

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2003

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SENATE BILL 1016

Short Title: Nursing Home/Medication Errors.

(Public)

Sponsors: Senator Berger.

Referred to: Health & Human Resources.

April 3, 2003

1 A BILL TO BE ENTITLED  
2 AN ACT REQUIRING NURSING HOMES TO ESTABLISH A MEDICATION  
3 MANAGEMENT ADVISORY COMMITTEE AND SPECIFYING THE DUTIES  
4 OF THE COMMITTEE, AND TO REQUIRE NURSING HOMES TO DO  
5 CERTAIN THINGS PERTAINING TO THE REDUCTION OF  
6 MEDICATION-RELATED ERRORS TO INCREASE PATIENT SAFETY.

7 The General Assembly of North Carolina enacts:

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

10 **"§ 131E-128.1. Nursing home medication management advisory committee.**

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

- 13 (1) 'Advisory committee' means a medication management committee  
14 established under this section to advise the quality assurance  
15 committee.
- 16 (2) 'Medication-related error' means any preventable medication-related  
17 event that adversely affects a patient in a nursing home and that is  
18 related to professional practice, or health care products, procedures,  
19 and systems, including, but not limited to, prescribing, prescription  
20 order communications, product labeling, packaging and nomenclature,  
21 compounding, dispensing, distribution, administration, education,  
22 monitoring, and use.
- 23 (3) 'Nursing home' means a nursing home licensed under this Chapter and  
24 includes an adult care home operated as part of a nursing home.
- 25 (4) 'Potential medication-related error' means a medication-related error  
26 that has not yet adversely affected a patient in a nursing home, but that  
27 has the potential to if not anticipated or prevented or if left unnoticed.
- 28 (5) 'Quality assurance committee' means a quality assurance committee  
29 established in accordance with federal and State regulations to identify

1 issues with respect to which quality assessment and assurance  
2 activities are necessary and to develop and implement appropriate  
3 plans of action to correct deficiencies in quality of care.

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

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

17 (1) The director of nursing.

18 (2) The consultant pharmacist.

19 (3) A physician designated by the nursing home administrator.

20 (4) At least three other members of the nursing home staff.

21 (d) Meetings. – The advisory committee shall meet as needed but not less  
22 frequently than quarterly. The pharmacist shall chair the advisory committee.

23 (e) Confidentiality. – The administrator shall ensure that a record is maintained  
24 of each meeting:

25 (1) The meetings or proceedings of the advisory committee, the records  
26 and materials it produces and the materials it considers, including  
27 analyses and reports pertaining to medication-related error reporting  
28 under G.S. 131E-128.2 and G.S. 131E-128.5 and pharmacy reports on  
29 drug defects and adverse reactions under G.S. 131E-128.4, shall be  
30 confidential and not considered public records within the meaning of  
31 G.S. 132-1, "Public records defined", and shall not be subject to  
32 discovery or introduction into evidence in any civil action against a  
33 nursing home licensed under this Article, or a provider of professional  
34 health services which results from matters which are the subject of  
35 evaluation and review by the committee. No person who was in  
36 attendance at a meeting of the committee may testify in any civil  
37 action as to any evidence or other matters produced or presented  
38 during the meetings or proceedings of the committee or as to any  
39 findings, recommendations, evaluations, opinions, or other actions of  
40 the committee or its members. However, information, documents, or  
41 records otherwise available, including any deficiencies found  
42 in the course of an inspection conducted under G.S. 131E-105, are not  
43 immune from discovery or use in a civil action merely because they  
44 were presented during meetings or proceedings of the committee. A

1           member of the committee or a person who testifies before the  
2           committee may testify in a civil action but cannot be asked about his  
3           testimony before the committee or any opinion formed as a result of  
4           the committee meetings or proceedings.

5           (2) Information that is confidential and is not subject to discovery or use  
6           in civil actions under subdivision (1) of this subsection may be  
7           released to a professional standards review organization that performs  
8           any accreditation or certification function. Information released to the  
9           professional standards review organization shall be limited to that  
10           which is reasonably necessary and relevant to the standards review  
11           organizations' determination to grant or continue accreditation or  
12           certification. Information released to the standards review organization  
13           retains its confidentiality and is not subject to discovery or use in any  
14           civil action as provided under subdivision (1) of this subsection, and  
15           the standards review organization shall keep the information  
16           confidential subject to subdivision (1) of this subsection.

17           (3) Information that is confidential and is not subject to discovery or use  
18           in civil actions under subdivision (1) of this section may be released to  
19           the Department of Health and Human Services pursuant to its  
20           investigative authority under G.S. 131E-105. Information released to  
21           the Department shall be limited to that which is reasonably necessary  
22           and relevant to the Department's investigation of compliance with Part  
23           1 of Article 6 of this Chapter. Information released to the Department  
24           retains its confidentiality and is not subject to discovery or use in any  
25           civil action as provided in subdivision (1) of this subsection, and the  
26           Department shall keep the information confidential subject to  
27           subdivision (1) of this subsection.

28           (4) Information that is confidential and is not subject to discovery or use  
29           in civil actions under subdivision (1) of this section may be released to  
30           an occupational licensing board having jurisdiction over the license of  
31           an individual involved in an incident that is under review or  
32           investigation by the advisory committee. Information released to the  
33           occupational licensing board shall be limited to that which is  
34           reasonably necessary and relevant to an investigation being conducted  
35           by the licensing board pertaining to the individual's involvement in the  
36           incident under review by the advisory committee. Information released  
37           to an occupational licensing board retains its confidentiality and is not  
38           subject to discovery or use in any civil action as provided in  
39           subdivision (1) of this subsection, and the occupational licensing board  
40           shall keep the information confidential subject to subdivision (1) of  
41           this subsection.

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

- 1           (1) Assess the facility's pharmaceutical management system, including,  
2 prescribing, distribution, and administration policies, procedures, and  
3 practices and identify areas at high risk for medication-related errors.
- 4           (2) Review the facility's pharmaceutical management quality indicators  
5 and respond accordingly to ensure that these indicators are being met.
- 6           (3) Review, investigate, and respond to facility incident reports,  
7 deficiencies cited by licensing or credentialing agencies, and resident  
8 grievances that involve actual or potential medication-related errors.
- 9           (4) Investigate and analyze the frequency and root causes of general  
10 categories and specific types of actual or potential medication-related  
11 errors.
- 12           (5) Develop recommendations for plans of action to correct identified  
13 deficiencies in the facility's pharmaceutical management practices.
- 14           (6) Identify goals and recommendations for the implementation of best  
15 practices and procedures, including risk reduction technology, to  
16 improve patient safety by reducing the risk of medication-related  
17 errors.
- 18           (7) Develop recommendations for the establishment of a mandatory,  
19 nonpunitive, confidential reporting system within the facility of actual  
20 and potential medication-related errors.
- 21           (8) Develop specifications for drug administration documentation  
22 procedures to ensure compliance with federal and State law.
- 23           (9) Develop specifications for self-administration of drugs by qualified  
24 patients in accordance with law, including recommendations for  
25 assessment procedures as to which patients may be qualified to  
26 self-administer their medications.

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

30 **"§ 131E-128.2. Nursing home quality assurance committee; duties related to**  
31 **medication error prevention.**

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

- 37           (1) Increase awareness and education of the patient and family members  
38 about all medications that the patient is using, both prescription and  
39 over-the-counter, including dietary supplements.
- 40           (2) Increase prescription legibility.
- 41           (3) Minimize confusion in prescription drug labeling and packaging,  
42 including unit dose packaging.
- 43           (4) Develop a confidential and nonpunitive process for internal reporting  
44 of actual and potential medication-related errors.

- 1           (5) Implement proven medication safety practices, including the use of  
2 automated drug ordering and dispensing systems.
- 3           (6) Reduce confusion that may result from similar-sounding drug names.
- 4           (7) Implement a system to accurately identify recipients before any drug is  
5 administered.
- 6           (8) Implement policies and procedures to ensure that medications are  
7 accurately administered and documented by properly authorized  
8 individuals, in accordance with prescribed orders and stop order  
9 policies.
- 10          (9) Implement policies and procedures for the self-administration of  
11 medication.

12 **"§ 131E-128.3. Staff orientation on medication error prevention.**

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

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

29 **"§ 131E-128.4. Nursing home pharmacy reports; duties of consultant pharmacist.**

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

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

- 39           (1) Drug therapy which may be affected by biological agents, laboratory  
40 tests, special dietary requirements, and foods used or administered  
41 concomitantly with other medication to the same recipient.
- 42           (2) Monitoring for potential adverse effects.
- 43           (3) Allergies.

- 1           (4)   Drug interactions, including interactions between prescription drugs  
2           and over-the-counter drugs, drugs and disease, and interactions  
3           between drugs and nutrients.
- 4           (5)   Contraindications and precautions.
- 5           (6)   Potential therapeutic duplication.
- 6           (7)   Over-extended length of treatment of certain drugs typically prescribed  
7           for a short period of time.
- 8           (8)   Beer's listed drugs which are potentially inappropriate for use by  
9           elderly persons.
- 10          (9)   Under treatment or medical conditions that are suboptimally treated or  
11          not treated at all that warrant additional drug therapy to ensure quality  
12          of care.
- 13          (10) Other identified problems and recommendations.

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

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

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

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

38 **§ 131E-128.5. Medication-related error reports to Secretary of Health and**  
39 **Human Services.**

40       (a)   A nursing home shall annually submit to the Secretary of Health and Human  
41 Services a report on the nursing home's medication-related errors. The report shall not  
42 contain information that would identify the patient, individual reporting the error, or  
43 other persons involved in the occurrence. The report shall include the following:

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

- 1           (2) A listing, by category, of the types of medication-related errors, the  
2           number of medication-related errors in each category, the root cause  
3           analysis of each category of error, and the staff level involved.  
4           (3) A listing, by category, of the types of injury caused and the number of  
5           injuries occurring within each category.  
6           (4) Types of liability claims filed based on an adverse incident or  
7           reportable injury.  
8       (b) The Department shall analyze the medication-related error reports to  
9       determine trends in the incidence of medication-related errors in nursing homes.  
10       Information released to the Department retains its confidentiality and is not subject to  
11       discovery or use in any civil actions as provided under G.S. 131E-128.1, and the  
12       Department shall keep the information confidential subject to that section."

13           **SECTION 2.** This act becomes effective January 1, 2004.