



State of New Mexico Human Services Department Human Services Register



I. DEPARTMENT NEW MEXICO HUMAN SERVICES DEPARTMENT

II. SUBJECT PHARMACY SERVICES

III. PROGRAM AFFECTED (TITLE XIX) MEDICAID

IV. ACTION PROPOSED RULES

V. BACKGROUND SUMMARY

The Human Services Department, Medical Assistance Division, is proposing amendments to 8.324.4 NMAC *Pharmacy Services* rule to clarify regulatory language, accuracy with existing rules and respond to current budgetary constraints.

If implemented as proposed, the following changes to Medicaid pharmacy benefit coverage will affect recipients:

- Coverage of over-the-counter (non-prescription) drug items for adults who are not in institutions, would be limited to insulin. Provisions are included to expand the list of covered over-the-counter items after making a determination that it is overall more economical to cover an over-the-counter item as an alternative to prescriptions items.
- Covered drugs would be subject to the generic-first coverage provisions, requiring a generic item to be tried by the eligible recipient before MAD covers a 'brand name' item. The prescriber must first use one or more generic items available to treat a condition before MAD covers a 'brand name' drug. The generic-first provisions would not apply to Indian Health Service (IHS) facilities and PL 93-638 tribally operated hospitals and clinics. The following categories of drug items would be exempt from the generic-first requirements:
 1. Anti-asthmatic and other respiratory drugs
 2. Anticoagulants
 3. Anticonvulsants
 4. Antipsychotics and antidepressants
 5. Cancer chemotherapy items, and

6. Thyroid hormones.

- For some categories of drugs, brand names will not be covered. For the following categories of drug items, only generic items will be covered:
 1. Acne medications
 2. Oral birth control pills
 3. Cough and cold medications.
- Compounded drug items will not be covered when the therapeutic ingredients have not been assigned national drug code numbers and are not approved for human use. This will terminate coverage for some 17-hydroxyprogesterone products compounded by pharmacists.

If implemented as proposed, the following changes to Medicaid pharmacy benefits will affect pharmacy providers by:

- Adding language for brand name drug products and for all A-rated therapeutic equivalents as to how MAD will determine state maximum allowable prices for multi-source drugs.
- Adding language to allow the baseline price of a multi-source drug as calculated by a national supplier of drug pricing information to serve as the state MAC price when a state MAC price has not otherwise been calculated by MAD.
- Adding language to accept a federal Department of Justice recommendation for pricing instead of a CMS price (such recommendations apply to very few items and are issued when the Department of Justice believes a manufacturer is reporting prices inaccurately.)
- Including language for 340B drug discount actual acquisition cost and 340B discount instructions.
- Changing the grace period for dispensing frequencies for maintenance drugs from 20 days to 14 days for necessary early refills.
- Adding to refill requirements that the consistent use of early refills will result in a calculation that the eligible recipient has sufficient stock of the drug item on hand and allowed refill dates will be adjusted accordingly.
- Adding controls on quantities dispensed for controlled substances.
- Adding language that overlapping use of multiple drug items with the same therapeutic uses that are potentially abused or otherwise dangerous may result in the prescriptions being subject to the prior authorization process.
- Removing language concerning over-the-counter items coverage in order to support the expanded description of these items.

- Removing language in 8.324.4 NMAC Section A subsection 14, Noncovered Services, in order to combine paragraph B with paragraph C.
- Removing language concerning UR contractor prior authorizations for durable medical equipment and medical supplies which can be dispensed by pharmacy services providers.
- Removing language concerning maximum allowable costs in order to support proposed changes.

Other changes in the rule being proposed at this time include the following:

- Adding New Mexico licensed mail order pharmacies as eligible providers.
- Replacing outdated word usage, such as Medicaid with MAD, the Medical Assistance Division.
- Providing more instruction on the eligibility of providers and their responsibilities.
- Directing providers to enroll and follow a MAD managed care or MAD fee-for-service coordinated care contractor's instructions for billing and authorization of services.

The changes in the pharmacy benefits are being proposed because the Department believes the changes are more in line with the benefits typically available from other pharmacy service insurers. Also, at this time there is a serious shortfall in state revenues which has resulted in reductions in many state agency budgets. The New Mexico Medicaid program budget is no exception. Program costs are outpacing available revenues. Therefore, the Department has looked at pharmacy and other program benefits to determine changes that can be made while still providing medically appropriate services.

The reduction in payments for these services in the Medicaid fee-for-service program is estimated to be \$2.5 million.

VI. RULES

These proposed rule changes refer to 8.324.4 NMAC of the Medical Assistance Program Rules Manual. This register and the proposed changes are available on the Medical Assistance Division web site at www.hsd.state.nm.us/mad/registers/2010 . If you do not have Internet access, a copy of the rules may be requested by contacting the Medical Assistance Division at 505-827-3156.

VII. EFFECTIVE DATE

The Department proposes to implement these rules effective December 1, 2010.

VIII. PUBLIC HEARING

A public hearing to receive testimony on these proposed rules will be held at 9:00 a.m. on October 15, 2010, at the ASD Conference Room, Plaza San Miguel, 729 St. Michaels Dr., Santa Fe, New Mexico.

If you are a person with a disability and you require this information in an alternative format or require a special accommodation to participate in the public hearing, please contact the Division toll free at 1-888-997-2583 and ask for extension 7-3156. In Santa Fe call 827-3156. The Department's TDD system may be accessed toll-free at 1-800-659-8331 or in Santa Fe by calling 827-3184. The Department requests at least ten (10) days advance notice to provide requested alternative formats and special accommodations.

Copies of all comments will be made available by the Medical Assistance Division upon request by providing copies directly to a requestor or by making them available on the MAD website or at a location within the county of the requestor.

IX. ADDRESS

Interested persons may address written or recorded comments to:

Kathryn Falls, Secretary
Human Services Department
P.O. Box 2348
Santa Fe, New Mexico 87504-2348

X. PUBLICATIONS

Publication of these rules approved by:

KATHRYN FALLS, SECRETARY
HUMAN SERVICES DEPARTMENT

TITLE 8 SOCIAL SERVICES
CHAPTER 324 ADJUNCT SERVICES
PART 4 PHARMACY SERVICES

8.324.4.1 ISSUING AGENCY: New Mexico Human Services Department (HSD).
[8.324.4.1 NMAC - Rp, 8 NMAC 4.MAD.000.1, 8/13/04; A, 12/1/10]

8.324.4.3 STATUTORY AUTHORITY: The New Mexico medicaid program ~~[is] and other health care programs are~~ administered pursuant to regulations promulgated by the federal department of health and human services under ~~[Title XIX of] the Social Security Act[, as amended and by the state human services department pursuant to state statute. See Section 27-2-12 et seq. NMSA 1978 (Repl. Pamp. 1991).] as amended or by state statute. See NMSA 1978, Section 27-2-12 et seq.~~
[8.324.4.3 NMAC - Rp, 8 NMAC 4.MAD.000.3, 8/13/04; A, 12/1/10]

8.324.4.6 OBJECTIVE: The objective of these ~~[regulations] rules~~ is to provide ~~[policies] instruction~~ for the service portion of the New Mexico ~~medicaid program. These policies describe eligible providers, covered services, nonecovered services, utilization review and provider reimbursement.] medical assistance programs.~~
[8.324.4.6 NMAC - Rp, 8 NMAC 4.MAD.000.6, 8/13/04; A, 12/1/10]

8.324.4.8 MISSION STATEMENT: ~~[The mission of the New Mexico medical assistance division (MAD) is to maximize the health status of medicaid-eligible individuals by furnishing payment for quality health services at levels comparable to private health plans.] To reduce the impact of poverty on people living in New Mexico and to assure low income and individuals with disabilities individuals in New Mexico equal participation in the life of their communities.~~
[8.324.4.8 NMAC - Rp, 8 NMAC 4.MAD.002, 8/13/04; A, 12/1/10]

8.324.4.9 PHARMACY SERVICES: The New Mexico ~~medicaid program (medicaid)] medical assistance division (MAD)~~ pays for medically necessary health services furnished to eligible recipients, including covered pharmacy services [42 CFR Section 440.120(a)]. ~~[This section describes eligible pharmacy providers, covered services, service limitations, and general reimbursement methodology.] Pharmacy claims must be submitted to the appropriate pharmacy claims processor as designated by [the medical assistance division] MAD. The pharmacy claims processor may vary based on the prescriber's license, practice specialty, network affiliation and/or the [client's] recipient's category of eligibility or enrollment in a contracted health plan.~~
[8.324.4.9 NMAC - Rp, 8 NMAC 4.MAD.753, 8/13/04; A, 7/1/05; A, 12/1/10]

8.324.4.10 ELIGIBLE PROVIDERS:

~~[A. — Upon MAD's approval of medical assistance program provider participation agreements, the following providers are eligible to furnish pharmacy services:]~~

A. Health care to New Mexico eligible recipients is furnished by a variety of providers and provider groups. The reimbursement and billing for these services is administered by MAD. Upon approval of a New Mexico MAD provider participation agreement by MAD or its designee, licensed practitioners, facilities and other providers of services that meet applicable requirements are eligible to be reimbursed for furnishing covered services to eligible recipients. A provider must be enrolled before submitting a claim for payment to the MAD claims processing contractors. MAD makes available on the HSD/MAD website, on other program-specific websites, or in hard copy format, information necessary to participate in health care programs administered by HSD or its authorized agents, including program rules, billing instructions, utilization review instructions, and other pertinent materials. When enrolled, a provider receives instruction on how to access these documents. It is the provider's responsibility to access these instructions, to understand the information provided and to comply with the requirements. The provider must contact HSD or its authorized agents to obtain answers to questions related to the material or not covered by the material. To be eligible for reimbursement, a provider must adhere to the provisions of the MAD provider participation agreement and all applicable statutes, regulations, and executive orders. MAD or its selected claims processing contractor issues payments to a provider using electronic funds transfer (EFT) only. Providers must supply necessary information in order for payment to be made. Eligible providers include:

- (1) pharmacies licensed by the New Mexico pharmacy board;
- (2) clinics licensed for outpatient dispensing by the New Mexico pharmacy board;
- (3) institutional pharmacies licensed for outpatient dispensing by the New Mexico pharmacy board;

- (4) family planning clinics and rural health clinics licensed for outpatient dispensing by the New Mexico pharmacy board;
- (5) prescribing practitioners practicing in communities more than fifteen (15) miles from a licensed pharmacy;
- (6) Indian health service (IHS), Indian Self-Determination and Education Assistance Act (“tribal 638”) and IHS contract pharmacies and drug rooms operated consistent with IHS standards of practice for pharmaceutical ~~care.~~ care; and
- (7) mail order pharmacies licensed to dispense in New Mexico.

~~[B. — Once enrolled, providers receive a packet of information, including medicaid program policies, billing instructions, utilization review instructions and other pertinent material from MAD. Providers are responsible for ensuring that they have received these materials and for updating them as new materials are received from MAD.]~~

B. When services are billed to and paid by a MAD fee-for-service coordinated services contractor, the provider must also enroll as a provider with the coordinated services contractor and follow that contractor’s instructions for billing and for authorization of services.

[8.324.4.10 NMAC - Rp, 8 NMAC 4.MAD.753.1, 8/13/04; A, 7/1/05; A, 12/1/10]

8.324.4.11 PROVIDER RESPONSIBILITIES:

~~[A. — Providers who furnish services to medicaid recipients must comply with all specified medicaid participation requirements. See 8.302.1 NMAC, *General Provider Policies*.~~

~~— B. — Providers must verify that individuals are eligible for medicaid at the time services are furnished and determine if medicaid recipients have other health insurance.]~~

A. A provider who furnishes services to medicaid and other health care programs eligible recipients must comply with all federal and state laws, regulations, and executive orders relevant to the provision of medical services as specified in the MAD provider participation agreement. A provider must adhere to the MAD program rules and instruction as specified in this manual and its appendices, and program directions and billing instructions as specified in this manual and its appendices, and program directions and billing instructions, as updated. A provider is also responsible for following coding manual guidelines and center for medicare and medicaid services (CMS) correct coding initiatives, including not improperly unbundling or up-coding manual guidelines. See 8.302.1 NMAC, *General Provider Policies*.

B. A provider must verify that individuals are eligible for a specific health care program administered by the HSD and its authorized agents, and must verify the eligible recipient’s enrollment status at the time services are furnished. A provider must determine if an eligible recipient has other health insurance. A provider must maintain records that are sufficient to fully disclose the extent and nature of the services provided to an eligible recipient. See 8.302.1 NMAC, *General Provider Policies*.

~~[C. — Providers must maintain records that are sufficient to fully disclose the extent and nature of the services furnished to recipients. See 8.302.1 NMAC, *General Provider Policies*.~~

~~(1) — Original prescriptions written by prescribing providers cannot be discarded and replaced with a copy of the medicaid claims forms. The original prescription must be retained by the pharmacy. If the prescriber certifies that a specific brand is medically necessary, by handwriting “brand medically necessary” on the face of the prescription, the allowed ingredient cost is the estimated acquisition cost (EAC). The documentation of the provider’s handwritten “brand medically necessary” must be maintained by the pharmacy provider and furnished upon request. Checked boxes, rubber stamps, requests by telephone and written words that do not include the statement “medically necessary” do not constitute appropriate documentation, pursuant to 42 CFR 447.331. “Brand medically necessary” prescriptions may be subject to prior authorization.~~

~~(2) — Any claim for which the “brand medically necessary” is claimed must be supported with documentation.~~

~~(3) — Recipients or their representatives should sign the drug claim form when receiving medication or supplies, when possible. For computer printed claims and electronically or tape billed claims, signatures can be accumulated in a log giving the date received, the prescription number, and the signature of the individual picking up the prescription. In the absence of a signature log, electronic prescription processing systems must have provisions for documenting receipt of services by authorized parties.]~~

C. Retention and storage of the original prescription, electronic prescription, and records of phone or fax orders must meet all pharmacy board requirements and must be retained for 6 years. If the prescriber certifies that a specific brand is medically necessary, by handwriting “brand medically necessary” or “brand necessary” on the face of the prescription, the allowed ingredient cost is the estimated acquisition cost (EAC) of the brand drug.

The documentation of the provider's handwritten certification must be maintained by the pharmacy provider and furnished upon request. Checked boxes, rubber stamps and requests by telephone do not constitute appropriate documentation, pursuant to 42 CFR 447.512. "Brand necessary" prescriptions may be subject to prior authorization. Any claim for which "brand necessary" is claimed must be supported with documentation in the prescriber's medical records. Electronic alternatives approved by the secretary of the federal department of health and human services are acceptable.

D. A pharmacy provider must discuss any matters with ~~[medicaid recipients or caregivers]~~ the eligible recipient or their personal representative that in the provider's professional judgment are significant. See 42 USC 1396r-8(g)(2)(A)(ii)(I) of the Social Security Act. Pharmacy counseling services are subject to the standards for counseling established under the State Pharmacy Practice Act. Counseling must be ~~[furnished, unless refused by recipients or caregivers.]~~ furnished unless declined by the eligible recipient or their personal representative.
[8.324.4.11 NMAC - Rp, 8 NMAC 4.MAD.753.2, 8/13/04; A, 12/1/10]

8.324.4.12 COVERED SERVICES: MAD covers most medically necessary prescription drugs and some over-the-counter drugs, subject to the limitations and restrictions delineated in this Part. Claims for injectable drugs, intravenous (IV) admixtures, IV nutritional products and other expensive medications ~~[can]~~ may be reviewed for medical necessity before or after reimbursement. Providers must consult MAD, or its designated contractor, before supplying items not specifically listed in this policy or billing instructions. ~~[Coverage of over-the-counter items is limited to situations where the over-the-counter items may be the drug of choice for common medical conditions and when the over-the-counter item provides an appropriate economical and therapeutic alternative to prescription drug items.]~~ Drug restrictions include dosage, day supply, and refill frequency limits necessary to ensure appropriate utilization or to prevent fraud and abuse. In establishing such limits, professional standards ~~[of health]~~ are considered.

A. For an adult eligible recipient not in a institution, coverage of over-the-counter items is limited to insulin. MAD or its designee may make a decision to cover other over-the-counter items after making a specific determination when it is overall more economical to cover an over-the-counter item as an alternative to prescription items. Such coverage is incorporated as part of the generic-first coverage provisions. Otherwise, the adult eligible recipient or their personal representative is responsible for purchasing or otherwise obtaining an over-the-counter item.

B. Covered drugs are subject to generic-first coverage provisions. The recipient must first use one or more generic items available to treat a condition before MAD covers a brand name drug for the condition. MAD publishes a list of the therapeutic categories of drug items that are exempt from the generic-first coverage provisions. Brand name drug items may be covered upon approval by MAD or its designee, based upon medical justification by the prescriber.

[8.324.4.12 NMAC - Rp, 8 NMAC 4.MAD.753.3, 8/13/04; A, 7/1/05; A, 12/1/10]

8.324.4.13 COVERAGE REQUIREMENTS:

A. **Legal requirements:** All drug items must be assigned a national drug code by the respective manufacturer, repackager or labeler. ~~[Any]~~ A prescription must meet all federal and state laws. Providers must fulfill all the requirements of federal and state laws relating to pharmacy practice and ethics.

B. **Rebate requirements:** Medicaid pays only for the drugs of pharmaceutical manufacturers that have entered into and have in effect a rebate agreement with the federal department of health and human services. This limitation does not apply to dispensing a single-source or innovator multiple-source drug if MAD has determined that the availability of the drug is essential to the health of eligible recipients.

~~[C. This limitation does not apply to dispensing a single-source or innovator multiple-source drug if MAD has determined that the availability of the drug is essential to the health of recipients.]~~

[8.324.4.13 NMAC - Rp, 8 NMAC 4.MAD.753.4, 8/13/04; A, 12/1/10]

8.324.4.14 NONCOVERED SERVICES OR SERVICE RESTRICTIONS: Pharmacy services are subject to the limitations and coverage restrictions that exist for other medicaid services. See 8.301.3 NMAC, *General Noncovered Services* ~~[[MAD-602]]~~.

A. Medicaid does not cover the following specific pharmacy items:

- (1) medication supplied by state mental hospitals to recipients on convalescent leave from the center;
- (2) methadone for use in drug treatment programs;
- (3) personal care items such as non-prescription shampoos, soaps;
- (4) cosmetic items, such as retin-A for aging skin, rogain for hair loss;

(5) drug items that are not eligible for federal financial participation, ~~including~~ drugs not approved as effective by the federal food and drug administration, known as DESI (drug efficacy study implementation) drugs; ~~by the federal food and drug administration, or DESI drugs);~~

(6) fertility drugs;

(7) antitubercular drug items available from the New Mexico department of health or the United States public health service;

(8) weight loss/weight control drugs~~are covered with prior authorization~~;

(9) ~~barbiturate hypnotic drugs, barbiturate drugs whose primary action is to induce sleep for recipients who do not reside in nursing homes; MAD covers barbiturate hypnotic drugs for recipients in nursing homes and for other recipients when authorized on a prior approval basis if related to an appropriate medical diagnosis;~~ Barbiturate hypnotic drugs whose primary action is to induce sleep unless the eligible recipient resides in a nursing home;

(10) drug items used to treat sexual ~~dysfunction~~ dysfunction;

(11) compounded drug items which lack an ingredient approved by the federal food and drug administration for the indication for which the drug is intended;

(12) compounded drug items for which the therapeutic ingredient do not have an assigned national drug code and are not in an ingredient assigned a national drug code and approved by the federal food and drug administration for human use; and

(13) cough and cold preparations for an eligible recipient under the age of four.

B. ~~MAD covers certain non-prescription drug items without special authorization or prior authorization when prescribed by a licensed [physician or other licensed practitioner billing and claims processing instructions providers receive once enrolled contain information on these drug items. The pharmacy must maintain the prescription, written request, or telephone order reduced to writing. Other non-prescription items can be considered on a prior approval basis when related to an appropriate medical diagnosis requiring an ongoing course of treatment.] MAD covers non-prescription drug items without prior authorization when prescribed by a licensed practitioner authorized to prescribe for eligible MAD recipients who reside in a nursing facility or an intermediate care facility for the mentally retarded (ICF-MR), when such items are not routinely included in the facility's reimbursable cost and a specific prescription for the item is dispensed based on a practitioner's order. The following cannot be charged to the recipient or billed to medicaid by a provider.~~

~~(a) diabetic testing supplies and equipment;~~

~~(b) aspirin and acetaminophen;~~

~~(c) routine ointments, lotions and creams, and rubbing alcohol; and~~

~~(d) other non-prescription items stocked at nursing stations and distributed for use individually in small quantities.~~

~~[C. MAD covers routine non-prescription drug items supplied in nursing facilities or intermediate care facilities for the mentally retarded with specified restrictions.~~

~~(1) Routine items are included in the facility's reimbursable cost and cannot be charged to the recipient or billed to medicaid by providers.]~~

~~(2) Routine drug items, include the following:~~

~~(a) diabetic testing supplies and equipment;~~

~~(b) alcohol and body rubs;~~

~~(c) aspirin and acetaminophen;~~

~~(d) routine ointments, lotions and creams; and~~

~~(e) other non-prescription items stocked at nursing stations and distributed or used individually in small quantities.]~~

~~[D.]~~ C. Medicaid does not cover drug items for recipients eligible for medicare part D when the drug item or class of drug meets the federal definition of a medicare part D covered drug. Medicaid does not cover any copayment due from the recipient towards a claim paid by medicare part D nor any medicare part D covered drug or class of drug where the recipient has a gap in medicare part D coverage due to a medicare coverage limit. Items or drug classes specifically excluded by medicare part D are covered, non-covered or limited to the same extent that medicaid covers the excluded drug items for full benefit medicaid recipients who are not dual eligibles.

[8.324.4.14 NMAC - Rp, 8 NMAC 4.MAD.753.5, 8/13/04; A, 1-1-06; A, 12/1/10]

8.324.4.15 PRIOR AUTHORIZATION AND UTILIZATION REVIEW: All medicaid services are subject to utilization review for medical necessity and program compliance. Reviews can be performed before services are furnished, after services are furnished and before payment is made, or after payment is made. See

8.302.5 NMAC, *Prior Authorization and Utilization Review*. Once enrolled, providers receive instructions and documentation forms necessary for prior authorization and claims processing. Review or prior authorization may be required for items for which a ~~[lesser]~~ less expensive or therapeutically preferred alternative should be used first. ~~[Establishing these]~~ In addition to the generic-first coverage provisions, applicable therapeutic “step” requirements will be based on published clinical practice guidelines, professional standards of health care, and economic considerations.

A. **Prior authorization:** MAD, or its designated contractor, reviews all requests for prior authorizations. ~~[The MAD utilization review (UR) contractor grants prior authorization on durable medical equipment and medical supplies which can be dispensed by pharmacy services providers.]~~ Services for which prior authorization was obtained remain subject to utilization review at any point in the payment process.

B. **Eligibility determination:** Prior authorization of services does not guarantee that individuals are eligible for medicaid. Providers must verify that individuals are eligible for medicaid at the time services are furnished and determine if medicaid recipients have other health insurance.

C. **Reconsideration:** Providers who disagree with prior authorization request denials or other review decisions can request a re-review and a reconsideration. See 8.350.2 NMAC, *Reconsideration of Utilization Review Decisions* [MAD-953].

D. **Drug utilization review:** The MAD drug utilization review (DUR) program is designed to assess the proper utilization, quality, therapy, medical appropriateness and costs of prescribed medication through evaluation of claims data, as required by 42 CFR 456.700-716. The DUR program is done on a retrospective, prospective and concurrent basis. This program shall include, but is not limited to, data gathering and analysis and a mix of educational interventions related to over-utilization, under-utilization, therapeutic duplication, drug-to-disease and drug-to-drug interactions, incorrect drug dosage or duration of treatment and clinical abuse or misuse. Information collected in the DUR program that identifies individuals is confidential and may not be disclosed by the MAD DUR board to any persons other than those identified as the recipient’s service providers or governmental entities legally authorized to receive such information.

(1) **Prospective drug use review:** Prospective DUR (ProDUR) is the screening for potential drug therapy problems (such as, over-utilization, under-utilization, incorrect drug dosage, therapeutic duplication, drug-disease contraindication, adverse interaction, incorrect duration of drug therapy, drug-allergy interactions, clinical abuse or misuse) before each prescription is dispensed. The dispensing pharmacist is required to perform prospective drug use review prior to dispensing. Only a licensed pharmacist or intern may perform ProDUR activities. The pharmacist may be required to insert appropriate DUR override codes when the ProDUR system detects drug therapy issues. In retrospective review of paid claims, payment may be recouped for claims in which the pharmacist has not followed accepted standards of professional practice.

(2) **Counseling:** Pursuant to 42 CFR 456.705, each dispensing pharmacist must offer to counsel each medicaid eligible recipient receiving benefits (or the caregiver of such individual) who presents a new prescription, unless the recipient or their personal representative refuses such counsel. Pharmacists must document these refusals. If no documentation of refusal of counseling is available or readily retrievable, it will be assumed that appropriate counseling and prospective drug use review has taken place. A reasonable effort must be made to record and maintain the pharmacist’s comments relevant to said counseling and prospective drug review, particularly when ProDUR overrides are performed. Counseling must be done in person, whenever practicable. If it is not practicable to counsel in person, providers whose primary patient population ~~[do]~~ does not have access to a local measured telephone service must provide access to a toll-free number.

[8.324.4.15 NMAC - Rp, 8 NMAC 4.MAD.753.7, 8/13/04; A, 7/1/05; A, 12/1/10]

8.324.4.16 REIMBURSEMENT: Pharmacy providers must submit claims for reimbursement on the separate pharmacy claim form or its successor. See 8.302.2 NMAC, *Billing for Medicaid Services* and 8.324.4.17 NMAC, *Pharmacy Point of Sale*. ~~[Once enrolled, providers receive instructions on documentation, billing and claims processing.]~~

A. **General reimbursement methodology:** ~~[MAD’s total reimbursement for a prescription drug must not exceed the lowest of the estimated acquisition cost (EAC), the maximum allowable cost (MAC), the federal upper limit (FUL), or the usual and customary charge.]~~ MAD’s total reimbursement for a prescription drug will not exceed the estimated ingredient cost plus a dispensing fee or the usual and customary charge. The estimated ingredient cost will not exceed the lowest of the estimated acquisition cost (EAC), the maximum allowable cost (MAC), the actual acquisition cost of a 340B drug, or the federal upper limit (FUL).

(1) **Estimated acquisition cost (EAC).** MAD determines EAC as follows:

(a) MAD establishes EAC, defined as MAD's approximation of the net or actual acquisition costs of such ~~[drugs to pharmacies in New Mexico for all covered drugs, following consultation with representatives of the New Mexico pharmacy profession. Dispensing fees are in addition to EAC.]~~ drugs;

(b) The factors MAD considers in setting rates for drugs under this subparagraph include:

(i) product cost, which may vary among purchasing contracts;

(ii) ~~[MAD's documented]~~ clinical concerns;

(iii) MAD's budget limits; ~~[and]~~

(iv) the actual package size ~~[dispensed.]~~ dispensed; and

(v) payments by other payers in New Mexico and other state medicaid and medicare

pricing policies.

(c) MAD uses the EAC as MAD's reimbursement for a drug when the EAC, plus a dispensing fee established by MAD, is the lowest of the rates calculated under the methods listed in general reimbursement methodology, Subsection A of 8.324.4.16 NMAC.

~~(d) [EAC cannot exceed the lowest of the current published average wholesale price of a drug less a percentage established by the department or EAC by reference to other pricing information sources selected by MAD pursuant to general reimbursement methodology, Subsection A of 8.324.4.16 NMAC.]~~ EAC is calculated using the current published average wholesale price (AWP) of a drug less a percentage established by the department, the average manufacturer price (AMP) plus a percentage established by the department, or the wholesale acquisition cost (WAC) plus a percentage established by the department, determined by reference to other pricing information sources selected by MAD pursuant to general reimbursement methodology, Subsection A of 8.324.4.16 NMAC; and

(e) MAD uses the ingredient cost indicated in the ingredient cost field on the billing transaction as the EAC when that indicated ingredient cost is lower than the MAD EAC.

(2) **Maximum allowable cost (MAC); MAC methodology.** MAD establishes a maximum allowable cost (MAC) applicable for certain multiple-source drugs with FDA rated therapeutic equivalents and for certain over-the-counter drugs and non-drug items on the following basis:

(a) at least one A-rated generic (as listed in the FDA orange book) is readily available to New Mexico pharmacies;

(b) ~~[the state MAC for the brand name drug products and for all A-rated therapeutic equivalents shall be determined by taking the lowest available cost for all of the A-rated therapeutic equivalent drugs regardless of manufacturer, and multiplying that by cost a factor set by MAD to cover the pharmacy's estimated administration and overhead plus a dispensing fee;]~~ the MAC for the brand name drug products and for all A-rated therapeutic equivalents shall be determined by arraying costs for the A-rated therapeutic equivalent drugs regardless of manufacturer, and selecting a reasonable price from the arrayed list in a manner consistent with the state plan approved by CMS subjecting that price to cost factors and tests for reasonableness;

~~[(c) the state MAC list will be updated at least quarterly, with on-going adjustments due to pricing changes and availability issues;~~

~~_____ (d) all products on the state MAC list will be reviewed at a minimum every 6 months;~~

~~_____ (e) if a "federal upper limit" (FUL) has been set for a product, then the MAC will not be applied if the FUL ingredient reimbursement rate is lower than the MAC reimbursement rate;~~

~~_____ (f) MAC will not be applied if the calculation equals an amount greater than the current EAC, as defined in estimated acquisition costs in Paragraph (1) of Subsection A of 8.324.4.16 NMAC;]~~

(c) when a state MAC price has not been calculated by MAD, a baseline price calculated by a national supplier of drug pricing information is used as the state MAC;

~~[(g)]~~ d. MAC will not be applied if a specific brand has been determined to be medically necessary, in which event the reimbursement rate will be the lower of the EAC of the product dispensed plus the dispensing [fee;] fee or the provider's billed usual and customary charge; and

~~[(h)]~~ e. for over-the-counter drugs and non-drug items, MAC may be established using the pricing sources in Subsection B of [8.324.16] 8.324.4.16 NMAC.

(3) **Federal upper limit (FUL) methodology:**

(a) MAD adopts the FUL that is set by the centers for medicare and medicaid services (CMS) or recommended by the federal department of justice.

(b) MAD's maximum payment for multiple-source drugs for which CMS has set FULs will not exceed, in the aggregate, the prescribed upper limits plus the dispensing fees set by MAD under the dispensing fee determination.

~~[(c) — Except as provided in MAC methodology and in subparagraph (4) below, MAD uses the FUL as MAD's reimbursement rate for all FDA A-rated, therapeutic equivalent drugs when the FUL price, plus a dispensing fee is the lowest of the rates calculated under the methods listed in general reimbursement methodology Subsection A of 8.324.4.16 NMAC.]~~

~~[(d)]~~ (c) MAD will not use the individual drug FUL as MAD's reimbursement rate when the prescribing practitioner has certified that a specific brand is medically necessary, in which event the reimbursement rate will be the lower of the EAC of the product dispensed plus the dispensing ~~[fee]~~ fee or the provider's usual and customary billed charge.

(4) 340B drug discount actual acquisition cost:

(a) The actual ingredient cost for drugs purchased under section 340B of the Public Health Service Act, 42 USC 256b, and dispensed to medicaid recipients must be placed in the ingredient cost field and indicated on the billing transaction as a 340B drug item.

(b) Drugs purchased under section 340B of the Public Health Service Act, 42 USC 256b, and dispensed to medicaid recipients must be billed at the actual acquisition cost of the provider and indicated on the billing transaction as a 340B drug item if an eligible recipient with a prescription written at a 340B entity, who requests the item to be dispensed by a 340B pharmacy under contract to the 340B entity then the pharmacist must dispense 340B purchased items when filling the prescription.

~~[(4)]~~ (5) **Usual and customary charge:**

(a) The provider's billed charge must be its usual and customary charge for services. Over-the-counter items must be billed with the over-the-counter price as the usual and customary charge, unless it is labeled and dispensed as a prescription.

(b) "Usual and customary charge" refers to the amount that the individual provider charges the general public in the majority of cases for a specific procedure or service.

(c) Usual and customary charges must reflect discounts given to non-medicaid recipients for certain reasons, such as age or nursing home residents, when a medicaid recipient meets the standards for the discount. Medicaid must be given the advantage of discounts received by the general public, including promotions or items sold at cost to the general public, if these are the prices usually and customarily charged to non-medicaid recipients.

(d) Providers must not add additional costs for their time, paperwork, or anticipated turnaround time for payment.

~~[(5) — 340B drug discount: Drugs purchased under section 340B of the Public Health Service Act, 42 USC 256b, and dispensed to medicaid recipients will be reimbursed at established rates, after consultation with representatives of the New Mexico pharmacy profession.]~~

(6) **Medicare reimbursement:** Reimbursement may be limited to medicare reimbursement limits where the total of the medicare-allowed amounts plus, if applicable, a dispensing fee, is the lowest of EAC, MAC, FUL, usual and customary charge or 340B drug discount amount as defined in Subsection A of 8.324.16 NMAC, *Reimbursement*.

B. **Pricing information to set EAC and MAC:** MAD selects the sources for pricing information used to set EAC and MAC. These sources may include pharmaceutical wholesalers, manufacturers, federal agencies, drug data information clearinghouses ~~{(e.g., first data bank)}~~ and pharmacy invoices.

C. **Assistance in establishing EAC and MAC:** MAD may solicit assistance from pharmacy providers, pharmacy benefit managers (PBMs), other government agencies, actuaries, and/or other consultants when establishing EAC and/or MAC.

D. **Pharmacy ~~[provider]~~ price reductions:** If the pharmacy provider offers a discount, rebate, promotion or other incentive that ~~[directly relates to the]~~ results in a reduction of the price of a prescription to the individual non-medicaid customer, the provider must similarly reduce its charge to MAD for the prescription.

E. **No claims for free products:** If a pharmacy gives a product free to the general public, the pharmacy must not submit a claim to MAD when giving the free product to a medicaid recipient.

F. **Solutions:** Solutions, such as saline for nebulizers, intravenous (IV) solutions without additives, electrolyte and irrigation solutions, and diluents are considered medical supply items for reimbursement purposes. See ~~[8.350.3]~~ 8.324.5 NMAC, *Durable Medical Equipment and Medical Supplies* [MAD-754].

G. **Non-drug items:** Urine test reagents, nutritional products, equipment and medical supplies, including syringes and alcohol swabs, are subject to restrictions for medical supplies. See 8.324.5 NMAC, *Durable Medical Equipment and Medical Supplies* ~~[[MAD-754].]~~

~~[(1) — When a pharmacy does not provide the ongoing clinical monitoring and care coordination involved with an episode of home infusion therapy, the NCPDP claim format must be used for billing the involved~~

drugs. If the pharmacy's business includes providing ongoing clinical monitoring and care coordination related to an episode of home infusion therapy, the drugs must be billed in CMS 1500 or ASC X12N 837 format, or as otherwise consistent with federally required national standards. When an order for infusion therapy includes medical supply items that do not have NDC numbers assigned to them by the manufacturer, repackager or labeler, those items must be billed in the CMS 1500 or ASC X12N 837 format, or as otherwise consistent with federally required national standards.

~~_____ (2) Reimbursement is calculated for the medical supply portion according to medical supply regulations and for the drug portion under these regulations.]~~

[8.324.4.16 NMAC - Rp, 8 NMAC 4.MAD.753.8, 8/13/04; A, 7/1/05; A, 12/1/10]

8.324.4.17 POINT OF SALE: The point-of-sale system provides relevant drug utilization information that the pharmacist must consider before dispensing a drug. If utilization information indicates that a recipient has an adequate supply of the drug item or that the quantity being dispensed is excessive, the claim will initially be denied. The pharmacist is responsible for resolving the issue and obtaining an authorization to dispense the drug, if necessary.

A. **General requirements:** All in-state and border area pharmacy providers are required to submit claims through the point-of-sale system.

B. **Exceptions to general requirements:** The following are exceptions to this general requirement:

- (1) the provider is out-of-state and is not a border area provider;
- (2) the provider is a family planning clinic dispensing prescriptions;
- (3) the provider submitted on average less than ~~[fifty (50)]~~ 50 claims per month [average] to MAD

for the preceding six ~~[(6)]~~ month period;

~~[(4) the provider dispenses prescriptions only to recipients in nursing facilities;]~~

~~[(5)]~~ (4) the claim requires an attachment or explanation; and

~~[(6)]~~ (5) a required data element on the claim cannot be entered in the current standard point-of-sale

format.

[8.324.4.17 NMAC - Rp, 8 NMAC 4.MAD.753.9, 8/13/04; A, 12/1/10]

8.324.4.18 PRESCRIPTIONS AND REFILLS:

A. **Dispensing frequencies:** Medicaid limits the frequency for which it reimburses the same pharmacy for dispensing the same drug to the same recipient.

(1) The limitation is established individually for each drug.

(2) ~~[Some drugs are subject to a maximum of three (3) times in ninety (90) days with a twenty (20)-day grace period to allow for necessary early refills.]~~ Maintenance drugs are subject to a maximum of three times in 90 days with a 14-day grace period to allow for necessary early refills.

(3) Certain drugs are given more flexibility due to their specific dosage forms, packaging or clinical concerns.

(4) The excessive dispensing limitation applies regardless of whether the claim is for a new prescription or refill.

B. **Refill requirements:** Refills must be consistent with the dosage schedule prescribed and with all applicable federal and state laws. Consistent use of early refills will result in a calculation that the eligible recipient has sufficient stock of the drug item on hand and allowed refill dates will be adjusted accordingly.

C. **Quantities dispensed:** Maintenance drugs are those on the MAD-approved maintenance drug list. For recipients with likely continuous eligibility due to age, disability or eligibility policy, prescriptions for maintenance drugs may be dispensed in amounts up to a ~~[ninety (90)]~~ 90-day supply. Prescriptions for non-maintenance drugs may be dispensed in up to 34 ~~[(thirty-four)]~~ day supplies. Oral contraceptives may be dispensed for up to a one-year supply if the appropriate contraceptive for the recipient has been established.

(1) Pharmacy providers shall not reduce prescriptions for maintenance drugs that are written for quantities larger than a ~~[thirty-four (34)]~~ 34-day supply and may dispense up to a 90 ~~[(ninety)]~~ day supply. MAD considers prescription splitting to be fraudulent. Pharmacies that do not have the entire prescribed amount on hand may dispense a partial fill.

(2) Coverage may be limited by the end date of the recipient's span of eligibility at the time of dispensing.

(3) Pharmacists are encouraged to consult with prescribers to achieve optimal drug therapy outcomes, consistent with NMSA 1978, Section 61-11-2(V).

(4) Controlled substances may have specific controls on the quantities dispensed.

D. **Unit dose packaging:** MAD does not pay for unit dose packaging or for prefilling syringes. MAD does reimburse for commercial unit dose packaged drugs.

E. **Prevention of abuse:** Drug items are to be dispensed for legitimate medical needs only. If the pharmacist suspects the eligible recipient of over-utilizing or abusing drug services, the pharmacist must contact the provider and MAD so that the eligible recipient's use of medications can be reviewed. Overlapping use of multiple drug items with the same therapeutic uses that are potentially abusive or otherwise dangerous may result in subjecting the prescriptions to the prior authorization process.

F. **Mail service pharmacy:** MAD may provide a mail service pharmacy for eligible recipient use.

(1) The mail service pharmacy is available as an option to all medicaid recipients.

(2) Retail pharmacies may mail, ship or deliver prescriptions to medicaid recipients consistent with applicable state and federal statutes and regulations.

[8.324.4.18 NMAC - Rp, 8 NMAC 4.MAD.753.10, 8/13/04; A. 12/1/10]

HISTORY OF 8.324.4 NMAC:

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ISD 310.0700, Pharmacy Services, filed 2/29/80.

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ISD 310.0700, Drug Services, filed 7/8/82.

ISD Rule 310.0700, Drug Services, filed 3/1/83.

ISD Rule 310.0700, Drug Services, filed 2/15/89.

ISD Rule 310.0700, Drug Services, filed 7/9/84.

MAD Rule 310.07, Drug Services, filed 3/31/89.

MAD Rule 310.07, Drug Services, filed 1/3/92.

MAD Rule 310.07, Drug Services, filed 4/20/92.

MAD Rule 310.07, Drug Services, filed 12/8/94.

History of Repealed Material:

MAD Rule 310.07, Drug Services, filed 12/8/94 - Repealed effective 2/1/95.

8 NMAC 4.MAD.753, Pharmacy Services, filed 1/18/95 - Repealed effective 8/13/04.