience treating
24				its with the same or similar injury, illness, or medical condition
25			_	covered person.
26		<u>(3)</u>		covered person's treating provider is a medical doctor, hold a
27		1,-,/		stricted license from the North Carolina Medical Board and, if a
28				alist medical doctor, a current certification by a recognized
29			_	ican medical specialty board in the area or areas appropriate to
30				bject of the external review.
31		<u>(4)</u>		covered person's treating provider is not a medical doctor, hold a
32		<u>\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ </u>		stricted North Carolina license, registration, or certification in the
33				allied health occupation as the covered person's treating provider.
34		<u>(5)</u>		no history of disciplinary actions or sanctions, including loss of
35		<u>(2)</u>		privileges or participation restrictions, that have been taken or are
36			_	ng by any hospital, governmental agency or unit, or regulatory
37			_	that raise a substantial question as to the clinical peer reviewer's
38			-	cal, mental, or professional competence or moral character.
39	(c)	In ad		o the requirements set forth in subsection (a) of this section, an
40	_			ganization may not own or control, be a subsidiary of or in any
41				olled by, or exercise control with a health benefit plan, a national,
42				ociation of health benefit plans, or a national, State, or local trade
43	associati	OH OH N	vailli Ca	are 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.
- "<u>§ 58-50-88:</u> Reserved.

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

No independent review organization or clinical peer reviewer working on behalf of an organization shall be liable in 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

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43 44 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 should include the number of reviews, character of the reviews, dollar amounts in question, and any other information relevant to the evaluation of the effectiveness of this Part."

SECTION 4.6. G.S. 58-50-61(a)(13) reads as rewritten:

"(13) 'Noncertification' means a determination by an insurer or its designated utilization review organization that an admission, availability of care, continued stay, or other health care service has been reviewed and, based upon the information provided, does not meet the insurer's requirements for medical necessity, appropriateness, health care

setting, level of care or effectiveness, or does not meet the prudent layperson standard for coverage of emergency services in G.S. 58-3-190, and the requested service is therefore denied, reduced, or terminated. A 'noncertification' is not a decision rendered solely on the basis that the health benefit plan does not provide benefits for the health care service in question, if the exclusion of the specific service requested is clearly stated in the certificate of coverage. A 'noncertification' includes any situation in which an insurer or its designated agent makes an evaluation or review of medical information about a covered person's condition to determine whether a requested treatment is experimental, investigational, or cosmetic and the extent to which coverage under the health benefit plan is affected by that decision."

SECTION 4.7. G.S. 58-50-61(a)(17)g. reads as rewritten:

"g. Retrospective review. – Utilization review of medically necessary services and supplies that is conducted after services have been provided to a patient, but not the review of a claim that is limited to an evaluation of reimbursement levels, veracity of documentation, accuracy of coding, or adjudication for payment. Retrospective review includes the review of claims for emergency services to determine whether the prudent layperson standard in G.S. 58-3-190 has been met."

SECTION 4.8. G.S. 58-50-61(i) reads as rewritten:

"(i) Requests for Informal Reconsideration. – An insurer may establish procedures for informal reconsideration of noncertifications and if established, such procedures shall be in writing. The reconsideration shall be conducted between the covered person's provider and a medical doctor licensed to practice medicine in this State designated by the insurer insurer, after a written notice of noncertification has been issued in accordance with subsection (h) of this section. An insurer shall not require a covered person to participate in an informal reconsideration before the covered person may appeal a noncertification under subsection (j) of this section. If, after informal reconsideration the insurer upholds the noncertification decision, the insurer shall issue a new notice in accordance with subsection (h) of this section. If the insurer is unable to render an informal reconsideration decision in fewer than 10 business days, it shall treat the request for informal reconsideration as a request for an appeal, except that the requirements of subsection (k) of this section shall apply on or before the 10th business day after receipt of the request for an informal reconsideration."

SECTION 4.9. G.S. 58-50-62 is amended by adding a new subsection to read:

- "(b1) Informal Consideration of Grievances. If the insurer provides procedures for informal considerations of grievances, the procedures shall be in writing and the following requirements apply:
 - (1) If the grievance concerns a clinical issue and the informal consideration decision is not in favor of the covered person, the insurer

1		shall treat the request as a request for a first-level grievance review,
2		except that the requirements of subdivision (e)(1) of this section shall
3		apply on the 10th business day after receipt of the grievance.
4	<u>(2)</u>	If the grievance concerns a nonclinical issue and the informal
5		consideration decision is not in favor of the covered person, the insurer
6		shall issue a written decision that includes the information set forth in
7		<u>G.S. 58-50-62(c).</u>
8	<u>(3)</u>	If the insurer is unable to render an informal consideration decision
9		within 10 business days of receipt of the grievance, the insurer shall
10		treat the request as a request for a first-level grievance review, except
11		that the requirements of subdivision (e)(1) of this section shall apply
12		on the 10th business day after receipt of the grievance."
13	SECT	FION 4.10. G.S. 58-50-61(k)(5) reads as rewritten:
14	"(5)	A statement advising the covered person of the covered person's right
15		to request a second-level grievance review and a description of the
16		procedure for submitting a second-level grievance under G.S 58-50-
17		62. G.S. 58-50-62 if the insurer's decision on the appeal is to uphold its
18		noncertification."
19	SECT	FION 4.11. G.S. 58-50-62(e)(2)e. reads as rewritten:
20		"e. A statement advising the covered person of his or her right to
21		request a second-level grievance review and a description of the
22		procedure for submitting a second-level grievance under this
23		section. section if the insurer's decision on the first-level
24		grievance review is not in favor of the covered person."
25	SECT	FION 4.12. G.S. 58-50-62(h)(7) reads as rewritten:
26	"(7)	A statement that the decision is the insurer's final determination in the
27	` ,	matter. In cases where the review concerned a noncertification and the
28		insurer's decision on the second-level grievance review is to uphold its
29		initial noncertification, a statement advising the covered person of his
30		or her right to request an external review and a description of the
31		procedure for submitting a request for external review to the
32		Commissioner of Insurance."
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34	Subpart B. Hea	alth Plan Liability
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36	SECT	FION 4.13. Chapter 90 of the General Statutes is amended by adding a
37	new Article to re	
38		"Article 1G.
39		"Health Care Liability.
40	"§ 90-21.50. De	<u> </u>
41		nis Article, unless the context clearly indicates otherwise, the term:
42	(1)	'Health benefit plan' means an accident and health insurance policy or
43	•	certificate; a nonprofit hospital or medical service corporation

contract; a health maintenance organization subscriber contract; a plan

1		provided by a multiple employer welfare arrangement. 'Health benefit
2		plan' does not mean any plan implemented or administered through the
3		Department of Health and Human Services or its representatives.
4		'Health benefit plan' also does not mean any of the following kinds of
5		insurance:
6		a. Accident;
7		<u>b.</u> <u>Credit;</u>
8		c. Disability income;
9		d. Long-term or nursing home care;
10		e. Medicare supplement;
11		 c. <u>Disability income;</u> d. <u>Long-term or nursing home care;</u> e. <u>Medicare supplement;</u> f. <u>Specified disease;</u>
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13		h. Coverage issued as a supplement to liability insurance;
14		 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
15		<u>j.</u> Medical payments under automobile or homeowners;
16		k. Insurance under which benefits are payable with or without
17		regard to fault and that are statutorily required to be contained
18		in any liability policy or equivalent self-insurance; and
19		1. Hospital income or indemnity.
20	<u>(2)</u>	'Health care provider' means:
21		a. An individual who is licensed, certified, or otherwise authorized
22		under this Chapter to provide health care services in the
23		ordinary course of business or practice of a profession or in an
24		approved education or training program; or
25		b. A health care facility, licensed under Chapters 131E or 122C of
26		the General Statutes, where health care services are provided to
27		patients;
28		'Health care provider' includes:
29		1. An agent or employee of a health care facility that is
30		licensed, certified, or otherwise authorized to provide
31		health care services;
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33		 2. The officers and directors of a health care facility; and 3. An agent or employee of a health care provider who is
34		licensed, certified, or otherwise authorized to provide
35		health care services.
36	(3)	'Health care service' means a health or medical procedure or service
37		rendered by a health care provider that:
38		a. Provides testing, diagnosis, or treatment of a human disease or
39		dysfunction; or
40		b. Dispenses drugs, medical devices, medical appliances, or
41		medical goods for the treatment of a human disease or
42		dysfunction.
43	<u>(4)</u>	'Health care treatment decision' means a determination that:
44	<u></u>	a. Is made by a managed care entity;
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1		b. Governs the extent to which health care services are provided
2		for, arranged for, paid for, or reimbursed under a health benefit
3		plan; and
4		c. Affects the quality of the diagnosis, care, or treatment provided
5		under the health benefit plan to an enrollee or insured of the
6		health benefit plan.
7	<u>(5)</u>	'Insured or enrollee' means a person that is insured by or enrolled in a
8		health benefit plan under a policy, plan, certificate, or contract issued
9		or delivered in this State by an insurer.
10	<u>(6)</u>	'Insurer' means an entity that writes a health benefit plan and that is an
11		insurance company subject to Chapter 58 of the General Statutes, a
12		service corporation organized under Article 65 of Chapter 58 of the
13		General Statutes, a health maintenance organization organized under
14		Article 67 of Chapter 58 of the General Statutes, or a multiple
15		employer welfare arrangement subject to Article 49 of Chapter 58 of
16		the General Statutes.
17	<u>(7)</u>	'Managed care entity' means an insurer that:
18		a. Delivers, administers, or undertakes to provide for, arrange for,
19		or reimburse for health care services, or assumes the risk for the
20		delivery of health care services; and
21		b. Has a system or technique to control or influence the quality,
22		accessibility, utilization, or costs and prices of health care
23		services delivered or to be delivered to a defined enrollee
24		population.
25		'Managed care entity' does not include: (i) an employer purchasing
26		coverage or acting on behalf of its employees or the employees of one
27		or more subsidiaries or affiliated corporations of the employer, or (ii) a
28		health care provider.
29	<u>(8)</u>	'Ordinary care' means that degree of care that a managed care entity of
30		ordinary prudence situated in the same or similar communities at the
31		time of the alleged act giving rise to the cause of action would use
32		under the same or similar circumstances.
33	<u>(9)</u>	'Physician' means:
34		a. An individual licensed to practice medicine in this State;
35		b. A professional association or corporation organized under
36		Chapter 55B of the General Statutes; or
37		c. A person or entity wholly owned by physicians.
38	" <u>§ 90-21.51. Du</u>	ity to exercise ordinary care; liability for damages for harm.
39	(a) Each	managed care entity for a health benefit plan has the duty to exercise
40	ordinary care wh	nen 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) <u>Its agents or employees; or</u>
 - (2) Representatives that are acting on its behalf and over whom it has the right to exercise influence or significant control with respect to 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.

- (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."

SECTION 4.14. 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, erosselaim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, erosselaims, 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.** 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 6. Sections 4.1 through 4.14 become effective December 1, 2002.
- 2 The remainder of this act is effective when it becomes law and applies to health benefit
- 3 plans that are delivered, issued for delivery, or renewed on or after January 1, 2002.