CHAPTER 70

DRUG UTILIZATION REVIEW COUNCIL

Authority

N.J.S.A. 24:6E–6(b).

Source and Effective Date

R.2003 d.271, effective June 10, 2003.
See: 35 N.J.R. 1331(b), 35 N.J.R. 2866(a).

Chapter Expiration Date

Chapter 70, Drug Utilization Review Council, expires on June 10, 2008.

Chapter Historical Note

Chapter 70 was adopted as R.1978 d.202, effective June 19, 1978. See: 10 N.J.R. 101(c), 10 N.J.R. 280(b). Chapter 70 was repealed by R.1978 d.248, effective July 24, 1978. See: 10 N.J.R. 341(c).

Chapter 70, Drug Utilization Review Council, was adopted as new rules by R.1978 d.341, effective September 18, 1978. See: 10 N.J.R. 333(a), 10 N.J.R. 430(f).

Pursuant to Executive Order No. 66(1978), Chapter 70, Drug Utilization Review Council, was readopted as R.1983 d.422, effective September 16, 1983. See: 15 N.J.R. 845(a), 15 N.J.R. 1663(a).

Pursuant to Executive Order No. 66(1978), Chapter 70, Drug Utilization Review Council, was readopted as R.1988 d.444, effective August 19, 1988. See: 20 N.J.R. 1507(a), 20 N.J.R. 2376(c).

Pursuant to Executive Order No. 66(1978), Chapter 70, Drug Utilization Review Council, was readopted as R.1993 d.333, effective June 14, 1993. See: 25 N.J.R. 1814(a), 25 N.J.R. 2879(b). Pursuant to Executive Order No. 66(1978), Chapter 70 expired on June 14, 1998.

Chapter 70, Drug Utilization Review Council, was adopted as new rules by R.1998 d.521, effective November 2, 1998. See: 30 N.J.R. 3011(a), 30 N.J.R. 3959(a).

Chapter 70, Drug Utilization Review Council, was readopted as R.2003 d.271, effective June 10, 2003. See: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. DRUG EVALUATION AND ACCEPTANCE CRITERIA

8:70–1.1 Purpose

The purpose of these rules is to provide standards for the evaluation of drugs proposed for inclusion in the Drug Utilization Review Council Formulary as generic substitutes for branded products, and to assure therapeutically equivalent medications at the most reasonable cost.

8:70–1.2 Scope

These rules regulate all manufacturers and repackagers of prescription drugs purveyed in the State of New Jersey as substitutes for branded products.

8:70–1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Bioavailability" means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action.

"Bioequivalence" means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

"Brand name" means the proprietary name assigned to a drug by the manufacturer of a drug.

"Council" means the Drug Utilization Review Council established in accordance with N.J.S.A. 24:6E–1 through 13.

"Dispenser" means a person licensed by the State Board of Pharmacy or by the State Board of Medical Examiners, or other appropriate State agency which licenses dispensers of prescription drug medications.

"Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use.

"Established name" means the name of a drug or ingredient of a drug as it is designated pursuant to 21 U.S.C. §§ 301 et seq., or the United States Pharmacopeia and National Formulary (USP and NF), or the Homeopathic Pharmacopeia, or, if not so designated, the common or usual name.

"Formulary" means the list of generic drug products found interchangeable with, and approved by the Council for substitution for, branded products, in accordance with N.J.A.C. 8:71.

"Integrity" means the capacity of a product to degrade at a specified rate under circumstances specific to its usual method of storage and prescribed use.

"Interchangeable drug products" means pharmaceutical equivalents that are determined by the Council to be bioequivalent and therapeutically equivalent.

"Pharmaceutical equivalence" means that drug products contain the same active drug ingredient, salt, ester, or chemical form, available in the same strength/concentration, manufactured in the same dosage form and given by the same route of administration, and meet the same compendial standards for strength, quality, purity, and identity.

"Prescription" means an order for drugs or combinations of drugs or mixtures thereof, written or signed by a duly licensed physician, dentist, optometrist, veterinarian, other medical practitioner, a certified nurse mid-wife, a nurse practitioner/clinical nurse specialist or a physician assistant or other practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

"Reference drug product" means the product, which is adopted by the Council as the standard for other bioequivalent and therapeutically equivalent drugs in accordance with this chapter.

"Repackager" means an entity which packages trade-size packages from bulk packages, for distribution through wholesalers to licensed dispensers.

"Therapeutic equivalence" means that drug products demonstrating pharmaceutical equivalence are assumed by the Council to exhibit the same therapeutic effect and potential for adverse effects when administered under the conditions specified by the label.

"United States Pharmacopeia and National Formulary (USP and NF)" means the compendium of standards for drugs published by the U.S. Pharmacopeial Convention, Inc.

Amended by R.2003 d.271, effective July 7, 2003.
See: 35 N.J.R. 1331(b), 35 N.J.R. 2866(a).
Rewrote "Bioavailability", "Established name", "Interchangeable drug products", "Prescription", "Regerence drug product", "United States Pharmacopeia"; added "Bioequivalence", "Pharmaceutical equivalence", "Therapeutic equivalence"; deleted "Bioequivalents", "Chemical equivalents", "Pharmaceutical equivalents", "Therapeutic equivalents".

8:70–1.4 Application for addition to the Formulary

(a) No drug shall be dispensed as a generic equivalent without the prior approval of the Council. Applications for the addition of drugs to the Formulary shall be submitted to the Council for evaluation, one application per dosage form. Different package sizes of the same dosage form shall be included in the same application. Different strengths of the same dosage form may be submitted on the same application form. Each application shall be typewritten or computer generated and shall include:

1. A completed OC–42 Drug Product Registration form, available upon request to the Council, indicating the following:

i. The name of the manufacturer;

ii The date of application;

iii. The mailing address of the manufacturer;

iv. The address of the manufacturing site, if different from (a)1iii above;

v. The name of the applicant contact person;

vi. The telephone number of the applicant contact person;

vii. The complete name of the brand for which the applicant drug is a substitute;

viii. The dosage form;

ix. The generic name and strength(s) of the applicant drug for single ingredient items, or the name and amount of each active ingredient;

x. Attestation that each batch of the drug conforms to Council standards prior to being marketed;

xi. The date of last inspection by the FDA for compliance with Current Good Manufacturing Practices;

xii. Attestation of FDA approval to market the applicant drug product;

xiii. Attestation that the applicant drug product is manufactured under an FDA-approved Abbreviated New Drug Application (ANDA) or New Drug Application (NDA) if applicable;

xiv. Attestation that bioequivalency studies have been submitted to the FDA;

xv. Attestation regarding litigation, including patent suits, during the two years immediately prior to the date of the application;

xvi. Attestation that the name of the manufacturer appears on all distributor's labels;

xvii. Attestation regarding current applicant drug product availability to pharmacies;

xviii. A list of four distributors doing business with pharmacies in New Jersey who carry or will carry the applicant drug product;

xix. The National Drug Code; and

xx. The usual cost to pharmacies for the applicant drug product.

2. A copy of the most recently completed FDA form 483, form 482 if no observations are noted, or the Establishment Inspection Report (EIR) providing documentation of compliance with the most recent FDA inspection;

3. A copy of the FDA ANDA approval letter;

4. Copies of labels that indicate the manufacturer's name;

5. Two copies of the biostudy summary of the drug approved by the FDA; and

6. Particulars of any litigation within the past two years.

(b) Applications shall not be deemed complete until all of the items in (a) above have been received by the Council. Any waiver of any of the items in (a) above shall be requested in writing and addressed to the Council, giving the reason(s) for the waiver request.

(c) The Council will act on applications at its next available meeting, will propose the addition of the drug in the New Jersey Register, receive comments for 30 days subsequent to the proposal, and will adopt and file its decision regarding the inclusion of the drug in the Formulary with the Office of Administrative Law within one year of the proposal. When the notice of adoption of the drug is published in the New Jersey Register, the drug may be substituted.

Amended by R.2003 d.271, effective July 7, 2003.
See: 35 N.J.R. 1331(b), 35 N.J.R. 2866(a).
Rewrote (a).

8:70–1.5 Criteria used for evaluation

(a) Generic drug products shall conform to the following, with respect to the branded reference drug product:

1. Pharmaceutical equivalence;

2. Bioequivalence, as established by:

i. The FDA in accordance with 21 C.F.R. 314, and published in the "Orange Book," available from the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250, or on the internet at http://www.fda.gov/cder/ob; or

ii. Other studies, as approved by the Council on a case-by-case basis; and

3. Therapeutic equivalence, which will be assumed by the Council once bioequivalence is demonstrated.

(b) Product criteria shall be as contained in 21 C.F.R. 314, the United States Pharmacopoeia and National Formulary or the Homeopathic Pharmacopoeia, as appropriate for the particular application.

Amended by R.2003 d.271, effective July 7, 2003.
See: 35 N.J.R. 1331(b), 35 N.J.R. 2866(a).
Rewrote (a).

8:70–1.6 Availability of products

There shall be adequate production capabilities and Statewide distribution capabilities to ensure product availability sufficient to meet patients' needs for continuity of care at dispensing locations.

Amended by R.2003 d.271, effective July 7, 2003.
See: 35 N.J.R. 1331(b), 35 N.J.R. 2866(a).
Deleted "all" prior to "dispensing locations".

8:70–1.7 Generic drugs manufactured by the brand manufacturer

Applications for generic drugs manufactured by the brand manufacturer, which are manufactured under the same NDA specifications as the brand product, shall not require an evaluation of bioequivalence. In such cases, the applicant shall specify the availability of the drug and provide other information required by N.J.A.C. 8:70–1.4. The application will then be processed as described in N.J.A.C. 8:70–1.4(c).

8:70–1.8 Inspection of production facilities

Production facilities for products proposed for the Formulary shall have been inspected not less than every five years by the FDA.

Amended by R.2003 d.271, effective July 7, 2003.
See: 35 N.J.R. 1331(b), 35 N.J.R. 2866(a).
Substituted "five" for "two" preceding "years".

8:70–1.9 Recalls and returns

(a) A record shall be maintained of all FDA recalls, which shall include the reason for the recall.

(b) Company policies shall exist which are adequate to handle products recalled or returned from all wholesale distributors, health care institutions, physicians, pharmacists, and pharmacies. The policies shall include procedures applicable in the case of emergencies.

8:70–1.10 Reconsideration of rejected products

Any product which has been rejected for inclusion in the Formulary will be reconsidered by the Council if a second application is made which addresses the specific deficiencies cited by the Council in that product's rejection.

8:70–1.11 Removal of approved products from the Formulary

Any product which has been accepted for inclusion in the Formulary will be reconsidered if new evidence is presented to the Council which indicates the existence of deficiencies which were not found at the time of the product's original evaluation.

8:70–1.12 Appeal of denial of application

An applicant may appeal the denial of an application in accordance with the provisions of the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, by submitting a statement in writing to the Council, specifying the provisions of the rules which are the basis for the appeal and the supporting information.

8:70–1.13 Confidentiality of application information

(a) If an applicant wishes to have the Council maintain as confidential any information submitted with an application, the applicant shall so inform the Council in writing, at the time of application, stating the basis for the request. Information that is demonstrated to be proprietary or a trade secret will be maintained as confidential. Other information may be maintained by the Council as confidential, on a case-by-case basis, depending upon the reason for the request.

(b) The results of any studies submitted will not be kept confidential, as the Council is required to open its proceedings and the bases of its decisions to the public.