(c) When a prescriber chooses not to allow product interchange on a telephone order, the statement "Substitution not permitted by prescriber-telephone Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the prescription order. A rubber stamp bearing the statement is acceptable.

(d) When a prescriber chooses to certify "Brand Medically Necessary" on a telephoned prescription for a product included on the Federal MAC list, a written signed prescription order containing the certification, shall be sent to the pharmacist within seven days of the date of the telephone order. The written prescription shall be retained by the pharmacist as the original prescription. Failure to comply will result in the payment for that prescription being reduced to the MAC reimbursement level.

Recodified from N.J.A.C. 10:51–1.16 by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.17, Changes or additions to the original prescription, recodified to N.J.A.C. 10:51–1.18.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (b), inserted a reference to NJ KidCare.

10:51–1.18 Changes or additions to the original prescription

Changes or additions to the original prescription, when approved by the prescriber, shall be clearly indicated (including date and time) and signed by the dispensing pharmacist. No changes (for example, dosage, quantity, number of refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

Recodified from N.J.A.C. 10:51–1.17 by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.18, Prescription refill, recodified to N.J.A.C. 10:51–1.19.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.

10:51–1.19 Prescription refill

(a) The provider shall submit a properly completed claim form or electronic claim in the proper EMC claim format to the fiscal agent for reimbursement of an allowable refill. An allowable refill shall comply with the following instructions in order to be reimbursed as such:

1. Refill instructions must be indicated in writing by the prescriber on the original prescription or verbally when telephoning the original prescription to the pharmacist. Verbal instructions shall be reduced to writing by the pharmacist, in accordance with N.J.S.A. 45:14–14.

2. When the prescriber indicates a prescription refill(s) on an original or telephone prescription for drugs, the number of refills shall be limited to a maximum of five refills within a six-month period.

3. Refill instructions indicating "refill prn" or indicating more than five refills, shall be subject to the limits imposed in (a)2 above, and shall be reimbursed up to these limits only.

4. A telephone authorized refill for a prescription with no refill remaining must be assigned a new prescription number.

5. Prescription refills shall not be dispensed until a reasonable quantity (approximately 75 percent) of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

i. Exception: When a prescription is lost or destroyed, requiring a replacement prescription to be dispensed before the original prescription could have been consumed in accordance with the prescriber's written directions for use, an original pharmacy claim with written justification shall be submitted to the fiscal agent for payment consideration.

Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).
In (a)2, inserted reference to telephone prescriptions; and deleted (a)2i, relating to an exception for oral contraceptives.
Recodified from N.J.A.C. 10:51–1.18 by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.19, Prescription Drug Price and Quality Stabilization Act, recodified to N.J.A.C. 10:51–1.20.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.

Case Notes

Prescription refills not reimbursable. Park Pharmacy v. Division of Medical Assistance and Health Services, 92 N.J.A.R.2d (DMA) 67.

10:51–1.20 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E–1 et seq., shall apply to the New Jersey Medicaid and NJ KidCare programs. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of

interchangeable products and bill Medicaid or NJ KidCare accordingly.

2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill Medicaid or NJ KidCare for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid or NJ KidCare beneficiary must accept the interchangeable product unless the beneficiary is willing to pay the pharmacy's full, usual and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid or NJ KidCare.

3. For non-MAC drugs (see N.J.A.C. 10:51–1.5) when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or NJ KidCare for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51–1.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (see Appendix D, Fiscal Agent Billing Supplement for instructions about the claim form and Appendix E regarding the proper EMC claim format).

4. When the prescriber orders by the generic name, the DURC Formulary (see N.J.A.C. 10:51–1.4) does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product need not necessarily be from the list of interchangeable products.

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or NJ KidCare–Plan A may reimburse for certain multi-source drugs. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription (see N.J.A.C. 10:51–1.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check-off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a handwritten statement "Do No Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E–1 does not apply to drugs which have a Federal MAC limit. The Division shall also apply these Federal requirements to NJ KidCare–Plans B and C.

(c) Blanket authorization denying substitutions shall not be permitted. Each prescription order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E–1 et seq. (see (a) above).

(d) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

(e) The "Brand Medically Necessary" requirement for MAC prescriptions shall not apply for Medicaid or NJ KidCare beneficiaries enrolled in a Medicaid or NJ KidCare participating Health Maintenance Organization (HMO).

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Recodified from N.J.A.C. 10:51–1.19 by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.20, Drug Efficacy Study Implementation (DESI), recodified to N.J.A.C. 10:51–1.21.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (a), inserted references to NJ KidCare throughout; in (b), inserted a reference to NJ KidCare-Plan A in the first sentence, and added the last sentence; and added (e).

10:51–1.21 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;

ii. The drug product is available only through prescription;

iii. The drug product is the subject of a notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. The drug product is at present the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.

2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.