



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

FINAL RULES

V. BACKGROUND SUMMARY

New Mexico Human Services Register Vol. 33 Number 36, dated August 27, 2010, issued proposed changes to Medical Assistance Division 8.324.4 Pharmacy Services rule.

A public hearing was held on October 15, 2010, to receive public comments on the proposed rules. The Human Services Department (the Department) received ten written comments and one public comment.

- Over half of the written comments and the sole public comment requested the Department continue to cover a broad range of over-the-counter items (OTC) for adults. One comment had very specific suggestions for drug items that should continue to be covered because it is economical to do so.

Department Response: Some of the comments expressed concern that the Department would cease paying for diabetic type supplies such as syringes and urine testing reagents, as well as electrolyte replacement items. Because these were considered as medical supplies, it was not intended for the limitation on OTC coverage to apply to those items.

Therefore, the wording in the final rule was changed to indicate these items as still covered. Based on comments received, the final rule includes coverage of OTC prenatal vitamins, ophthalmic lubricants, scabicides, pediculicides, sodium chloride as an adjunct for inhalants, and topical and vaginal fungicides and anti-inflammatories, all as cost effective alternatives to the prescription drug items. Following concerns expressed regarding medical necessity of some items for the disabled recipients, the Department has included coverage provisions through prior authorization when a specific regimen of over the counter drugs is required to treat chronic disease conditions.

- A number of written comments were received requesting the Department to reconsider its proposed generic-first provisions.

Department Response: The Department appreciates the information presented. The Department has made the decision to retain proposed changes in the final rule to implement a generic-first program. Safeguards are in place in this rule as well as other Medical Assistance Division rules that allow for exceptions based on medical necessity. The wording was changed to assure appropriate access to drug items.

Based on comments, drugs used to treat HIV are being added to the list of drug categories that will not be subject to generic-first requirements. The categories of drug items that will be exempt from the generic-first requirements are:

1. Anti-asthmatic and other respiratory drugs
2. Anticoagulants
3. Anticonvulsants
4. Antipsychotics and antidepressants
5. Cancer chemotherapy items
6. Thyroid hormones, and
7. Drugs used to treat HIV.

For the following categories of drug items, only generic items will be covered:

1. Acne medications
2. Cough and cold medications.

As stated in the register for the proposed rule, 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.

- Advocates, professional organizations, providers and one recipient requested the Department reconsider the restriction of cough and cold preparations for children less than four years of age, the restriction to cover drug items to only those eligible for federal rebate and financial participation, and the restriction to cover only drugs that are approved by the Federal Drug Administration (FDA) as effective.

Department Response: The Department believes it is in the best interest of the Medicaid recipients to follow the recommendations of the FDA. The Department believes that its decision to limit these types of pharmacy drug items does not deny appropriate medically necessary care of a recipient. The Department believes that the FDA safeguards protect recipients while still providing the most current approved medical treatment. Federal rules specifically limit Medicaid coverage of drugs not classified as effective and drugs for which the manufacturer has not signed a rebate agreement with the federal government. These provisions have been in place for many years and were not proposed as changes to the current rule.

- Professional and provider organizations' written comments and the sole public comment requested the Department reconsider including 340B pricing when establishing state maximum allowable amounts for drug items.

Department Response: When establishing state maximum allowable amounts for drug items, the Department does not intend to use 340B prices in establishing state maximum costs allowed. The wording was changed for clarity in the final rule.

- Opinion was divided in the written comments and the sole public comment on the additional language for more closely monitoring the utilization of controlled substances and multi-drug items within the same therapeutic class. The professional organization stated that their membership welcomed the language, while the advocate organizations expressed concern that the new language would allow the Department to deny access to recipients for these medications.

Department Response: The Department believes the wording, as proposed, allows appropriate access to controlled substances while, at the same time, provides for adequate control over abusable items. Safeguards are in place in this rule as well as other Medical Assistance Division rules that allow for exceptions based on medical necessity.

- Comments were received expressing concern that pharmacies would, under the proposed rule, be required to maintain the prescriber's medical records for a claim marked "brand necessary"; that variations in wording should be allowed; and that there were no provisions for electronic prescriptions.

Department Response: The wording proposed is consistent with federal requirements so will remain as stated in the proposed rule. The rule does contain provisions to allow the program to follow changes made by the federal government regarding electronic prescriptions.

- One professional organization in written and public comment expressed concerns about the Department's use of electronic fund transfers (EFT) stating it will "give the Department access to their bank accounts."

Department Response: The Department is reaffirming that in using EFT, money is sent to the bank. The bank then deposits the money into the proper account. The Department does not actually have any access to the provider's account.

- Two written comments and one public comment were made requesting the Department reconsider requiring pharmacy providers to verify Medicaid eligibility of a recipient.

Department Response: The section requiring verification of recipient eligibility was not changed from the current rule. Verifying eligibility assures the provider will be paid.

Changes that were in the proposed rule which will remain in the final rule as they were proposed are:

- Adding language 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 maximum allowed costs (MAC) 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.)
- 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.
- 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 managed care or coordinated care contractor's instructions for billing and authorization of services.
- Adding wording stating that payment is made by electronic funds transfer (EFT).
- Adding clarification for providers on their responsibilities and obligations under federal and state laws, regulations, and executive orders as stated in the MAD Provider Participation Agreement and any MAD provider rules, appendices, program directions and billing instructions.

VI. RULE

This rule, 8.324.4 NMAC, *Pharmacy Services*; will be contained in of the Medical Assistance Division Program Manual. All manual sections are available on the Medical Assistance Division web site at www.hsd.state.nm.us/mad/registers/2010 and the corresponding rule has been posted at www.hsd.state.nm.us/mad/RPolicyManual. 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. PUBLICATION

Publication of these regulations approved by:

KATHRYN FALLS, SECRETARY
HUMAN SERVICES DEPARTMENT