

**CHAPTER 70**  
**DRUG UTILIZATION REVIEW COUNCIL**

**Authority**

N.J.S.A. 24:6E-6(g).

**Source and Effective Date**

R.1993 d.333, effective June 14, 1993.  
See: 25 N.J.R. 1814(a), 25 N.J.R. 2879(b).

**Executive Order No. 66(1978) Expiration Date**

Chapter 70, Drug Utilization Review Council, expires on June 14, 1998.

**Chapter Historical Note**

Chapter 70 was originally adopted pursuant to authority of N.J.S.A. 24:6E-1 et seq. and was filed and became effective on June 19, 1978 as R.1978 d.202. See: 10 N.J.R. 101(c), 10 N.J.R. 280(b).

1978 Revisions: Repeal of this chapter became effective on July 24, 1978 as R.1978 d.248. See: 10 N.J.R. 341(c). New rules became effective on September 18, 1978 as R.1978 d.341. See: 10 N.J.R. 333(a), 10 N.J.R. 430(f). Further amendments became effective December 12, 1978 as R.1978 d.422. See: 11 N.J.R. 15(a).

1979 Revisions: Amendments became effective October 17, 1979 as R.1979 d.412. See: 11 N.J.R. 438(b), 11 N.J.R. 551(a). Further amendments became effective December 14, 1979 as R.1979 d.483. See: 11 N.J.R. 278(c), 12 N.J.R. 15(a).

1983 Revisions: Amendments became effective February 7, 1983 as R.1983 d.33. See: 14 N.J.R. 1030(a), 15 N.J.R. 147(d). This chapter was readopted (with amendments) pursuant to Executive Order 66(1978), effective September 16, 1983 as R.1983 d.422. See: 15 N.J.R. 845(a), 15 N.J.R. 1663(a).

1988 Revisions: Amendments became effective July 18, 1988 as R.1988 d.328. See: 20 N.J.R. 870(a), 20 N.J.R. 1710(a). This chapter was readopted pursuant to Executive Order 66(1978) effective August 19, 1988 as R.1988 d.444. See: 20 N.J.R. 1507(a), 20 N.J.R. 2376(c).

Pursuant to Executive Order No. 66(1978), Chapter 70 was readopted as R.1993 d.333. See: Source and Effective Date. See, also, section annotations for specific rulemaking activity.

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**SUBCHAPTER 1. DRUG EVALUATION AND ACCEPTANCE CRITERIA**

**8:70-1.1 Drug Utilization Review Council**

(a) The Drug Utilization Review Council shall establish and maintain an approved list of drugs entitled, "The Drug

Utilization Review Council Formulary". The formulary shall be used in the implementation of New Jersey Assembly Bill No. 2021, known as the "Prescription Drug Price and Quality Stabilization Act". Its purpose is to assure quality medications at the most reasonable costs.

(b) In evaluating and accepting drugs into the formulary, all products will be compared to reference standards such as, but not limited to, those available from the Food and Drug Administration, the United States Pharmacopoeia and the National Formulary.

(c) Drug products submitted to the council for evaluation will be required to conform to the following criteria in relation to the minimum reference standards:

1. Chemical and physical equivalence;
2. Bioavailability equivalence where appropriate standards and methodology have been established by the Food and Drug Administration, or therapeutic equivalence in terms of adequate and well-controlled clinical studies in the absence of appropriate standards, or where otherwise deemed necessary by the council;
3. Product criteria;
4. Manufacturer and repackager criteria.

(d) The following statements are provided to detail and explain the evaluation criteria.

As amended, R.1979 d.412, effective October 17, 1979.  
See: 11 N.J.R. 438(b), 11 N.J.R. 551(a).

**8:70-1.2 Bioavailability data**

(a) Bioavailability has been defined as the extent and rate of absorption from a dosage form, as reflected by the time-concentration curve of the administered drug in any appropriate biological fluid. Bioequivalents are those chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability. Three parameters describing a single-dose blood concentration curve are considered important for comparison in evaluating bioequivalence. These are the maximal concentration, the time of maximal concentration and the area under the concentration/time curve.

(b) A general explanation of bioequivalence parameters would include such items as:

1. Maximal concentration is that concentration of drug attained in the blood following a single standard dose, and for single dose drugs, must be above the minimum effective concentration and below the minimum toxic concentration. This is also true for multiple dose drugs which do not accumulate, such as penicillin G. For drugs which do accumulate, and for which only single

dose data are available, multiple dose kinetics must be used to establish the steady state concentration range.

2. Time until maximal concentration is an indirect measure of time to onset of action, since the faster a drug reaches its maximal concentration, the faster it is likely to provide an effect.

3. Area under the curve is an indication of the extent of absorption of a drug from a dosage form. This should be available for as much time as it takes until the concentration in the body fluid being evaluated is down to 10 percent of the maximal concentration. Area under the curve is critical for drugs given on a multiple dosing schedule and must be considered when comparing such products.

### 8:70-1.3 Physical criteria

(a) Physical criteria (tablets and capsules) are:

1. Uniformity of weight, color and coating;
2. Adequacy of markings;
3. Integrity.

### 8:70-1.4 Manufacturer and repackager criteria

(a) The actual manufacturer of the drug product must be identified and the active ingredient(s) must be given. In addition, the manufacturer and repackager must certify that the active and inactive ingredients, sources and the final dosage form are approved by the Federal Food and Drug Administration or the New Jersey Department of Health. Products for which a manufacturer or repackager refuses to provide this information will not be approved.

(b) The manufacturer and repackager must provide verification of their compliance with the quality control standards established by the current Good Manufacturing Practices Act for the reference product.

(c) Additional rules are:

1. Production facilities for submitted products must be inspected not less than every two years by an appropriate and acceptable Federal or State agency as determined by the council. When product is submitted for formulary consideration, the inspection records for the prior two years must be included. In addition, copies of all violation citations and records of violation corrections must be made available for review by the committee.

2. A record of Federal Food and Drug Administration drug product recalls, together with the reason for the recall, shall be maintained in the Department of Health. This information will be made available to the council for review as needed.

(d) Placement of an identification mark (such as NDC number or trademark) on drug labels and catalogs is required. In addition, effective January 1, 1980, the name of the manufacturer must appear on all labels of products proposed for inclusion in the list. Products which were included in the list prior to January 1, 1980, and which do not bear the manufacturer's name on the label will be proposed for deletion in the first revision of the list after January 1, 1980.

(e) Adequate company policies and procedures for accepting returned products from all wholesale distributors, health care institutions, physicians, pharmacists and pharmacies are required should recall be necessary.

(f) References for adequate emergency consultation should be provided by the manufacturer.

(g) There must be adequate production capabilities and Statewide distribution capabilities which will ensure product availability to meet patients' needs at all authorized dispensing locations. This standard should provide all patients with uninterrupted continuity of care.

(h) Any product which has been rejected for admission to the Formulary by the Drug Utilization Review Council shall be reconsidered only if new evidence is submitted which addresses the specific deficiencies which formed the basis for that product's rejection.

(i) Any product which has been approved for admission to the Formulary shall be reconsidered only if new evidence indicates the existence of deficiencies which were not found at the time of the product's original consideration.

(j) The Executive Director shall publish in the New Jersey Register at the earliest possible date a notice of the action taken by the Council on a drug product. The action taken by the Council on a drug product shall be effective on the date the notice of adoption appears in the New Jersey Register. A manufacturer who disagrees with the Council's action must follow the process outlined in (h) and (i) above.

As amended, R.1978 d.422, effective December 12, 1978.

See: 11 N.J.R. 15(a).

As amended, R.1979 d.412, effective October 17, 1979.

See: 11 N.J.R. 438(b), 11 N.J.R. 551(a).

As amended, R.1979 d.483, effective December 14, 1979.

See: 11 N.J.R. 278(c), 12 N.J.R. 15(a).

As amended, R.1983 d.422, effective September 16, 1983.

See: 15 N.J.R. 845(a), 15 N.J.R. 1663(a).

In (c)2, deleted "Department of Human Services" and added "Department of Health".

As amended, R.1983 d.33, effective February 7, 1983.

See: 14 N.J.R. 1030(a), 15 N.J.R. 147(d).

Added (h) and (i).

Amended by R.1988 d.328, effective July 18, 1988.

See: 20 N.J.R. 870(a), 20 N.J.R. 1710(a).

Added (j).