NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Kaye Howerton, Executive Director, Department of Health, 4052 Bald Cypress Way, BIN #C05, Tallahassee, FL 32399-3255

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 11, 2001

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 18, 2001

Section III
Notices of Changes, Corrections and Withdrawals

DEPARTMENT OF LABOR AND EMPLOYMENT SECURITY

Unemployment Appeals Commission

RULE NOS.:	RULE TITLES:
38E-2.002	Form of Appeal
38E-2.003	Filing an Appeal

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 27, No. 20, May 18, 2001, issue of the Florida Administrative Weekly. Based upon comments received from JAPC, the Commission clarifies that a Statement of Estimated Regulatory Cost was prepared by the agency. Due to the procedural nature of the proposed amendments, however, it was not anticipated that the parties or entities covered by the rule, or as otherwise contemplated under Section 120.541(2), F.S., would incur any additional costs above those associated with the existing rule.

A copy of the Statement of Estimated Regulatory Cost can be obtained from the person listed below. Additionally, as requested by JAPC, Rule 38E-2.002(1)(a) is amended to read as follows:

(a) The Unemployment Appeals Commission (Suite 300, Webster Building, 2671 Executive Center Circle, West, Tallahassee, FL 32399-0681);

The remainder of the rule reads as previously published.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: John W. Kunberger, Clerk-Unemployment Appeals Commission, Suite 300 Webster Building, 2671 Executive Center Circle, West, Tallahassee, Florida

DEPARTMENT OF LABOR AND EMPLOYMENT SECURITY

Unemployment Appeals Commission

RULE NO.:	RULE TITLE:
38E-3.007	Orders of the Commission

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 27, No. 20, May 18, 2001, issue of the Florida Administrative Weekly. Based upon comments received from JAPC, the Commission clarifies that a Statement of Estimated Regulatory Cost was prepared by the agency. Due to the procedural nature of the proposed amendments, however, it was not anticipated that the parties or entities covered by the rule, or as otherwise contemplated under Section 120.541(2), F.S., would incur any additional costs above those associated with the existing rule. A copy of the Statement of Estimated Regulatory Cost can be obtained from the person listed below.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: John W. Kunberger, Clerk-Unemployment Appeals Commission, Suite 300 Webster Building, 2671 Executive Center Circle, West, Tallahassee, Florida

DEPARTMENT OF LABOR AND EMPLOYMENT SECURITY

Unemployment Appeals Commission

RULE NOS.:	RULE TITLES:
38E-5.003	Form of Appeal
38E-5.004	Place for Filing Appeal
38E-5.005	Time for Filing Appeal

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 27, No. 20, May 18, 2001, issue of the Florida Administrative Weekly. Based upon comments received from JAPC, the Commission clarifies that a Statement of Estimated Regulatory Cost was prepared by the agency. Due to the procedural nature of the proposed amendments, however, it was not anticipated that the parties or entities covered by the rule, or as otherwise contemplated under Section 120.541(2), F.S., would incur any additional costs above those associated with the existing rule. A copy of the Statement of Estimated Regulatory Cost can be obtained from the person listed below. Additionally, as requested by JAPC, Rule 38E-5.004(2) is amended to read as follows:

(2) The central Office of Appeals (Woodcrest Office Park, 325 John Knox Rd., Bldg. L, Suite 210, Tallahassee, FL 32303) or district appeals referee offices maintained by the Office of Appeals;

The remainder of the rule reads as previously published.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: John W. Kunberger, Clerk-Unemployment Appeals Commission, Suite 300 Webster Building, 2671 Executive Center Circle, West, Tallahassee, Florida

WATER MANAGEMENT DISTRICTS

South Florida Water Management District

RULE CHAPTER NO.: RULE CHAPTER TITLE:
40E-7 Supplier Diversity & Outreach MBE Contracting Rule

NOTICE OF CORRECTION

Notice is hereby given that the following correction has been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in the June 8, 2001 issue of the Florida Administrative Weekly. The specific correction is as follows:

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST FOR SUPPLIER DIVERSITY AND OUTREACH M/WBE CONTRACTING RULE 40E-7, PART VI, F.A.C.

The proposed revisions to the Supplier Diversity and Outreach, MBE Rule (Chapter 40E-7, Part VI, Florida Administrative Code) are required in order to make the Rule conform to recent changes in Chapter 288, Florida Statutes. Several of the revisions are expected to result in cost savings, both to the agency and to those contracting with the District. Specific provisions expected to result in cost savings to the agency include:

1) sheltered markets – Rule 40E-7.631;

2) bid incentives – Rule 40E-7.628; and

3) annual, long-term, and project specific goals – Rule 40E-7.635.

In addition, the proposed rule changes are expected to reduce costs to those firms, particularly MBE firms, seeking to do business with the District by streamlining the District MBE certification process. It is intended that these cost savings be achieved without significantly reducing the effectiveness of the District Supplier Diversity and Outreach MBE Contracting Rule and without compromising the District's commitment to diversity.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Sandy Hammerstein, Procurement Division, South Florida Water Management District, Post Office Box 24680, West Palm Beach, FL 33416-4680, telephone 1(800)432-2045, Extension 2847 or (561)682-2847

AGENCY FOR HEALTH CARE ADMINISTRATION

Division of Managed Care and Health Quality

RULE NO.: RULE TITLE:
59A-4.1075 Medical Directors

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 27, No. 21, May 25, 2001, issue of the Florida Administrative Weekly.

Paragraph (1) through Paragraph (2)(b) No change.

(b) A Medical Director who does not have hospital privileges shall be certified or credentialed through a recognized certifying or credentialing body, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Medical Directors Association, the Healthcare Facilities Accreditation Program of the American Osteopathic Association, the Bureau of Osteopathic Specialists of the American Osteopathic Association, the Florida Medical Directors Association or a health maintenance organization licensed in Florida.

Paragraph (2)(c):

(c) A physician must have his/her principal office within 60 miles of all facilities for which he/she serves as Medical Director. Principal office is the office maintained by a physician pursuant to ss. 458.351 or 459.026, Florida Statutes, and applicable rules, where the physician delivers the majority of medical services. The physician must specify the address of his/her principal office at the time of becoming Medical Director. The agency may approve a request to waive this requirement for rural facilities that exceed this distance requirement. A rural facility is a facility located in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other nursing home facility within the same county.

Paragraph (2)(d) through Paragraph (5) No change.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Engineers

RULE NOS.: RULE TITLES:
61G15-22.009 Exemptions
61G15-22.011 Board Approval of Continuing Education Providers

NOTICE OF ADDITIONAL PUBLIC HEARING

The Florida Board of Professional Engineers hereby gives notice of an additional public hearing on the above-referenced rule(s) to be held on July 3, 2001 at 10:00 a.m. at the Florida Board of Professional Engineers, 1208 Hayes Street, Tallahassee, Florida 32301. The rules were originally published in Vol. 27, No. 20, of the May 18, 2001, Florida Administrative Weekly.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Natalie Lowe, Administrator, Florida Board of Professional Engineers, 1208 Hayes Street, Tallahassee, Florida 32399-0750

Any person requiring a special accommodation at this hearing because of a disability or physical impairment should contact the Board's Executive Director at least five calendar days prior to the hearing. If you are hearing or speech impaired, please contact the Board office using the Florida Dual Party Relay System which can be reached at 1(800)955-8770 (Voice) and 1(800)955-8771 (TDD).

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Surveyors and Mappers

RULE NO.: RULE TITLE:
61G17-4.007 Re-examination

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 27, No. 20, May 18, 2001, Florida Administrative Weekly has been withdrawn.

DEPARTMENT OF HEALTH

Division of Environmental Health

RULE NO.: RULE TITLE:
64E-5.210 Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made in the proposed rules in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 27, No. 17, April 27, 2001, of the Florida Administrative Weekly:

The changes were made in response to written comments received from the Joint Administrative Procedures Committee.

Subsection (10) of Section 64E-5.210, Florida Administrative Code, is changed so that when adopted will read:

(10) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part VI for the uses listed in Rules 64E-5.626, 64E-5.627, and 64E-5.630, F.A.C., will be approved if:

(a) The applicant satisfies the general requirements specified in Rule 64E-5.208, F.A.C.;

(b) The applicant submits evidence that:

1. The applicant is registered or licensed with the U.S. Food and Drug Administration as a drug manufacturer; ~~The radiopharmaceutical containing radioactive material will be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA,~~ or

2. The applicant is registered or licensed as a drug manufacturer as specified in Chapter 499, F.S.; ~~The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;~~ or

3. The applicant has a nuclear pharmacy permit and only authorized nuclear pharmacists compound or dispense radiopharmaceuticals as specified in Section 465.0193, F.S.

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by medical use ~~group~~ licensees; ~~and~~

(d) The applicant satisfies the following labeling requirements:

1. The label affixed to each transport radiation shield of any material of a radioactive drug transferred for commercial distribution includes the radiation symbol and the words "Caution, Radioactive Material" or "Danger, Radioactive Material"; the name of the radioactive drug or its abbreviation; and the quantity of the radioactive material at a specified date and time. The time can be omitted for radioactive drugs with a half life greater than 100 days. ~~The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity and date of assay and the label affixed to each package contains a statement that the radiopharmaceutical is licensed by the department for distribution to persons licensed pursuant to Part VI and Rule 64E-5.626, 64E-5.627, 64E-5.630, F.A.C., as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.~~

2. A label affixed to each syringe, vial, or other container used to hold a radioactive drug transferred for commercial distribution includes the words "Caution, Radioactive Material" or "Danger, Radioactive Material" and an identifier that correlates the syringe, vial, or other container with the information on the transport radiation shield label; and ~~The labels, leaflets or brochures required by (10)(d)1., above, are in addition to the labeling required by the Federal Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.~~

(e) A licensee shall possess and use instruments to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instruments. The licensee shall measure by direct measurements or by combination of measurements and calculations the amount of radioactivity in doses of alpha-emitting, beta-emitting, or photon-emitting radioactive drugs before transfer for commercial distribution. In addition, the licensee shall:

1. Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence appropriate for the use of the instrument and make adjustments when needed; and

2. Check each instrument for constancy and proper operation at the beginning of each day of use.