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Health

The General Assembly enacted more than forty new laws affecting health during the 2001 legislative session. As usual, the law with the most significant impact on the state's public health system was the Appropriations Act. This was an extremely difficult year for North Carolina's state budget process. Revenue estimates were revised downward several times during the course of the General Assembly's deliberations, anticipated savings did not materialize, and the close scrutiny of budget proposals by bond-rating agencies raised concerns about the state's continuing fiscal soundness. Lawmakers ultimately enacted tax increases as well as significant budget cuts. The state's Department of Health and Human Services (DHHS) sustained reductions in many of its services and programs, including significant cuts in public health programs and in Medicaid. At the same time, significant budget expansions provided additional funds for children to enroll in Health Choice, the state children's health insurance program, and for state agencies to implement the requirements of the federal Health Insurance Portability and Accountability Act (HIPAA).

After many years of debate about managed care reform, lawmakers finally passed significant reform legislation in this session. The new Patients' Bill of Rights authorizes patients to sue managed care organizations for failing to exercise due care in making treatment decisions, establishes a binding procedure for independent review of adverse coverage decisions, and creates a new program to assist patients in exercising their rights under the law. Several additional laws addressed mandatory benefits and other obligations of health insurers to persons enrolled in their plans.

Other significant legislation included an overhaul of the laws governing the state's emergency medical services system, a new set of laws regulating the practice of pharmacy technicians, the creation of a central registry for advance health care directives, and a law granting immunity from liability for health care providers who honor portable do not resuscitate (DNR) orders.

Budget

Public Health

The 2001 Appropriations Act, S.L. 2001-424 (S 1005) cuts the budget for the state Division of Public Health (DPH) by 4.3 percent—nearly \$5 million. To provide for the cut, a number of

public health contracts and programs were eliminated entirely, while others were significantly pared down. Some of the most significant reductions affecting the public health system were the following:

- Funding for the nurse midwifery program was eliminated. This program funded start-up nurse midwifery practices in North Carolina.
- Funding for the Rural Obstetrics Incentive Program was eliminated. The purpose of this program was to encourage physicians in rural areas to provide care for Medicaid patients. The program paid a portion of the malpractice insurance for participating physicians.
- The funding for a number of contracts with other entities that provided various types of public health services was eliminated, including a contract with the Association of North Carolina Boards of Health for local board of health training activities, and contracts with the University of North Carolina School of Public Health for local health services and intensive home visiting programs.
- One million dollars in recurring funds for health promotion activities was eliminated.
- Nine positions within DPH were eliminated.
- Funding for sickle cell program educational counselors was reduced, as was funding for the newborn screening program. In both cases, increased Medicaid receipts to pay for the services are anticipated.
- Funding for the AIDS Drug Assistance Program was reduced by \$1.5 million for the 2001–2002 fiscal year only. This reduction was partially offset by an increase in funding for AIDS treatment in the amount of \$500,000 for each fiscal year of the biennium.

The budget also includes new or additional funding for several public health activities and programs. Among other things, the legislature

- provided \$700,761 in recurring funds for varicella (chicken pox) vaccinations for children,
- provided \$175,000 in recurring funds for the state’s birth defects registry,
- provided \$200,000 in recurring funds to support a centralized system to assist eligible individuals in obtaining prescription drugs at no or low cost through pharmaceutical companies’ programs or initiatives,
- provided \$200,000 in recurring funds to the Alice Aycock Poe Center for Health Education,
- provided \$1 million in nonrecurring funds for the Healthy Carolinians program,
- provided \$400,000 in nonrecurring funds for the Healthy Start Foundation to improve access to prenatal care and reduce poor birth outcomes,
- provided \$200,000 in nonrecurring funds to the state Office of Minority Health to fund activities to reduce disparities in the health status of minorities,
- provided \$100,000 in nonrecurring funds to the Heart Disease and Stroke Prevention Task Force,
- provided \$200,000 in nonrecurring funds to promote the use of folic acid to prevent birth defects, and
- provided \$250,000 in nonrecurring funds to support asthma management, surveillance, and educational activities.

The state budget laws include a number of substantive requirements affecting public health. S.L. 2001-395 (S 61), which was enacted in late August 2001 to authorize continued state expenditures while a final budget had not yet been approved, appropriates funds for health and human services block grants and specifies how some of those funds must be expended. Among other things, the law specifies that \$395,000 from the Preventive Health Services Block Grant must be used to create a position in the Office of the Secretary to enhance activities for HIV/AIDS awareness and education. The prevention activities are to be targeted to the general public and should not augment current programs that target high-risk populations through community-based organizations. The final budget adds to this provision a requirement that DHHS coordinate its HIV/AIDS awareness and educational efforts with the North Carolina AIDS Advisory Council, the North Carolina Minority Health Advisory Council, representatives of faith communities, representatives of nonprofit agencies, and other state agencies. It also requires DHHS to report to the legislature’s Health and Human Services Appropriations Committees by March 15, 2002.

The final budget includes a number of other substantive provisions affecting public health. S.L. 2001-424 enacts the following requirements and changes to public health laws and programs:

- Requires DHHS to control drug utilization in all the prescription drug assistance programs operated by the department. Those programs generally must use generic drugs unless the health care provider indicates on the prescription that a brand-name drug is medically necessary. (There is a limited exception for some antipsychotic and other drugs.) Supplies of prescription drugs must be limited to thirty-four days.
- Expands eligibility for the AIDS Drug Assistance Program. Currently, an individual is only eligible for this program if his or her income is less than 125 percent of the federal poverty level. Beginning July 1, 2002, eligibility for participation will be extended to individuals with incomes up to 200 percent of the federal poverty level.
- Amends G.S. 108A-88, which requires the Secretary of Health and Human Services to notify local officials about state and federal funds expected to be available for certain programs. Previously, the law required the secretary to notify county directors of social services of the amount estimated to be available for social services by February 15 each year. The amended law requires the Secretary to notify social services directors, county commissioners, county managers, and local health directors about funds expected to be available for social services and public health programs.
- Makes health care providers liable for restitution to the state when they negligently permit state-supplied vaccine in their inventory to spoil or become unstable. The state supplies vaccine to health care providers who agree to limit their fees for administering vaccinations and to comply with special reporting requirements.
- Directs DHHS to provide funding for teen pregnancy prevention initiatives targeted to counties that have the highest teen pregnancy rates or meet other criteria.

Health Choice (State Children's Health Insurance Program)

North Carolina Health Choice is the state's program that provides health insurance for children who would otherwise be uninsured because their family incomes are too high for them to qualify for Medicaid but too low to allow them to afford private insurance. Early in 2001, enrollment in Health Choice was frozen because of an anticipated shortfall in funding for the program. The legislature expanded the funding for Health Choice by \$8 million in fiscal year 2001-2002 and by \$12.5 million in fiscal year 2002-2003. In addition, a special provision in the budget law eliminates the waiting period for Health Choice. Previous law required a child to be uninsured for at least sixty days before applying for Health Choice.

Medicaid

Medicaid is a state and federally funded entitlement program that provides payment for health care services for people with low incomes. It is an extremely significant component of the state budget, accounting for more than 10 percent of total state expenditures each fiscal year. The state provided an additional \$460 million for the Medicaid program in fiscal year 2001-2002—a 30 percent increase over 2000-2001. The increase was not enough, however, to cover the program's anticipated costs, so the legislature made several cuts to the Medicaid budget. It reduced provider reimbursement rates and eliminated inflationary increases in those rates. It reduced anticipated expenses for prescription drugs by increasing co-payments, lowering dispensing fees, and requiring the use of generic drugs in most instances. It also reduced or limited reimbursement for certain types of services, such as in-home personal care services.

A significant expansion item in the Medicaid budget provides \$622,000 in fiscal year 2001-2002 and \$1.2 million in 2002-2003 to treat women with breast or cervical cancer.

Another significant expansion item provides additional funding for dental services for Medicaid-eligible children and adults. In November 2000, the state Medicaid program was sued by clients who alleged that the program's reimbursement rates for dental services were so low as

to effectively deny dental care to Medicaid-eligible children and adults, in violation of federal law. A settlement agreement was negotiated in which the state would provide an additional \$7.5 million in Medicaid funding for dental services and would undertake other activities to improve access to dental care. The legislature declined to approve the settlement agreement, however, and instead provided additional funding for Medicaid dental services in the amount of \$1 million for fiscal year 2001–2002 and \$2 million for fiscal year 2002–2003.

The state budget law also includes a number of special provisions with substantive requirements affecting Medicaid. One special provision requires the Division of Medical Assistance (DMA), the state agency that administers Medicaid, to contain costs by reducing the rate of growth of the Medicaid program—but not the rate of growth in the number of persons eligible for the program—to 8 percent or less of the total expenditures in fiscal year 2001–2002. The cost-containment activities may include, but are not limited to, prospective reimbursement methods, incentive-based reimbursement methods, service limits, prior authorization of services, periodic medical necessity reviews, revised medical necessity criteria, and service provision in the least costly settings. Another provision requires DHHS to implement a pharmacy benefits management plan for Medicaid. A third special provision exempts the adoption of new or amended medical coverage policies from the rule-making requirements of the Administrative Procedure Act (APA). Instead, DHHS must publish proposed new or amended policies on its Web site, notify Medicaid providers at least forty-five days before it adopts the proposed policies, and accept oral or written comments during that period. If the proposed policy is modified after the comment period, DHHS must notify providers at least fifteen days before adopting the policy and must accept additional comments during the fifteen-day period.

Health Insurance Portability and Accountability Act

The state budget includes a \$15 million appropriation to a reserve fund to implement the Health Insurance Portability and Accountability Act (HIPAA), a federal law that—among other things—requires health plans, health information clearinghouses, and health care providers to standardize their electronic transactions of health information and to protect the privacy and security of the information. S.L. 2001-424 places the reserve fund in the Office of State Budget and Management and directs that office, in consultation with the state Chief Information Officer and the Secretary of Health and Human Services, to develop a strategic plan to implement HIPAA within the state’s agencies.

Health and Wellness Trust Fund

The Health and Wellness Trust Fund Commission was created during the 2000 legislative session to oversee the distribution of a portion of the funds that North Carolina received in the tobacco settlement (S.L. 2000-147). The Commission must develop criteria for awarding grants to programs and initiatives designed to improve health. A special provision in the 2001 Appropriations Act directs the commission to include criteria that will address the need to expand access to prescription medications for the elderly and disabled.

Other Requirements for DHHS

Several special provisions in the budget law require DHHS to consolidate, centralize, or coordinate activities or programs. These provisions:

- Require DHHS to consolidate its regional, district, field, and satellite offices and to report on anticipated cost savings and efficiencies resulting from the consolidation.
- Require DHHS to centralize its activities relating to the coordination and processing of criminal record checks.

- Establish an Office of Policy and Planning within the Office of the Secretary to coordinate the development of departmental policies, plans, and rules and provide a process for coordinating and reviewing policies before they are disseminated.
- Create an Intervention Services Unit in the Office of the Secretary. The unit will be responsible for planning, monitoring, and conducting data analyses for the purpose of enhancing coordination among preschool education and Smart Start programs as well as activities in the Division of Public Health, the Division of Social Services, and the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services.
- Direct DHHS to implement a centralized system for the development and execution of contracts.
- Direct DHHS to coordinate all family support contracts and activities across divisions.
- Require the Secretary to transfer components of the State Center for Health Statistics and related functions in other departmental divisions in order to centralize the Department's statistical management and analysis functions.

DHHS is also directed to study and report on the feasibility of other consolidations or centralizations. The Department must determine the feasibility of combining all its existing toll-free telephone lines. Another provision requires DHHS, in partnership with local health departments, to determine the feasibility of consolidating all nurse and health educator consultant positions in the Division of Public Health.

Public Health

Public Health Authorities

North Carolina counties have a legal duty to provide public health services within the county. Counties most commonly meet this duty by operating a county health department or participating in a multi-county district health department. In 1997 the General Assembly authorized counties to form single- or multi-county public health authorities, which would be responsible for providing public health services within the county or counties and would be governed by boards with more powers and duties than traditional local boards of health. The act authorizing public health authorities, S.L. 1997-502, specified that single-county public health authorities could be formed by resolution of the board of county commissioners alone, while the formation of multi-county public health authorities required the approval of each county's commissioners and local board of health. S.L. 2001-92 (S 221) amends the Public Health Authorities Act so that a joint resolution of the county commissioners and the local board of health is now required to create a single-county public health authority. The law also exempts employees under the supervision of a public health authority director from the State Personnel Act.

Civil Penalties for Violations of Local Rules

Local boards of health in North Carolina have rule-making authority. Violation of a board's rules is a misdemeanor. Local health rules also can be enforced civilly, through an injunction issued by a superior court. A new law, S.L. 2001-120 (H 837), provides an additional remedy—the imposition of civil penalties—for violations of local health rules in counties in which the board of commissioners has abolished the local board of health and assumed direct control of its activities, pursuant to G.S. 153A-77. If a local rule provides for civil penalties, an individual may not be held criminally liable for violating it unless the rule expressly states that violation is a misdemeanor.

G.S. 153A-77(a) authorizes only the boards of commissioners of counties with populations of 425,000 or more to abolish health boards and act in their place. Currently, only Mecklenburg County operates in this manner; therefore, Mecklenburg is now the only county that may impose civil penalties under this new law.

Disease Reporting

The control of communicable and other diseases is a traditional public health activity that depends in part on private parties making reports of known or suspected cases of illness. S.L. 2001-28 (H 286) clarifies the legal duty of laboratories to report findings suggestive of communicable and selected other diseases to the local health department or state Division of Public Health. Previously, state law established a reporting requirement for “clinical and pathological” laboratories. Under the new law, the words “clinical and pathological” are deleted, thus making clear that the following statutes are applicable to all laboratories:

- G.S. 130A-139, requiring the reporting of certain laboratory findings related to communicable diseases;
- G.S. 130A-144, requiring laboratories to permit local health directors or the state health director to examine, review, and copy records pertaining to communicable disease; and
- G.S. 130A-458, requiring the reporting of certain laboratory findings related to occupational disease and illness.

Bioterrorism

In the fall of 2001, the state’s public health system faced a new challenge: the threat of bioterrorism. Many local health departments were called upon to respond to public fears of anthrax-laced mail, and most participated in various types of bioterrorism preparedness activities. The General Assembly also weighed in on the issue, with three new laws addressing biological and other forms of terrorism.

The first new law to be enacted was S.L. 2001-457 (H 1471), which authorizes the Governor to use up to \$30 million in 2001–2002 from the savings reserve account to implement measures to defend against all forms of terrorism. The law also appropriates \$1.9 million to the Department of Crime Control and Public Safety to address terrorism.

S.L. 2001-469 (H 1472) requires DHHS to establish a biological agents registry. The purpose of the registry is to identify the biological agents possessed and maintained by any person in North Carolina and to provide other information that may be important in the event of a communicable disease or law enforcement investigation. The term *biological agents* is defined to include all of the bacteria and viruses that are on the Centers for Disease Control and Prevention’s Category A (highest priority) list of agents likely to be used by bioterrorists, including the bacteria that cause anthrax, botulism, tularemia, and plague and the viruses that cause smallpox and hemorrhagic fevers such as Ebola. Any person who possesses or maintains biological agents must register. Information that is prepared for or maintained in the registry is confidential and not a public record but may be released for the purpose of conducting or aiding in a communicable disease or law enforcement investigation. A person who willfully or knowingly violates the registry law is subject to a civil penalty of up to \$1,000. The person may also be charged with a misdemeanor.¹

Finally, S.L. 2001-470 (H 1468) creates new criminal penalties for the manufacture, possession, or use of biological, chemical, or nuclear weapons. The law is summarized in detail in Chapter 6, “Criminal Law and Procedure.”

Public Health Studies

The 2001 Studies Act, S.L. 2001-491 (S 166), authorizes the Legislative Research Commission to study the following issues related to public health:

- How to improve core and essential public health services in tier one counties
- Capacity to respond to bioterrorism, including the state’s ability to provide laboratory or epidemiological support when bioterrorism is suspected or when there is a question of food supply safety and security

1. All violations of public health laws and rules are punishable as misdemeanors. G.S. 130A-25.

The Studies Act authorizes the Public Health Study Commission to study the following issues:

- Public health impact of hepatitis C
- Improving HIV/AIDS prevention and care programs
- State law and policy pertaining to the treatment of rape victims and health care workers who risk HIV infection through needle-stick injuries

The act authorizes the Environmental Review Commission, in consultation with the Public Health Study Commission, to study the appointment of local health directors; the relationships among local health directors, local boards of health, and boards of county commissioners in the appointment and evaluation of local health directors; and the benefits of extending to all counties the authority of county commissioners under G.S. 153A-77. That statute permits county commissioners in counties with populations of 425,000 or more to abolish their local boards of health and assume direct control of the boards' activities, or to combine public health, social services, and mental health, developmental disabilities, and substance abuse services into a single consolidated human services agency.

The act requires DHHS to study health care disparities and to make recommendations for eliminating disparities and barriers to health care for ethnic and racial minorities.

Finally, the Studies Act authorizes the Joint Legislative Health Care Oversight Committee to study the county share of the cost of Medicaid and to develop strategies to eliminate or equalize county costs and lessen the state's financial burden.

Other Laws of Interest

Public health officials and employees may also be interested in the following new laws, which are summarized in other chapters:

- S.L. 2001-268 (H 63), which requires children who operate or are passengers on bicycles to use appropriate safety equipment, is addressed in Chapter 19, "Motor Vehicles."
- S.L. 2001-291 (H 275), which decriminalizes the abandonment of newborn infants under designated circumstances, is addressed in Chapter 3, "Children and Families."
- S.L. 2001-360 (S 1081), which makes it a felony for an inmate to emit bodily fluids or excrement at a state or local government employee who is performing his or her duties, is addressed in Chapter 6, "Criminal Law and Procedure."
- A number of new laws affecting public health agencies' environmental health programs are summarized in Chapter 10, "Environment and Natural Resources."

Emergency Medical Services

Two new laws make significant changes to North Carolina's emergency medical services (EMS) system. S.L. 2001-220 (H 452) updates and substantially revises the Emergency Medical Services Act (G.S. Chapter 143, Article 56). The law upgrades DHHS's EMS program to a comprehensive statewide EMS system. The comprehensive system addresses the provision of medical services, dispatch and routing of EMS vehicles and personnel, communications related to EMS, and follow-up lifesaving and restorative care as well as injury prevention and wellness initiatives within the community. The legal duty of counties with respect to EMS is clarified by a provision in the new law that requires each county to ensure that EMS services are provided to its citizens.

The North Carolina Medical Care Commission has the legal authority and duty to make rules governing EMS in North Carolina. The commission is authorized to

- establish standards and criteria for the credentialing of EMS agencies, trauma centers, and EMS educational institutions, and standards and criteria for denying, suspending, or revoking those credentials;

- establish standards and criteria for the education and credentialing of EMS personnel, and standards and criteria for denying, suspending, or revoking those credentials;
- establish standards and criteria for data collection as part of the statewide emergency services information system;
- define the practice settings of credentialed EMS personnel;
- establish standards for vehicles and equipment used in the EMS system;
- establish standards for a statewide EMS communications system;
- establish standards and criteria for education and credentialing of persons trained to administer lifesaving treatment to a person who suffers a severe adverse reaction to insect stings; and
- establish standards for the voluntary submission of hospital emergency medical care data (the law does not specify to whom the data would be submitted).

S.L. 2001-220 creates the EMS Disciplinary Committee and charges it with reviewing all disciplinary matters related to credentialed EMS personnel. It also alters the membership of the EMS Advisory Council, a twenty-five-member body that advises the Secretary of Health and Human Services on policy issues regarding the EMS system.

Finally, the new law clarifies the status of records held by the EMS system that contain medical information. New confidentiality provisions specify that medical records and patient-identifiable information maintained by DHHS or EMS providers are confidential and not public records and may only be released under limited circumstances.

Another law, S.L. 2001-210 (H 453), has numerous provisions regulating the EMS system that complement the changes in S.L. 2001-220. S.L. 2001-210 overhauls the statute that regulated ambulances to create a more comprehensive regulation scheme for ambulances, EMS providers (defined as organizations or agencies that provide EMS, not individual persons), and EMS personnel. EMS providers must be licensed and EMS personnel must be credentialed by DHHS. A separate permit from DHHS is required to operate an ambulance. All ambulances must be staffed by credentialed EMS personnel, with the exception of ambulances owned and operated by licensed health care facilities and used solely for transporting patients with known, nonemergency medical conditions to and from scheduled medical appointments.

Health Insurance

Patients' Bill of Rights and Related Laws

Patients' Bill of Rights. Managed care reform has been an issue in the General Assembly for the better part of a decade; however, even though numerous bills were introduced each legislative session, few changes were enacted. This year, a Patients' Bill of Rights was approved and brought about a number of significant changes. Among other things, S.L. 2001-446 (S 199) authorizes patients to sue managed care organizations for failing to exercise due care in making treatment decisions, establishes a binding procedure for independent review of coverage decisions that are adverse to insured persons, and creates a new program to assist patients in exercising their rights under the law. The major provisions of the legislation are described below.

- **External review:** The law requires insurers to establish procedures by which an insured can obtain an independent, external review of noncertification and other adverse decisions. A *noncertification* is a determination by the plan that it will not pay for a health care service because the service did not meet the plan's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or did not meet the prudent layperson standard for coverage of emergency services. In most circumstances, an insured must exhaust the insurer's internal appeal and grievance processes before seeking external review. External review decisions are binding on the insurer and on the insured, except to the extent that the insured has other remedies available under state or federal law.

- **Health plan liability:** The law establishes that managed care entities have a duty to exercise ordinary care when making *health care decisions*, defined as an entity's noncertification decisions that affect the quality of the diagnosis, care, or treatment provided to an insured. Managed care entities may be held liable for harm to insureds proximately caused by the entity's failure to exercise ordinary care. An insured must exhaust all administrative remedies and appeals before filing suit under this provision.
- **Managed Care Patient Assistance Program:** The purpose of this program is to provide information and assistance to individuals enrolled in managed care plans. Among other things, the program must assist managed care plan enrollees with grievance, appeal, and external review procedures. The law does not specify where the program will be located administratively, but it specifies that the program's director will be appointed by the Governor.
- **No financial inducements to withhold care:** The law prohibits managed care plans from financially inducing a health care provider to deny, withhold, limit, or delay medically necessary and appropriate services that are covered by the plan. However, capitation payment plans are expressly permitted, as are bonuses or the withholding of payments based on the aggregate services rendered by the provider.
- **Mandated disclosures:** Health plans are required to disclose drug formularies and lists of restricted access drugs to plan participants and prospective participants. Plans that use provider networks must maintain provider directories that are updated at least once a year and must also supply up-to-date provider information by telephone. Health insurers must provide clear explanations of how benefit amounts for covered services are calculated and how the payment obligations of the plan and the insured are determined.
- **Mandated benefits:** The law requires health plans to cover participation in clinical trials for some patients. Plans must also cover hearing screening tests for newborns.
- **Continuity of care:** The law permits patients who are enrolled in HMOs and have certain ongoing health conditions—such as chronic disabling illness, terminal illness, or pregnancy—to continue receiving care from a health care provider whose contract with the HMO is terminated. The HMO must cover the continued care from the provider for a prescribed transitional period after the contract with the provider ends. The HMO may place some conditions on the continued coverage, including a condition that the provider must accept reimbursement at rates applicable before the start of the transitional period as payment in full.
- **Selection of primary care providers:** The law requires health insurers to have procedures by which an insured with a serious or chronic degenerative, disabling, or life-threatening illness may select a specialist as his or her primary care provider. Insurers must also permit insureds to choose a pediatrician as the primary care provider for a child under the age of eighteen.

Utilization review and grievance procedures. S.L. 2001-417 (H 351) makes several significant changes to the laws governing managed care utilization reviews and grievance procedures. First, it adds to the definition of *noncertification* a determination by an insurer or its utilization review organization that a health care service did not meet the prudent layperson standard for coverage of emergency services. It also clarifies that noncertification includes any situation in which an insurer makes a decision about an insured's condition in order to decide whether a requested treatment is experimental, investigative, or cosmetic, and as a result of that decision, the extent of coverage provided by the health plan is affected.

Second, S.L. 2001-417 clarifies the procedures that must be provided for informal reconsideration of noncertifications. Previous law allowed insurers to establish procedures for informal reconsideration but didn't specify how they were to be conducted. Among other things, the new law requires insurers that permit informal reconsiderations to put those procedures in writing. If, after informal reconsideration, the insurer upholds the noncertification decision, it must notify the insured in writing. If the insurer cannot render an informal reconsideration decision within ten business days after receiving a request for informal reconsideration, it must treat the request as a request for an appeal and follow appeal procedures.

Finally, S.L. 2001-417 clarifies that an insurer need not provide access to its grievance processes for an insured whose noncertification decision was based solely on the ground that the services requested were not covered under the plan, so long as the exclusion of the specific service requested is stated clearly in the certificate of coverage.

Mandated benefits. Two new laws require health insurers to provide coverage for specified benefits. As noted above, the Patients' Bill of Rights (S.L. 2001-446) requires coverage for newborn hearing screenings and certain clinical trials. A separate law, S.L. 2001-116 (S 132), requires health plans to cover colorectal cancer screening examinations and laboratory tests for plan enrollees who are at least fifty years of age, or younger than fifty but at high risk for developing colorectal cancer. The screening that is covered must be in accordance with the most recently published guidelines of the American Cancer Society or the North Carolina Advisory Committee on Cancer Coordination and Control. Laws such as these are known as *mandated benefits* laws. In S.L. 2001-453 (H 1048), lawmakers called for a study of health insurance mandates and imposed a delayed moratorium on new mandates. The law states that legislators shall not mandate additional coverage beyond what is required on June 1, 2003, and that the moratorium on new mandates will expire on July 1, 2005.

Newborn and adopted children. An insurance omnibus bill, S.L. 2001-334 (H 310), makes a number of changes to health insurance plans, including several changes affecting the rights of consumers. The law requires health plans to extend coverage to newborn children without requiring prior notification unless there is an additional premium charge to add the child to the coverage. If there is an additional premium charge, the plan must cover the child from the moment of birth, provided that the child is enrolled within thirty days of birth. Foster and adopted children must be covered with no prior notification required unless there is an additional premium charge. If there is an additional premium charge, the coverage must be from the date of placement in the foster home or placement for adoption, provided that the child is enrolled within thirty days after placement.

New notices required. S.L. 2001-334 also requires insurers to provide certain notices to insureds. HMO group coverage plans must give written notice of premium changes upon receipt of the group's finalized benefits or forty-five days before the effective date of the change, whichever is earlier. Another provision requires insurers to give notice of the status of claims that are under investigation. G.S. 58-3-100(c) requires insurers to acknowledge a claim by making payment, making an offer of settlement, denying the claim, or informing the claimant that the claim is being investigated. The new law provides that if the claim is being investigated, the insurer must send a claim status report within forty-five days, and every forty-five days thereafter until the claim is paid or denied. The report must give details sufficient for the insured to understand why processing of the claim is incomplete and to determine whether the insurer needs additional information.

Other omnibus bill requirements. The omnibus bill enacted the following requirements as well:

- Requires successor group health plans that are contracted within fifteen days of termination of a previous group plan to cover the hospital confinement or pregnancy of a person who is otherwise eligible for coverage under the plan
- Requires a sixty-day period for employees whose employment has been terminated to elect continuing coverage under an employer-sponsored health plan
- Prohibits health insurers from imposing preexisting condition exclusions for conditions diagnosed or treated while the person had qualifying previous coverage, provided that the coverage did not end more than sixty-three days before enrollment for the new coverage
- Provides that persons eligible for Medicare by reason of disability before age sixty-five whose coverage in a managed care plan is terminated through cancellation, nonrenewal, or disenrollment have the guaranteed right to purchase Medicare Supplement Plans A and C from any insurer within sixty-three days

Insurance fiduciaries. A new law addresses the obligations of insurance fiduciaries to insured persons. An *insurance fiduciary* is defined as any person, employer, principal, agent,

trustee, or third-party administrator responsible for the payment of group health or life insurance premiums or responsible for funding a group health plan. Under previous law, insurance fiduciaries were prohibited from causing the cancellation or nonrenewal and consequential loss of coverage to insured persons by willfully failing to pay premiums. S.L. 2001-422 (S 241) adds that an insurance fiduciary may not terminate a group health plan by willfully failing to fund it. An insurance fiduciary must provide written notice of its intention to stop paying premiums or funding a plan at least forty-five days before the termination of the insurance. Willful failure to do so is a Class H felony.

Teachers' and State Employees' Health Plan

Benefits under the Teachers' and State Employees' Comprehensive Major Medical Plan (State Health Plan) were curtailed in this tight budget year. S.L. 2001-253 (S 824) raises required deductibles and authorizes the State Health Plan's Executive Administrator and Board of Trustees to increase deductibles annually by a percentage equal to the percentage increase in the CPI-Medical Index. Certain co-payments for services were increased, as were out-of-pocket maximums for deductibles and co-payments. Prescription drug co-payments were increased and made subject to a separate out-of-pocket maximum. Maximum benefit amounts were set for certain services or products, including cardiac rehabilitation services, therapeutic shoes for persons with diabetes, and other specified conditions. The maximum lifetime benefit amount available under the State Health Plan was increased from \$2 million to \$5 million. The law authorizes the Executive Administrator and Board of Trustees to require prior approval for several services, including varicose vein surgery, botulinum toxin treatments,² and outpatient prescriptions for growth hormone, weight loss drugs, and antifungal drugs for the treatment of nail fungus. Another law, S.L. 2001-258 (H 109), authorizes the State Health Plan to reimburse licensed marriage and family therapists for mental health and chemical dependency services.

G.S. 135-40.12(a)(6) permits laid-off state employees who were employed for twelve months or more before their termination to continue their health coverage on a noncontributory basis for up to twelve months following their termination. G.S. 135-40.12(b)(12) authorizes those employees to continue their coverage after expiration of the twelve months on a fully contributory basis. Section 86(a) of S.L. 2001-487 (H 338), the 2001 Technical Corrections Act, provides that former state employees have ninety days after termination of their noncontributory continuing coverage to elect fully contributory continuing coverage.

S.L. 2001-192 (S 825) exempts contract disputes between the State Health Plan and entities under contract with the plan from the contested case provisions of the Administrative Procedure Act.

Finally, Section 4 of S.L. 2001-516 (H 1284) provides that state health plan contract terms pertaining to reimbursement rates for hospitals, medical care providers, and pharmacy benefit managers are not public records until thirty months after the contract's expiration date.

Other Health Insurance Regulation

Several new laws make miscellaneous changes affecting health insurance. Two laws were enacted in the context of a dispute between the Teachers' and State Employees' Comprehensive Major Medical Plan (State Health Plan) and an HMO with which it had contracted. In February 2001, the HMO WellPath announced its intention to end its coverage for state employees in thirteen North Carolina counties. State officials contended that this was a breach of contract and took actions to force the company to continue the coverage. In the meantime, the General Assembly enacted S.L. 2001-5 (S 168), which authorizes the Insurance Commissioner to issue an order directing an HMO to cease and desist from engaging in any act or practice in violation of

2. The botulinum toxin treatments mentioned in S.L. 2001-253 presumably are those that are known colloquially as "botox" and are often used for cosmetic purposes.

any provision of G.S. Chapter 58 applicable to HMOs. An HMO in receipt of such an order is authorized to seek review of the order in accordance with the state Administrative Procedure Act (APA).

Early in the spring, WellPath and the state entered a consent agreement in which WellPath agreed to continue the coverage until the Office for Administrative Hearings (OAH) or a court made a decision about the contract issue. In May 2001, OAH ruled that WellPath could end its coverage for state employees if it gave thirty days' notice and forfeited a \$500,000 deposit. WellPath subsequently gave notice that it would end coverage for all state employees effective July 1, 2001. The legislature then enacted S.L. 2001-192, which exempts contract disputes between the State Health Plan and entities under contract with the plan from the contested case provisions of the APA. The law also provides that state agencies may apply for declaratory judgments in superior court. The state then filed a lawsuit charging WellPath with breach of contract and unfair and deceptive trade practices. On June 19, 2001, a superior court temporarily enjoined WellPath from changing its coverage of state employees. WellPath ultimately provided coverage for state employees through the end of the contract year.

Although they may have been prompted by the state's dispute with WellPath, neither of the two new laws has a sunset date or any other provision limiting its application to that context.

The credentialing of health care providers by insurance companies is addressed by S.L. 2001-172 (H 1160), which requires health insurers that credential providers for their networks to assess and verify providers' qualifications within sixty days of receipt of a completed provider credentialing application form. The law also requires the Insurance Commissioner to adopt a uniform provider credentialing application form and prohibits insurers from requiring applicants to submit information that is not on the form.

S.L. 2001-297 (H 593) requires health insurers that pay or reimburse the services of licensed professional counselors to make payment either by direct payment to the provider or by reimbursement of the insured.

Health Insurance Studies

The 2001 Studies Act, S.L. 2001-491, authorizes the Legislative Research Commission to study the following issues related to health insurance:

- High-risk health insurance pools
- Insurance availability in beach and coastal areas
- The moratorium on health insurance mandates established in S.L. 2001-453 (summarized above)

Health Care Facilities

Adult and Long-Term Care Facilities

For several years, the legislature has attempted to slow the development of beds in adult care homes in North Carolina. In the past, it has done this by directing DHHS not to approve the addition of any adult care home beds for any home or facility in the state unless certain conditions for exemption from the moratorium were met. This year, the General Assembly enacted S.L. 2001-234 (S 937), which makes adult care homes subject to the state's certificate of need law. In addition, S.L. 2001-234 provides that a person who obtained a license to develop beds in previous years by satisfying the conditions for exemption is no longer authorized to develop the beds unless the person can satisfy criteria indicating that development is already well underway.

S.L. 2001-85 (H 736), as clarified by the 2001 Technical Corrections Act,³ requires adult care homes and nursing homes subject to licensure under G.S. Chapter 131E to post notices about

3. S.L. 2001-487, Section 85 (H 338).

required staffing levels. The notices must enable residents and their family members to ascertain the number of direct care and supervisory staff that are legally required to be on duty for each shift in a given day.

Previous state law required adult care homes with a capacity of seven or more beds to submit audited reports of actual costs to DHHS. S.L. 2001-157 (H 958) adds a new requirement for adult care homes with special care units for patients with Alzheimer's disease or other specified conditions. The new law requires separate cost reports that are specific to the special care unit and that do not average special care costs with other costs. DHHS must use the data from those reports to develop a designated reimbursement system for residents in special care units.

The 2001 Appropriations Act, S.L. 2001-424, includes several special provisions pertaining to adult care homes or long-term care facilities. One provision requires DHHS to implement recommendations that appeared in a state auditor's report regarding adult care home reimbursement rates. Among other things, DHHS must continue its efforts to obtain a federal waiver to pay adult care homes directly for client services and must develop a plan to phase in electronic filing of cost reports. Another provision directs DHHS to develop a system that provides a continuum of long-term care for elderly and disabled individuals.

S.L. 2001-17 (H 193) provides partial or total exclusions from property taxes to adult care homes and nursing homes that meet certain criteria. To qualify, a facility must be nonprofit with tax-exempt income status under state law, must have an active program to generate funds through grants or other means, and must apply all of its revenues toward providing uncompensated goods and services to the elderly and the local community.

Several North Carolina statutes require long-term and adult care facilities to conduct national criminal history checks on prospective employees. However, federal requirements have limited the distribution of national criminal history checks until January 1, 2003. Accordingly, in S.L. 2001-465 (S 826), the General Assembly temporarily suspended the national check requirement for certain long-term care employees. For nursing homes and home care agencies, the requirement of a national criminal history check will apply only to employment positions involving direct patient care. Requirements to conduct the checks for other positions are suspended until January 1, 2003. Requirements for national criminal history checks are also suspended until that date for the following entities: contract agencies of nursing homes and home care agencies; adult care homes and their contract agencies; and area mental health, developmental disabilities, and substance abuse services programs.

S.L. 2001-482 (S 178) directs DHHS to develop an instrument for assessing the quality of care provided by adult care homes. The instrument must address care, services, and physical plant amenities and conditions. The assessments may be conducted by the state or local government.

The 2001 Studies Act, S.L. 2001-491, directs the DHHS Division of Aging to study whether counties should designate local lead agencies to organize a local long-term care planning process.

Finally, S.L. 2001-385 (H 1068) directs DHHS to undertake several studies and other activities relating to the quality of care in long-term care facilities. The Department must

- develop an Adult Care Home Quality Improvement Consultation Program to assist providers in developing quality improvement plans for their facilities,
- develop a Skilled Nursing Facility Quality Improvement Consultation Program to provide similar services for long-term care facilities offering skilled nursing services,
- convene a Skilled Nursing Facility Quality of Standards Work Group to explore alternatives to existing oversight and survey practices, and
- explore methods to improve and reward quality of care in adult care homes. (DHHS must study whether the licensure period and survey period for adult care homes are factors in providing quality care, whether to cap allowable indirect costs for the homes, whether a different approach to setting reimbursement rates should be adopted, and whether aspects of the quality assessment and monitoring process should be changed.)

Hospitals and Ambulatory Surgical Facilities

In June 2000, the North Carolina Court of Appeals held that the state had applied certificate of need law arbitrarily and capriciously when it imposed requirements on an ambulatory surgical facility that planned an expansion and did not impose the same requirements on a hospital planning a similar expansion. The General Assembly responded by enacting a moratorium on the relocation or expansion of ambulatory surgical facilities (S.L. 2000-135). During the 2001 legislative session, the legislature enacted S.L. 2001-242 (S 714), which repeals the moratorium and modifies certificate of need law to apply the same requirements to all operating rooms. The law exempts from its provisions projects that meet two criteria. First, a capital expenditure (or a legally binding obligation for a capital expenditure) exceeding \$50,000 must have been in effect on or before June 23, 2001. Second, the project must reasonably be expected to be completed by December 31, 2002.

S.L. 2001-410 (H 1147) makes several changes to the laws governing hospitals. First, it authorizes a hospital to temporarily increase its bed capacity by up to 10 percent over its licensed capacity by using observation beds for hospital inpatients if the hospital notifies and obtains the approval of the state Division for Facility Services. The temporary increase may not continue for more than sixty consecutive days. Second, the law authorizes the Medical Care Commission to adopt temporary rules setting forth conditions for licensing all levels of neonatal care beds. Finally, it replaces the existing reimbursement schedule for hospitals that treat workers' compensation patients with a provision authorizing the Industrial Commission to set reasonable fees.

Previous law exempted from North Carolina's public records law information maintained by public hospitals that related to competitive health care activities, with the exception of contracts entered by or on behalf of a public hospital. S.L. 2001-516 (H 1284) amends that law to exempt public hospitals' contracts that contain competitive health care information from the public records law. The new law authorizes public hospitals, upon a good faith belief that a contract contains competitive health care information, to redact those portions of the contract before disclosing it. If the entire contract constitutes competitive health care information, the hospital may refuse to disclose it.

Health Care Facilities Studies

The 2001 Studies Act, S.L. 2001-491, authorizes the Legislative Research Commission to study the availability of liability insurance for physicians, long-term care facilities, and hospitals. The act authorizes the Joint Legislative Health Care Oversight Committee to study long-term care aide workforce issues.

Health Care Providers

Physicians

In S.L. 2001-27 (S 118), the legislature amended G.S. 90-18 to clarify that any person who uses the Internet, a toll-free telephone number, or other electronic means to prescribe medication or otherwise practice medicine in North Carolina must be licensed by the North Carolina Medical Board. The law provides an exception for physicians in other states or foreign countries who are contacted by a regular patient for treatment while the patient is temporarily in North Carolina.

Nurses

The North Carolina Board of Nursing was given new means by which to discipline a nurse in S.L. 2001-98 (S 463). The law authorizes the board to place a nurse on probation, to set conditions of probation, and to invoke other disciplinary measures against a licensee that the board deems fit

and proper. The board may reinstate a nurse's license or revoke censure or probation when it finds that the reasons for the disciplinary action no longer exist and that the nurse can reasonably be expected to practice safely and properly.

S.L. 2001-371 (S 195) authorizes the Board of Nursing to require criminal history record checks of persons who apply to practice nursing in North Carolina.

Dentists

S.L. 2001-511 (S 772) authorizes the North Carolina Board of Dental Examiners to regulate the administration and monitoring of outpatient enteral sedation. The new law does not define enteral sedation, but it states that oral premedication administered for minimal sedation shall not be included in the definition. Previously, the board was authorized to set standards only for general anesthesia and parenteral sedation.

Chiropractors

S.L. 2001-281 (H 722) authorizes the Board of Chiropractic Examiners to seek an injunction in superior court to prevent a person from practicing chiropractic without a license in North Carolina.

Pharmacists and Pharmacy Technicians

The legislature enacted a new law requiring pharmacy technicians to be registered and authorizing the North Carolina Board of Pharmacy to establish registration criteria. The law also authorizes the board to discipline pharmacy technicians. S.L. 2001-375 (S 446) defines a *pharmacy technician* as "a person who may, under the supervision of a pharmacist, perform technical functions to assist the pharmacist in preparing and dispensing prescription medications." The law makes it unlawful for any owner or manager of a pharmacy to allow anyone other than a pharmacist to dispense or compound prescription drugs unless that person is a pharmacy technician or a student in a board-approved school of pharmacy and is working under the supervision of a pharmacist. A person employed as a pharmacy technician before January 1, 2002, may register with the board without completing a required training program if the person's pharmacist-manager certifies to the board that the person has the training necessary to serve as a pharmacy technician and the person registers by July 1, 2002.

Another law, S.L. 2001-339 (H 437), clarifies that any entity that delivers or dispenses devices or medical equipment to a user in North Carolina must comply with the registration requirements of the North Carolina Board of Pharmacy, regardless of whether the entity is located in this state. This requirement does not apply to a pharmaceutical manufacturer that is registered with the federal Food and Drug Administration.

Provider Liability

Volunteer providers. G.S. 90-21.16, the "Good Samaritan law," provides qualified immunity to health care providers who volunteer their services at specified health care facilities or to specified patients. Providers who fall within the scope of the law cannot be held liable for injuries or deaths they cause unless it can be shown that the injuries or deaths were caused by gross negligence, wanton conduct, or intentional wrongdoing. S.L. 2001-230 (S 160) extends those liability limitations to additional health care providers. Previously the law applied to volunteer providers providing services at health departments or nonprofit community health centers, volunteer providers providing services in their own offices to patients of health departments or nonprofit community health centers, volunteer providers serving as medical directors of EMS agencies, and retired physicians holding limited volunteer licenses. The new law adds volunteer providers providing services at a nonprofit free clinic facility.

Portable DNR orders. Another new law clarifies the immunity from liability of health care providers who honor portable do not resuscitate (DNR) orders. S.L. 2001-445 (S 703) requires DHHS to develop a portable DNR order form and authorizes physicians to issue a portable DNR order for a patient upon the receipt of proper consent. It provides that no physician, emergency medical professional, hospice provider, or other health care provider may be held criminally or civilly liable for withholding cardiopulmonary resuscitation from a patient in good faith reliance on an original DNR order unless there are reasonable grounds for doubting the validity of the order or the identity of the patient, or the provider has actual knowledge that the order has been revoked. Immunity from liability is also extended to providers who fail to follow portable DNR orders if the provider had no actual knowledge of the existence of the order.

Health Care Provider Studies

The 2001 Studies Act, S.L. 2001-491, authorizes the Legislative Research Commission to study the following issues related to health care providers:

- Impact of licensure and reimbursement requirements for licensed psychological associates on health care and on these practitioners
- Availability of liability insurance for physicians, long-term care facilities, and hospitals

Other Laws

Advance Health Care Directives Registry

North Carolina law authorizes individuals to execute a number of documents that are known collectively as “advance health care directives.” This catchall category includes: declaration of desire for a natural death, health care power of attorney, advance instruction for mental health treatment, and declaration of an anatomical gift. In S.L. 2001-455 (H 1362), the legislature directed the Secretary of State to establish and maintain a statewide, Internet-based central registry for advance health care directives. The new law permits persons who execute advance health care directives to submit those documents and revocations of directives to the Secretary of State for filing in the registry. Each document entered in the registry must be assigned a unique file number and password and must be accessible only to persons who enter both the file number and the password. Advance directives need not be filed with the registry to be valid.

Anatomical Gifts

S.L. 2001-255 (S 1075) makes two substantive amendments to the Uniform Anatomical Gift Act. First, it adds to the definition of *tissue bank* facilities and programs registered with the federal Food and Drug Administration. Second, it authorizes additional persons to perform procedures related to gifts of eye tissue. Under previous law, the only individuals authorized to enucleate eyes were those who had completed coursework and been certified as competent by an accredited school of medicine in North Carolina. S.L. 2001-255 adds to the definition of *qualified individuals* persons who have been certified as competent by an eye bank accredited by the Eye Bank Association of America.

S.L. 2001-481 (S 907) amends G.S. 130A-404(a) to clarify that if an organ, eye, or tissue donor makes a gift in accordance with G.S. 130A-406,⁴ the gift is legally sufficient and additional authority from the donor’s family or estate is neither required nor permitted. The law states that an anatomical gift made in accordance with G.S. 130A-406 may not be revoked upon the donor’s death, nor may the donor’s family or health care agent refuse to honor the gift or thwart the procurement of the donation. S.L. 2001-481 also requires the Division of Motor Vehicles to make

4. G.S. 130A-406 specifies the ways in which individuals may make anatomical gifts.

donor cards available to interested individuals in offices that issue driver's licenses or special identification cards, and it directs the DHHS Division of Public Health to study the establishment of a state donor registry.

Studies

In addition to the studies already noted in this chapter, the 2001 Studies Act, S.L. 2001-491, authorizes the Legislative Research Commission to study the following:

- State medical examiner system
- Naturopathy

The Studies Act authorizes the Joint Legislative Health Care Oversight Committee to study the following:

- Medical services to persons with disabilities
- Several issues associated with the cost and availability of prescription drugs, particularly for elderly or disabled persons

The act authorizes the Joint Select Committee on Information Technology to study a number of issues related to privacy and security, including the privacy and security of medical records, personal health information, and personal insurance information.

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