CR 91-106

CERTIFICATE

STATE OF WISCONSIN)
) SS
DEPARTMENT OF HEALTH AND SOCIAL SERVICES)

I, Gerald Whitburn, Secretary of the Department of Health and Social Services and custodian of the official records of the Department, do hereby certify that the annexed rules relating to coverage of prescription and over-the-counter drugs under the Medical Assistance program were duly approved and adopted by this Department on November 13, 1991.

I further certify that this copy has been compared by me with the original on file in the Department and that this copy is a true copy of the original, and of the whole of the original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at the State Office Building, 1 W. Wilson Street, in the city of Madison, this 13th day of November, 1991.

SEAL:

Gerald Whitburn, Secretary
Department of Health and Social Services

RECEIVED
NOV 13 1991
1:30 pm
Revisor of Statutes
Bureau

1-1-92

ORDER OF THE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
AMENDING AND REPEALING AND RECREATING RULES

To amend HSS 105.15 and to repeal and recreate HSS 107.10, relating to coverage of prescription and over-the-counter drugs under the Medical Assistance (MA) program.

Analysis Prepared by the Department of Health and Social Services

This order modifies the Department's rules under which the Medical Assistance (MA) program pays for prescription and over-the-counter drugs provided to MA recipients. The principal change makes permanent the changes made by emergency rule order on April 26, 1991 that permit the program to comply with the requirements of s. 4401(a)(3) of Public Law 101-508, the federal Omnibus Budget Reconciliation Act (OBRA) of 1990, which established a federal/state drug rebate program. Under this new law the federal Health Care Financing Administration (HCFA) enters into agreements with pharmaceutical companies to secure rebates on drugs prescribed for MA recipients who are not inpatients in hospitals and other health care facilities. In general, federal financial participation is not available for a drug manufactured by a company that has not entered into a rebate agreement with HCFA for that drug. However, the state may pay for a drug not included in a rebate agreement if prior authorization is requested and received on grounds that the drug is medically necessary and cost-effective for the treatment of a particular recipient, and the state may approve a drug not covered by an agreement if that drug is medically necessary and cost-effective in treating a specific diagnosis.

Another change made by this order to implement provisions of Public Law 101-508 (OBRA 90) is addition of a subsection to require that a recipient's pharmacist review the recipient's drug therapy before filling or delivering a prescription, offer to counsel the recipient about how to take the drug and its possible side effects, and make an effort to obtain, record and maintain relevant information about the recipient and the recipient's drug therapy.

Other changes made by this order in the MA drug covered benefit rules reflect current prescribing and dispensing practices under state and federal laws.

The Department's authority to adopt these rules is found in s. 49.45(10), Stats. The rules interpret s. 49.46(2)(b)6.h, Stats.

SECTION 1. HSS 105.15 is amended to read:

HSS 105.15 CERTIFICATION OF PHARMACIES. For MA certification, pharmacies shall meet the requirements for registration and practice ~~enumerated in ss. 450.02 and 450.04, Stats., and chs. Phar 1 to 6~~ under ch. 450, Stats., and chs. Phar 1 to 14.

SECTION 2. HSS 107.10 is repealed and recreated to read:

HSS 107.10 DRUGS. (1) COVERED SERVICES. Drugs and drug products covered by MA include legend and non-legend drugs and supplies listed in the Wisconsin medicaid drug index which are prescribed by a physician licensed under s. 448.04, Stats., by a dentist licensed under s. 447.05, Stats., by a podiatrist licensed under s. 448.04, Stats., or by an optometrist licensed under ch. 449, Stats., or when a physician delegates prescription of drugs to a nurse practitioner or to a physician's assistant certified under s. 448.04, Stats., and the requirements under s. N 6.03 for nurse practitioners and under s. Med 8.08 for physician assistants are met.

Note: The Wisconsin medicaid drug index is available from the State of Wisconsin Document Sales, P.O. Box 7840, Madison, WI 53707.

(2) SERVICES REQUIRING PRIOR AUTHORIZATION. The following drugs and supplies require prior authorization:

(a) All schedule II stimulant drugs, except methylphenidate;

(b) All schedule III and IV stimulant drugs;

(c) All food supplement or replacement products including ensure and ivonex;

(d) Drugs which have been demonstrated to entail substantial cost or utilization problems for the MA program, including antibiotics which cost $100 or more a day. These drugs shall be noted in the Wisconsin medicaid drug index; and

(e) Any drug produced by a manufacturer who has not entered into a rebate agreement with the federal secretary of health and human services, as required by 42 USC 1396r-8, if the prescribing provider under sub. (1) demonstrates to the department's satisfaction that no other drug sold by a manufacturer who complies with 42 USC 1396r-8 is medically appropriate and cost-effective in treating the recipient's condition.

Note: For more information on prior authorization, see s. HSS 107.02(3).

(3) OTHER LIMITATIONS. (a) Dispensing of schedule III, IV and V drugs shall be limited to the original dispensing plus 5 refills, or 6 months from the date of the original prescription, whichever comes first.

(b) Dispensing of non-scheduled legend drugs shall be limited to the original dispensing plus 11 refills, or 12 months from the date of the original prescription, whichever comes first.

(c) Generically-written prescriptions for drugs listed in the federal food and drug administration approved drug products publication shall be filled with a generic drug included in that list. Prescription orders written for brand name drugs which have a lower cost generically available drug equivalent shall be filled with the lower cost drug product equivalent, unless the prescribing provider under sub. (1) writes "brand medically necessary" on the face of the prescription.

(d) Except as provided in par. (e), legend drugs shall be dispensed in amounts not to exceed a 34-day supply.

(e) The following drugs may be dispensed in amounts up to but not to exceed a 100-day supply, as prescribed by a physician:

1. Digoxin, digitoxin and digitalis;
2. Hydrochlorothiazide and chlorothiazide;
3. Prenatal vitamins;
4. Fluoride;
5. Levothyroxine, liothyronine and thyroid extract;
6. Phenobarbital;
7. Phenytoin; and
8. Oral contraceptives.

(f) Provision of drugs and supplies to nursing home recipients shall comply with the department's policy on ancillary costs in s. HSS 107.09(4)(a).

(g) Provision of special dietary supplements used for tube feeding or oral feeding of nursing home recipients shall be included in the nursing home daily rate pursuant to s. HSS 107.09(2)(b).

(h) To be included as a covered service, an over-the-counter drug shall be used in the treatment of a diagnosable condition and be a rational part of an accepted medical treatment plan. Only the following general categories of over-the-counter drugs are covered:

1. Antacids;
2. Analgesics;
3. Insulins;
4. Contraceptives;
5. Cough preparations;
6. Ophthalmic lubricants; and
7. Iron supplements for pregnant women.

(i) Any innovator multiple-source drug is a covered service only if the prescribing provider under sub.(1) certifies by writing the phrase "brand medically necessary" on the prescription to the pharmacist that a specific brand drug, rather than a generic drug, is medically necessary. The prescribing provider shall document the reason why the drug is medically necessary in the patient's record. In this paragraph, "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the U. S. food and drug administration.

(j) A drug produced by a manufacturer who does not meet the requirements of 42 USC 1396r-8 may be a covered service if the department determines that the drug is medically necessary and cost-effective in treating the condition for which it is prescribed.

(k) The department may determine whether or not a drug judged by the U.S. food and drug administration to be "less than effective" shall be reimbursable under the program based on the medical appropriateness and cost-effectiveness of the drug.

(4) NON-COVERED SERVICES. The department may create a list of drugs or drug categories to be excluded from coverage, known as the medicaid negative drug list. These non-covered drugs may include drugs determined "less than effective" by the U.S. food and drug administration, drugs not covered by 42 USC 1396r-8, drugs restricted under 42 USC 1396r-8(d)(2) and experimental or other drugs which have no medically accepted indications. In addition, the following are not covered services:

(a) Claims of a pharmacy provider for reimbursement for drugs and medical supplies included in the daily rate for nursing home recipients;

(b) Refills of schedule II drugs;

(c) Refills beyond the limitations imposed under sub. (3)(a) and (b);

(d) Personal care items such as non-therapeutic bath oils;

(e) Cosmetics such as non-therapeutic skin lotions and sun screens;

(f) Common medicine chest items such as antiseptics and band-aids;

(g) Personal hygiene items such as tooth paste and cotton balls;

(h) "Patent" medicines such as drugs or other medical preparations that can be bought without a prescription;

(i) Uneconomically small package sizes;

(j) Items which are in the inventory of a nursing home;

(k) Drugs not listed in the medicaid drug index, including over-the-counter drugs not included in sub. (3)(h) and legend drugs;

(l) Drugs included in the medicaid negative drug list maintained by the department; and

(m) Drugs produced by a manufacturer who does not meet the requirements of 42 USC 1396r-8, unless sub. (2)(e) or (3)(j) applies.

(5) DRUG REVIEW, COUNSELING AND RECORDKEEPING. In addition to complying with ch. Phar 7, a pharmacist shall fulfill the requirements of 42 USC 1396r-8(g)(2)(A) as follows:

(a) The pharmacist shall provide for a review of drug therapy before each prescription is filled or delivered to an MA recipient. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, including serious interactions with non-prescription or over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions and clinical abuse or misuse.

(b) The pharmacist shall offer to discuss with each MA recipient, the recipient's legal representative or the recipient's caregiver who presents the prescription, matters which, in the exercise of the pharmacist's professional judgment and consistent with state statutes and rules governing provision of this information, the pharmacist deems significant, including the following:

1. The name and description of the medication;

2. The route, dosage form, dosage, route of administration, and duration of drug therapy;

3. Special directions and precautions for preparation, administration and use by the patient;

4. Common severe side effects or adverse effects or interactions and therapeutic contra-indications that may be encountered, including how to avoid them, and the action required if they occur;

5. Techniques for self-monitoring drug therapy;

6. Proper storage;

7. Prescription refill information; and

8. Action to be taken in the event of a missed dose.

(c) The pharmacist shall make a reasonable effort to obtain, record and maintain at least the following information regarding each MA recipient for whom the pharmacist dispenses drugs under the MA program:

1. The individual's name, address, telephone number, date of birth or age and gender;

2. The individual's history where significant, including any disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

3. The pharmacist's comments relevant to the individual's drug therapy.

(d) Nothing in this subsection shall be construed as requiring a pharmacist to provide consultation when an MA recipient, the recipient's legal representative or the recipient's caregiver refuses the consultation.

The repeal and rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 227.22(2), Stats.

Wisconsin Department of Health and
Social Services

Dated: November 13, 1991

By: _____
Gerald Whitburn
Secretary

SEAL:

Tommy G. Thompson
Governor

Gerald Whitburn
Secretary

Revisor

State of Wisconsin
Department of Health and Social Services

November 13, 1991

Mr. Bruce E. Munson
Revisor of Statutes
119 Martin Luther King, Jr., Blvd.
Madison, WI 53703

Dear Mr. Munson:

As provided in s. 227.20, Stats., there is hereby submitted a certified copy of HSS 105.15 and 107.10, administrative rules relating to coverage of prescription and over-the-counter drugs under the Medical Assistance program.

These rules are also being submitted to the Secretary of State as required by s. 227.20, Stats.

Sincerely,

Gerald Whitburn
Secretary

Enclosure