**GENERAL ASSEMBLY OF NORTH CAROLINA**
**SESSION 2003**

**SESSION LAW 2003-393**
**SENATE BILL 1016**

AN ACT REQUIRING NURSING HOMES TO ESTABLISH A MEDICATION MANAGEMENT ADVISORY COMMITTEE AND SPECIFYING THE DUTIES OF THE COMMITTEE AND TO REQUIRE NURSING HOMES TO DO CERTAIN THINGS PERTAINING TO THE REDUCTION OF MEDICATION-RELATED ERRORS TO INCREASE PATIENT SAFETY.

The General Assembly of North Carolina enacts:

**SECTION 1.** Part 2 of Article 6 of Chapter 131E of the General Statutes is amended by adding the following new sections to read:

"**§ 131E-128.1. Nursing home medication management advisory committee.**

(a) Definitions. – As used in this section, unless the context requires otherwise, the term:

(1) 'Advisory committee' means a medication management committee established under this section to advise the quality assurance committee.

(2) 'Medication-related error' means any preventable medication-related event that adversely affects a patient in a nursing home and that is related to professional practice, or health care products, procedures, and systems, including prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

(3) 'Nursing home' means a nursing home licensed under this Chapter and includes an adult care home operated as part of a nursing home.

(4) 'Potential medication-related error' means a medication-related error that has not yet adversely affected a patient in a nursing home, but that has the potential to if not anticipated or prevented or if left unnoticed.

(5) 'Quality assurance committee' means a committee established in a nursing home in accordance with federal and State regulations to identify circumstances requiring quality assessment and assurance activities and to develop and implement appropriate plans of action to correct deficiencies in quality of care.

(b) Purpose. – It is the purpose of the General Assembly to enhance compliance with this Part through the establishment of medication management advisory committees in nursing homes. The purpose of these committees is to assist nursing homes to identify medication-related errors, evaluate the causes of those errors, and take appropriate actions to ensure the safe prescribing, dispensing, and administration of medications to nursing home patients.

(c) Advisory Committee Established; Membership. – Every nursing home shall establish a medication management advisory committee to advise the quality assurance committee on quality of care issues related to pharmaceutical and medication management and use in the nursing home. The nursing home shall maintain the advisory committee as part of its administrative duties. The advisory committee shall be interdisciplinary and consist of the nursing home administrator and at least the following members appointed by the nursing home administrator:

(1) The director of nursing.
(2) The consultant pharmacist.
(3) A physician designated by the nursing home administrator.
(4) At least three other members of the nursing home staff.

(d) Meetings. – The advisory committee shall meet as needed but not less frequently than quarterly. The Director of Nursing or Staff Development Coordinator shall chair the advisory committee. The nursing home administrator shall ensure that a record is maintained of each meeting.

(e) Confidentiality. – The meetings or proceedings of the advisory committee, the records and materials it produces, and the materials it considers, including analyses and reports pertaining to medication-related error reporting under G.S. 131E-128.2 and G.S. 131E-128.5 and pharmacy reports on drug defects and adverse reactions under G.S. 131E-128.4, shall be confidential and not be considered public records within the meaning of G.S. 132-1. The meetings or proceedings and records and materials also shall not be subject to discovery or introduction into evidence in any civil action against a nursing home or a provider of professional health services resulting from matters that are the subject of evaluation and review by the committee. No person who was in attendance at a meeting of the committee shall testify in any civil action as to any evidence or other matters produced or presented during the meetings or proceedings of the committee or as to any findings, recommendations, evaluations, opinions, or other actions of the committee or its members. Notwithstanding the foregoing:

(1) Information, documents, or records otherwise available, including any deficiencies found in the course of an inspection conducted under G.S. 131E-105, shall not be immune from discovery or use in a civil action merely because they were presented during meetings or proceedings of the advisory committee. A member of the advisory committee or a person who testifies before the committee may testify in a civil action but cannot be asked about that person's testimony before the committee or any opinion formed as a result of the committee meetings or proceedings.

(2) Information that is confidential and not subject to discovery or use in civil actions under this subsection may be released to a professional standards review organization that performs any accreditation or certification function. Information released to the professional standards review organization shall be limited to information reasonably necessary and relevant to the standards review organization's determination to grant or continue accreditation or certification. Information released to the standards review organization retains its confidentiality and is not subject to discovery or use in any civil action as provided under this subsection. The standards review organization shall keep the information confidential subject to this subsection.

(3) Information that is confidential and not subject to discovery or use in civil actions under this subsection may be released to the Department of Health and Human Services pursuant to its investigative authority under G.S. 131E-105. Information released to the Department shall be limited to information reasonably necessary and relevant to the Department's investigation of compliance with Part 1 of Article 6 of this Chapter. Information released to the Department retains its confidentiality and is not subject to discovery or use in any civil action as provided in this subsection. The Department shall keep the information confidential subject to this subsection.

(4) Information that is confidential and is not subject to discovery or use in civil actions under this subsection may be released to an occupational licensing board having jurisdiction over the license of an

individual involved in an incident that is under review or investigation by the advisory committee. Information released to the occupational licensing board shall be limited to information reasonably necessary and relevant to an investigation being conducted by the licensing board pertaining to the individual's involvement in the incident under review by the advisory committee. Information released to an occupational licensing board retains its confidentiality and is not subject to discovery or use in any civil action as provided in this subsection. The occupational licensing board shall keep the information confidential subject to this subsection.

(f) Duties. – The advisory committee shall do the following:

(1) Assess the nursing home's pharmaceutical management system, including its prescribing, distribution, administration policies, procedures, and practices and identify areas at high risk for medication-related errors.

(2) Review the nursing home's pharmaceutical management goals and respond accordingly to ensure that these goals are being met.

(3) Review, investigate, and respond to nursing home incident reports, deficiencies cited by licensing or credentialing agencies, and resident grievances that involve actual or potential medication-related errors.

(4) Identify goals and recommendations to implement best practices and procedures, including risk reduction technology, to improve patient safety by reducing the risk of medication-related errors.

(5) Develop recommendations to establish a mandatory, nonpunitive, confidential reporting system within the nursing home of actual and potential medication-related errors.

(6) Develop specifications for drug dispensing and administration documentation procedures to ensure compliance with federal and State law, including the North Carolina Nursing Practice Act.

(7) Develop specifications for self-administration of drugs by qualified patients in accordance with law, including recommendations for assessment procedures that identify patients who may be qualified to self-administer their medications.

(g) Penalty. – The Department may take adverse action against the license of a nursing home upon a finding that the nursing home has failed to comply with this section, G.S. 131E-128.2, 131E-128.3, 131E-128.4, or 131E-128.5.

"**§ 131E-128.2. Nursing home quality assurance committee; duties related to medication error prevention.**

Every nursing home administrator shall ensure that the nursing home quality assurance committee develops and implements appropriate measures to minimize the risk of actual and potential medication-related errors, including the measures listed in this section. The design and implementation of the measures shall be based upon recommendations of the medication management advisory committee and shall:

(1) Increase awareness and education of the patient and family members about all medications that the patient is using, both prescription and over-the-counter, including dietary supplements.

(2) Increase prescription legibility.

(3) Minimize confusion in prescription drug labeling and packaging, including unit dose packaging.

(4) Develop a confidential and nonpunitive process for internal reporting of actual and potential medication-related errors.

(5) To the extent practicable, implement proven medication safety practices, including the use of automated drug ordering and dispensing systems.

(6) Educate facility staff engaged in medication administration activities on similar-sounding drug names.
(7) Implement a system to accurately identify recipients before any drug is administered.
(8) Implement policies and procedures designed to improve accuracy in medication administration and in documentation by properly authorized individuals, in accordance with prescribed orders and stop order policies.
(9) Implement policies and procedures for patient self-administration of medication.
(10) Investigate and analyze the frequency and root causes of general categories and specific types of actual or potential medication-related errors.
(11) Develop recommendations for plans of action to correct identified deficiencies in the facility's pharmaceutical management practices.

"**§ 131E-128.3. Staff orientation on medication error prevention.**

The nursing home administrator shall ensure that the nursing home provide a minimum of one hour of education and training in the prevention of actual or potential medication-related errors. This training shall be provided upon orientation and annually thereafter to all nonphysician personnel involved in direct patient care. The content of the training shall include at least the following:

(1) General information relevant to the administration of medications including terminology, procedures, routes of medication administration, potential side effects, and adverse reactions.
(2) Additional instruction on categories of medication pertaining to the specific needs of the patient receiving the medication.
(3) The facility's policy and procedures regarding its medication administration system.
(4) How to assist patients with safe and accurate self-administration of medication, where appropriate.
(5) Identifying and reporting actual and potential medication-related errors.

"**§ 131E-128.4. Nursing home pharmacy reports; duties of consultant pharmacist.**

(a) The consultant pharmacist for a nursing home shall conduct a drug regimen review for actual and potential drug therapy problems in the nursing home and make remedial or preventive clinical recommendations into the medical record of every patient receiving medication. The consultant pharmacist shall conduct the review at least monthly in accordance with the nursing home's policies and procedures.

(b) The consultant pharmacist shall report and document any drug irregularities and clinical recommendations promptly to the attending physician or nurse-in-charge and the nursing home administrator. The reports shall include problems identified and recommendations concerning:

(1) Drug therapy that may be affected by biological agents, laboratory tests, special dietary requirements, and foods used or administered concomitantly with other medication to the same recipient.
(2) Monitoring for potential adverse effects.
(3) Allergies.
(4) Drug interactions, including interactions between prescription drugs and over-the-counter drugs, drugs and disease, and interactions between drugs and nutrients.
(5) Contraindications and precautions.
(6) Potential therapeutic duplication.
(7) Overextended length of treatment of certain drugs typically prescribed for a short period of time.

(8) Beer's listed drugs that are potentially inappropriate for use by elderly persons.

(9) Undertreatment or medical conditions that are suboptimally treated or not treated at all that warrant additional drug therapy to ensure quality of care.

(10) Other identified problems and recommendations.

(c) The consultant pharmacist shall report drug product defects and adverse drug reactions in accordance with the ASHSP-USP-FDA Drug Product Defect Reporting System and the USP Adverse Drug Reaction Reporting System. The term "ASHSP-USP-FDA" means American Society of Health System Pharmacists-United States Pharmacopoeia-Food and Drug Administration. Information released to the ASHSP-USP-FDA retains its confidentiality and is not subject to discovery or use in any civil action as provided under G.S. 131E-128.1.

(d) The consultant pharmacist shall ensure that all known allergies and adverse effects are documented in plain view in the patient's medical record, including the medication administration records, and communicated to the dispensing pharmacy. The specific medications and the type of allergy or adverse reaction shall be specified in the documentation.

(e) The consultant pharmacist shall ensure that drugs that are not specifically limited as to duration of use or number of doses shall be controlled by automatic stop orders. The consultant pharmacist shall further ensure that the prescribing provider is notified of the automatic stop order prior to the dispensing of the last dose so that the provider may decide whether to continue to use the drug.

(f) The consultant pharmacist shall, on a quarterly basis, submit a summary of the reports submitted under subsections (a) and (b) of this section to the medication management advisory committee established under G.S. 131E-128.1. The summary shall not include any information that would identify a patient, a family member, or an employee of the nursing home. The purpose of the summary shall be to facilitate the identification and analysis of weaknesses in the nursing home's pharmaceutical care system that have an adverse impact on patient safety.

"**§ 131E-128.5. Medication-related error reports.**

(a) The Secretary of Health and Human Services shall contract with a public or private entity to develop and implement a Medication Error Quality Initiative. The Initiative would provide for, among other things, receipt and analysis by the contracting entity of annual reports from each nursing home on the nursing home's medication-related errors. The report submitted by the nursing home shall not contain information that would identify the patient, the individual reporting the error, or other persons involved in the occurrence. The report shall include the following:

(1) The total number of medication-related errors for the preceding year.

(2) A listing of the types of medication-related errors, the number of medication-related errors, the root cause analysis of each error, and the staff level involved.

(3) A listing of the types of injuries caused and the number of injuries occurring.

(4) The types of liability claims filed based on an adverse incident or reportable injury.

(b) The contracting entity shall provide for analysis of the medication-related error reports to determine trends in the incidence of medication-related errors in nursing homes. Information released to the contractor retains its confidentiality and is not subject to discovery or use in any civil action as provided under G.S. 131E-128.1, and the contractor shall keep the information confidential subject to that section."

**SECTION 2.** The Department shall use available grants and federal funds to implement G.S. 131E-128.5 as enacted in this act.

**SECTION 3.** This act becomes effective January 1, 2004.

In the General Assembly read three times and ratified this the 16th day of July, 2003.

s/ Marc Basnight
President Pro Tempore of the Senate

s/ Richard T. Morgan
Speaker of the House of Representatives

s/ Michael F. Easley
Governor

Approved 5:27 p.m. this 7th day of August, 2003