CHAPTER 70

DRUG UTILIZATION REVIEW COUNCIL

Authority

N.J.S.A. 24:6E–6(g).

Source and Effective Date

R.1998 d.521, effective November 2, 1998.
See: 30 N.J.R. 3011(a), 30 N.J.R. 3959(a).

Executive Order No. 66(1978) Expiration Date

Chapter 70, Drug Utilization Review Council, expires on November 2, 2003.

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 Chapter 70 was repealed by R.1978 d.248, effective July 24, 1978.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: Source and Effective Date.

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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 extent and rate of absorption from a dosage form, as reflected in the time-concentration curve of the administered drug in the systemic circulation.

"Bioequivalents" means those drugs which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability.

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

"Chemical equivalents" means those drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage form that also meet the standards for drug excipients and drug products contained in the United States Pharmacopoeia and the National Formulary.

"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 Pharmacopoeia, or the Homeopathic Pharmacopoeia, 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 or bioequivalents that are determined by the Council to be therapeutic equivalents.

"Pharmaceutical equivalents" means those drug products that contain the same amounts of the same therapeutically active ingredients in the same form which meet the standards contained in this chapter.

"Physical equivalents" means those drug products that possess the same characteristics when weight, color, coating, markings and integrity are compared.

"Prescription" means an order for drugs or combinations of drugs or mixtures thereof, written or signed by a duly licensed physician, dentist, veterinarian or other practitioner licensed to write prescriptions.

"Reference drug product" means the product which is adopted by the Council as the standard for other chemically 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 equivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide the same efficacy or toxicity as the reference drug product.

"United States Pharmacopoeia (USP)" means the compendium of standards for drugs published by the U.S. Pharmacopoeial Convention, Inc.

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. Each application shall be typewritten and shall include:

1. A completed OC–42 (Council form, available upon request to the Council), indicating the following:

i. The name, mailing address, and address of the manufacturing site, of the manufacturer or repackager;

ii. The name and telephone number of the applicant contact person;

iii. The complete name of the brand for which the application drug is a substitute;

iv. The dosage form;

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

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

vii. The date of last inspection for Good Manufacturing Practices by the U.S. Food and Drug Administration;

viii. The National Drug Code number;

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

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

xi. Cost to pharmacies per 100 (if other, specify);

xii. Product availability;

xiii. Name and address of four distributors doing business in New Jersey who carry the product;

xiv. Attestation of FDA approval;

xv. Specification of the FDA status of the drug (NDA, ANDA, DESI or other);

xvi. Status of bioequivalency studies submission to FDA; and

xvii. Notarized certification of correctness of information;

2. A copy of the most recently completed FDA inspection form 482 or 483, providing documentation of compliance with the most recent FDA inspection;

3. A copy of the FDA ANDA approval letter;

4. Copies of labels;

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.

8:70–1.5 Criteria used for evaluation

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

1. Chemical equivalence;
2. Physical equivalence; and
3. Bioavailability equivalence, as established by

i. The U.S. Food and Drug Administration in accordance with 21 C.F.R. 314, and published in "Orange Book," available from the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250; or

ii. Clinical studies demonstrating therapeutic equivalence, as approved by the Council on a case-by-case basis.

(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.

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 all 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 two years by the U.S. Food and Drug Administration.

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.