

Bulletin

Michigan Department of Community Health

Distribution: Pharmacy 01-06

Issued: December 1, 2001

Subject: Pharmacy Manual, Chapter III

Effective: January 2, 2002

Programs Affected: Medicaid, Children's Special Health Care Services, State Medical Plan

Attached to this bulletin is a revised Chapter III, Coverages and Limitations. The revised chapter includes new policy related to changes in prior authorization requirements (see Section 2, page 1), the reporting of the prescriber ID (see Section 4, page 1), policy previously transmitted in policy bulletins, as well as clarification of existing policy.

Manual Maintenance

Replace existing Chapter III with the attached chapter.

Pharmacy 00-02 and Pharmacy 01-03 should be discarded.

Discard this bulletin upon completion of manual maintenance.

Questions

Any questions regarding this bulletin should be directed to: Provider Inquiry, Medical Services Administration, P.O. Box 30479, Lansing, Michigan 48909-7979, or e-mail at ProviderSupport@state.mi.us. When you submit an e-mail, be sure to include your name, affiliation, and a phone number so you may be contacted if necessary. Providers may phone toll free 1-800-292-2550.

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Deputy Director for

Medical Services Administration



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GENERAL INFORMATION

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INTRODUCTION

This chapter and the Michigan Department of Community Health Pharmaceutical Product List for Medicaid, Children's Special Health Care Services (CSHCS), and State Medical Program (SMP) (Michigan Pharmaceutical Product List [MPPL]) comprise the pharmacy policies for the Michigan Medicaid Fee-for-Service Program (including the Refugee Assistance Program), the Children's Special Health Care Services, and the State Medical Program. These policies explain coverage and reimbursement for the services dispensed and billed by pharmacies enrolled as a Medicaid Provider Type 50.

CHILDREN'S SPECIAL HEALTH CARE SERVICES [CSHCS]

Pharmacy coverage for beneficiaries who only have CSHCS coverage is limited to those pharmaceutical products that are required for the treatment of the CSHCS qualifying diagnoses. CSHCS qualifying diagnoses are listed on the eligibility letter by International Classification of Diseases-9 (ICD-9) code. Pharmacies may not bill for pharmaceutical products not required for the treatment of the CSHCS qualifying diagnosis.

PROGRAM DEFINITION

Throughout this chapter the term 'Program' is used to refer to the Michigan Medicaid Fee-for-Service Program (including the Refugee Assistance Program), the Children's Special Health Care Services (CSHCS), and the State Medical Program as a collective.

PLACE OF SERVICE

Coverage and payment policies for products dispensed in the settings listed below are not contained in this chapter or the Michigan Department of Community Health Pharmaceutical Product List for Medicaid, CSHCS, and SMP (Michigan Pharmaceutical Product List). Health care providers should refer to the Program manuals for Hospital, Practitioner, Long Term Care/Nursing Facility, or Laboratory for these services. Health care providers should contact the individual county and not MDCH for questions or issues relating to SMP beneficiaries enrolled in counties that administer their own SMP program.

- Physician's office or clinic
 - Injectable products used in physician offices or clinics are reimbursed to the health care provider administering the drug, **NOT** a pharmacy (Provider Type 50). If a pharmacy sells injectable products to a physician or clinic, a pharmacy must obtain payment directly from the purchasing provider and not the Program. Injectable products are **NOT** to be dispensed to the beneficiary for the purpose of administration at the physician's office.
- Inpatient hospital
- Mental health, hospital long-term care, and medical care facilities with in-house pharmacies
- Laboratory



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OUTPATIENT HOSPITAL

Outpatient hospitals enrolled in the Program as a Pharmacy (Provider Type 50) should bill for pharmaceutical products to be taken in, and/or administered in, the beneficiary's home. Such services cannot be billed under the outpatient hospital's Provider Type 40, 41, or 75.

Injectable drugs and single doses given *on the premises*, including products used in conjunction with lab, radiology, and other medical procedures, must be billed under the outpatient hospital's Provider Type 40, 41, or 75, **NOT** as a Pharmacy Provider Type 50.

HOSPICE

Level of Care (LOC) 16

All services, including drugs and nutritional supplements related to the beneficiary's terminal illness, are provided by the hospice. The hospice will reimburse pharmacies for these services. Coverage, payment amounts, and billing procedures of the particular hospice must be followed. To confirm that the product is not related to the terminal illness, the pharmacist must contact the hospice regarding coverage before billing. A pharmacy must **not** bill the Program for prescription services related to the terminal illness.

The Program will separately reimburse a pharmacy for HIV drugs that the beneficiary had previously used to prevent the terminal illness. For example, *Retrovir* (commonly known as AZT) will be paid by the Program for hospice beneficiaries even though related to the terminal illness.

<u>Covered drug products not related to the terminal illness</u> may be separately billed by the pharmacy. For example: A hospice beneficiary has leukemia and a lifelong condition of diabetes. The services related to the diabetes can be separately billed.

The Program's Pharmacy Benefits Manager (PBM) will be messaging back to the pharmacy on claims submitted for beneficiaries with a LOC of 16. It is the <u>responsibility of the pharmacy</u> to assure that the claim submitted is not related to the beneficiary's terminal illness. If billings contrary to this policy are found in post-payment review, the Program will recover inappropriate payment.

LONG TERM CARE

Refer to Long-Term Care, Section 17, of this chapter.

MEDICAID HEALTH PLANS [MHP] & SPECIAL HEALTH PLANS [SHP]

Coverage criteria (including prior authorization) and reimbursement limits for members of the Michigan Department of Community Health's contracted Medicaid Health Plans (MHP) and Special Health Plans (SHP) must be obtained from the specific MHP or SHP.

Each MHP or SHP enrolls its own providers, structures its own billing system, and sets up its own drug list. Providers must contact the contracted MHP or SHP for information regarding reimbursement issues.

MHP and SHP beneficiary enrollment is indicated on the Medicaid ID card with LOC 07 or 17. The name and phone number of the MHP is also indicated on the Medicaid card. SHP beneficiary enrollment is indicated on the Children's Special Health Care Services beneficiary eligibility letter.



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Pharmacy Aspects of MHP & SHP: Quick Reference

Level of Care: 07 or 17

Provider Enrollment:: Pharmacies must follow the MHP or SHP procedures for enrollment to ensure

payment.

Pharmaceutical Coverage: Approved MHP or SHP pharmaceutical products may differ from Michigan Department of Community Health Medicaid, CSHCS and SMP Fee-for-Service Programs.

Co-payment: Co-payments may differ.

Payment and Billing: Payment levels and billing methods are set by the MHP or SHP, not the Michigan

Department of Community Health.

Prior Authorization: Follow the MHP or SHP prior authorization procedures.

For questions concerning a specific managed care beneficiary or program, call the beneficiary's physician, MHP, or SHP listed on the beneficiary's Program ID card/letter.

For general managed care questions, call:

MDCH's Provider Inquiry Helpline 1-800-292-2550

MDCH's Beneficiary Helpline 1-800-642-3195



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MICHIGAN PHARMACEUTICAL PRODUCT LIST

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The Michigan Department of Community Health Pharmaceutical Product List for Medicaid, CSHCS, and SMP (Michigan Pharmaceutical Product List) identifies the pharmaceutical products that are covered and the applicable limitations, such as prior authorization requirements.

The Michigan Pharmaceutical Product List (MPPL) is available on microfiche or paper, and can be downloaded from the State of Michigan's web site or the PBM's web site. Pharmacies may receive a microfiche of the MPPL at no charge. A one-year subscription to the paper copy or an additional microfiche copy is available for the following charges:

Paper Version \$84

Microfiche \$21

Specify if your request is for paper or microfiche.

Make your check payable to State of Michigan

Mail your request to:

State of Michigan Cashier's Unit/Medical Services Administration P.O. Box 30223 Lansing, Michigan 48909

Web site addresses: www.mdch.state.mi.us/msa/mdch msa/medicaid data.htm

www.michigan.fhsc.com

The MPPL is published quarterly, and pharmaceutical product deletions will be published 30 days prior to the effective date of the change.

Requesting Pharmaceutical Product Coverage

A provider or manufacturer may request coverage of a pharmaceutical product by sending an application to the Michigan Clinical Pharmacy Account Manager. The application is available on the PBM's web site (www.michigan.fhsc.com) or may be obtained by writing or faxing to First Health Services Corporation [FHSC]. The application may be sent to:

Michigan Clinical Account Manager First Health Services Corporation 4300 Cox Road Glen Allen, Virginia 23060

Phone: 1-804-335-5200 Fax: 1-804-241-7813



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MDCH'S PHARMACY BENEFITS MANAGER (PBM) 01-02-02 Pharmacy 01-06

On July 5, 2000, the Michigan Department of Community Health converted the Program's claims processing system to a point of sale system through a pharmacy benefits manager. The MDCH's contracted Pharmacy Benefits Manager currently is First Health Services Corporation (FHSC).

FIRST HEALTH SERVICES CORPORATION (FHSC)

MDCH currently contracts with FHSC for the Program's pharmacy claims payment [all forms, i.e., paper and electronic] and claims instruction, prior authorization, prospective drug utilization, retrospective drug utilization, clinical consultation, provider enrollment, beneficiary and provider phone lines, and provider audits.

The Michigan Department of Community Health retains all Program decisions for policy, coverage, and reimbursement.

FHSC's address, call centers, and web site are:

First Health Services Corporation 4300 Cox Road Glen Allen, Virginia 23060

Enrollment & Claims Processing Instructions
Clinical Call Center (Prior Authorization):
1-877-864-9014
Technical Call Center (Pharmacies):
1-877-624-5204
Beneficiary Call Center:
1-877-681-7540

Web site: www.michigan.fhsc.com

The FHSC web site contains:

- First Health's Pharmacy Claims Processing System for Michigan Medicaid
- > Department of Community Health Pharmaceutical Product List for Medicaid, CSHCS, and SMP

NOTE: The claims instruction manual is <u>First Health's Pharmacy Claims Processing System for Michigan Medicaid.</u> This will be referred to as the PBM's Pharmacy Claims Processing Instructions.

AUDITS

FHSC contracts with Heritage, Inc. to perform provider audits on behalf of the State of Michigan. Heritage makes recommendations to MDCH based on audit findings. MDCH will determine the appropriate actions to take.

Heritage Information Systems, Inc. 410 W. Franklin Street Richmond, Virginia 23220 Phone: 1-804-644-8707



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PRESCRIBER AND PHARMACY
REQUIREMENTS

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PRESCRIPTION REQUIREMENT

All legend and over-the-counter drugs (OTC) covered by the Program must be dispensed on the written or oral prescription of a licensed prescriber, except for condoms.

PRESCRIBER

Coverage of pharmaceutical products is based on limitations stated in this chapter, the MPPL, and on medical necessity. Determination of medical necessity and appropriateness of service is the responsibility of the prescribing physician/provider (prescriber) within the scope of currently accepted medical practice and the limitations of the Program. Applicable State and Federal laws, rules, regulations, and policies must be observed by the participating providers. The Program may impose additional constraints to reduce misuse.

Scope of Practice

The Program only reimburses for claims prescribed by a licensed prescriber that are within the prescriber's scope of currently accepted medical practice and the limitations of the Program.

Prescriber DEA Number

For claims with dates of service on or after January 2, 2002, the pharmacy provider must provide the State of Michigan Prescriber DEA number on the submitted claim. Claims submitted without the Prescriber DEA number in the Referring Provider field will be rejected.

Sanctioned Prescribers

The Program does not reimburse for pharmaceuticals prescribed by providers sanctioned by the Federal Government, the State of Michigan, or for prescribers having a limited or revoked license. A list of sanctioned providers is provided through the MDCH bulletin process, on the MDCH Website and FHSC Website.

PHARMACY CONDITIONS OF PARTICIPATION

A provider who complies with all licensing and regulation laws applicable to the practice of pharmacy in Michigan may enroll as a provider in the Program. Applicable State and Federal laws, rules, regulations, and policies must be observed by the participating pharmacies.

Refer to Chapter I for other conditions of participation.



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PHARMACY ENROLLMENT

The PBM will enroll pharmacy providers as type 50 providers on behalf of the State of Michigan and send them First Health's Pharmacy Claims Processing System for Michigan Medicaid. To request an enrollment form, contact First Health Services Corporation:

By Phone: 1-804-965-7619 In Writing: 4300 Cox Road

Glen Allen, Virginia 23060



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COORDINATION OF BENEFITS (COB)

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Coordination of benefits (also referred to as Third Party Liability [TPL]) requires providers to bill other insurances, including Medicare Part B, before billing the Program. Regardless of participation by the pharmacy provider with the other insurance and/or Medicare, the Program will only reimburse for the coinsurance and deductible amounts up to the MDCH allowable fee screen. If the other insurance's (including Medicare) reimbursement exceeds the reimbursement level of the Program, no additional monies will be paid. The provider must submit as its charge the amount allowed by the other insurance, indicating the other insurance payment (including the dispensing fee) and the other insurance co-payment. In addition, the provider is to use the drug list established by the beneficiary's other insurance carrier. If the other carrier's drug list covers a drug not on the MPPL, prior authorization must be obtained from the Program by the prescriber.

If a provider receives payment from another insurance and/or Medicare after the Program has made full payment, the payment must be returned to Medicaid through a claim adjustment. Failure to reimburse Medicaid may be construed as fraud under the Medicaid False Claim Act.

COB EDIT OVERRIDE

When billing the Program for a beneficiary who has other insurance, the provider must enter the appropriate National Council for Prescription Drug Program [NCPDP] code based on the status of the other insurance. These are:

- 0= Not specified
- 1= No other coverage identified
- 2= Other coverage exists, payment collected
- 3= Other coverage exists, this claim is not covered
- 4= Other coverage exists, payment not collected

COB EDIT EXCEPTIONS

In the following situations, the provider may override the COB edit using the National Council for Prescription Drug Program [NCPDP] code indicated in parentheses:

- Medicare does not cover the pharmaceutical product for the beneficiary's condition (3).
- The beneficiary indicates, or the pharmacy is aware, that the beneficiary no longer has the other insurance on the date the prescription is dispensed (1).
- The beneficiary's other insurance requires the beneficiary to pre-pay for the drug (4).
- The beneficiary is in a nursing facility, and the dispensing pharmacy is not a part of the insurance carrier's network (4).
- The other insurance carrier only has mail order pharmacy coverage (4).

COB EDIT OVERRIDE EXCLUSIONS

In the following situations, the Provider may not override the COB edit.

The beneficiary has other insurance and the pharmaceutical product is covered and would be paid to the
provider if the insurance carrier's rules (e.g. obtain prior authorization, use of a network provider, or proper
claim submission) had been followed.



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- The other insurance requires a generic instead of the brand equivalent covered by the Program. The provider must bill the other insurance for the generic.
- The pharmacy is not part of the carrier's network and is not able to obtain authorization from the carrier to provide the drug. The pharmacy should instruct the beneficiary to have the prescription filled at a participating pharmacy. If the beneficiary is not familiar with the carrier's network, the pharmacy should instruct the beneficiary to contact their carrier for a list of network pharmacies.
- The beneficiary is required to pre-pay, but only because the pharmacy is not part of the carrier's network. The beneficiary should be instructed to have the prescription filled at a participating pharmacy.

OTHER INSURANCE APPENDIX

INFORMATION

For complete information on MDCH's policy regarding other insurance, refer to the Other Insurance Appendix of this manual

BILLING INFORMATION

For billing information, including NCPDP codes and a list of the specific Medicare Part B covered drug products, refer to the PBM's Pharmacy Claims Processing Instructions or the FHSC web site (www.michigan.fhsc.com) or call the FHSC Technical Call Center at 1-877-624-5204.



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CHARGES TO THE BENEFICIARY
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PRIOR AUTHORIZATION

A pharmacy must not charge a beneficiary for a prescription if the pharmacy or prescriber fails to request prior authorization (P.A.). For all products listed in the Michigan Pharmaceutical Product List with a pound sign (#) indicating prior authorization is required, the pharmacy is required to call for prior authorization, or notify the prescriber that a P.A. is needed.

A pharmacy may charge the beneficiary its usual and customary charge for a product requiring prior authorization <u>only</u> if the pharmacy has written documentation the patient was informed of the attempt and failure to obtain P.A. and of the resultant desire to purchase the drug privately. The pharmacy must not charge any portion of this claim to Michigan Medicaid.

The beneficiary must be made aware that prior authorization and reimbursement cannot be obtained later.

CO-PAYMENT

Beneficiaries age 21 and older have a **\$1 co-payment** for each drug dispensed, unless the beneficiary meets one of the exemptions from co-payment stated below.

Over Age 21 Exclusions

- The pharmaceutical product is a family planning or pregnancy-related product.
- The beneficiary is in a long-term care facility with a level of care 02, 08, 16, 56 (see Section 17, Page 1).
- The beneficiary is in the State Medical Program.

Other Exclusions

- Medicaid beneficiaries who are under the age of 21 are excluded from the co-pay requirement.
- All CSHCS beneficiaries are excluded, including those over age 21.

Co-Pay Discounts

No pharmacy may discount the co-payment for promotional purposes.

CHARGES TO THE BENEFICIARY

A pharmacy may only charge a beneficiary the Program's established co-payment for covered services. A beneficiary may not be charged for any cost of the prescription above the Program's reimbursement level. A pharmacy may only charge a beneficiary its usual and customary charge if the service is a non-covered service, or if the Program has denied the services based on lack of medical necessity and the beneficiary has indicated a desire to purchase the service privately. Furthermore, a beneficiary may not be charged for a prescription in lieu of the Pharmacy accepting the reimbursement paid by the Program, or in lieu of obtaining prior authorization when indicated.



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CHARGES TO THE BENEFICIARY AND CO-PAYMENT

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Advertising

Advertisements shall convey only participation in the Program. Advertising shall not be used to influence the free choice of a pharmacy by a beneficiary. Promotions offering beneficiaries free goods, gift certificates, or shopping sprees in exchange for filled prescriptions are prohibited.



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BASIC PHARMACY INFORMATION

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GENERAL NON-COVERED SERVICES

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This section specifies *general* coverage restrictions. However, drugs in other classes may not be covered. Pharmacies should review the MPPL for specific coverage. When possible, pharmacies are encouraged to suggest alternative covered therapy to the prescriber if a product is not covered.

The following drug categories are **not covered** as a benefit:

- Standard Infant Formulas
- Anorexiants used for anorexia or weight loss
- Agents used for weight gain
- · Agents used for cosmetic purposes or hair growth
- Agents used for symptomatic relief of cough and colds
- Experimental or investigational drugs
- · Agents used to promote fertility
- · Agents used to promote smoking cessation not on the Michigan Pharmaceutical Product List
- Vitamin/Mineral combinations not for prenatal care, end stage renal disease or pediatric fluoride supplementation
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Less-than-effective (LTE) drugs identified by the Drug Efficacy Study Implementation (DESI) program
- Over-the-counter drugs not on the Michigan Pharmaceutical Product List
- Legend drugs that have become available as over-the counter drugs with the same formulation, even if other brand name products remain as legend drugs
- · Drugs of manufacturers not participating in the Rebate Program
- Drugs prescribed for "off label" use if there is no generally accepted medical indication in peer reviewed medical literature (Index Medicus), or listing of such use in standard pharmaceutical references such as Drug Facts and Comparisons, AMA Drug Evaluations, American Hospital Formulary Service Drug Information, or DRUGDEX Information Systems
- Drugs discontinued or recalled by manufacturers
- Lifestyle agents
- Covered outpatient drugs where the manufacturer limits distribution.



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BASIC PHARMACY INFORMATION

SECTION TITLE
COUNSELING REQUIREMENTS

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Pharmacies must follow the counseling requirements mandated in State and Federal regulations. These requirements do not apply to drugs dispensed in long-term care facilities which are in compliance with the drug regimen review procedures specified by licensing providers.

OFFER TO DISCUSS

For every new prescription presented by the beneficiary, the pharmacy's representative must offer the beneficiary the opportunity to discuss/receive counseling from the pharmacist regarding the new prescription. The offer for counseling must be in a positive helpful manner. If practical, the offer to counsel must be face-to-face and verbal. Otherwise, it is permissible for the offer to discuss to be made in writing or by telephone. If messages are left for beneficiaries (or their representatives) to contact the pharmacist, the individual must be able to make the call toll-free. A pharmacist is not required to provide counseling when a beneficiary or representative refuses the offer for counseling.

DISCUSSION

When the offer is accepted by the beneficiary (or representative), the counseling must be provided by the pharmacist in person (whenever practical) or by telephone. It may include written materials. The information must be in a language that can be understood by the beneficiary (or representative) and must include an opportunity for questions.

In addition to discussing interactions with drugs previously dispensed by the pharmacist, the discussion should also include the potential interaction with any other drugs the beneficiary indicates he or she is taking. The beneficiary (or representative) must be counseled in a confidential manner, consistent with any State or Federal regulations. Federal law requires that the pharmacist must discuss all the items indicated below, and any others deemed significant in the pharmacist's professional judgment.

- The name and description of the medication
- The dosage form, dosage, route of administration, and duration of drug therapy
- Special directions and precautions for preparation and use by the beneficiary
- Common side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur
- Techniques for self-monitoring drug therapy
- Proper storage
- Prescription refill information
- Action to be taken in the event of a missed dose

NOTE: If an interpreter is required, the provider must provide free of charge.



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BASIC PHARMACY INFORMATION

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SIGNATURE LOG, DATA COLLECTION, DOCUMENTATION

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SIGNATURE LOG

The pharmacy provider shall maintain a chronological log containing the following information: beneficiary's name; the signature of the beneficiary or that of his/her representative; and the date of receipt of the prescription. The log must effectively differentiate between prescriptions received by a beneficiary for which counseling was accepted by the beneficiary and was provided, and those for which counseling was offered and was declined. This log shall be retained for review by the Department or the Department's agent for six (6) years and is subject to audit.

The signature log serves as verification of the beneficiary receiving the prescription billed. The absence of the appropriate signature indicates the beneficiary did not receive the prescription, and funds will be recouped from the pharmacy.

BENEFICIARY INFORMATION & DATA COLLECTION REQUIREMENTS

To meet specified State and Federal requirements, pharmacies must make a reasonable effort to obtain, record, and maintain on file at least the following information:

- Name, address, telephone number, date of birth (or age), and gender of the beneficiary
- Pharmacist notes on the beneficiary's drug therapy
- · Beneficiary history when significant, including
 - 1. Disease state or states
 - 2. Known allergies and drug reactions
 - 3. Comprehensive list of drugs and relevant devices.
- Whether the offer to counsel was made and whether this offer was accepted or rejected by the beneficiary
 or the beneficiary's representative

DOCUMENTATION REQUIREMENTS

To assure that pharmacy counseling and other data collection requirements were performed, pharmacies must record the information required in the beneficiary's manual or electronic profile, in the prescription signature log, or any other system of records. Regardless of the format used, the associated documentation must be kept for <u>at least six years</u> and be readily accessible.



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SECTION TITLE

DRUG UTILIZATION REVIEW (DUR)

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PROSPECTIVE DRUG UTILIZATION REVIEW (PRODUR)

Effective July 5, 2000, the State implemented ProDUR edits in its Point of Sale (POS) system. Prospective Drug Utilization Review (ProDUR) encompasses drug therapy screening, including problem detection, evaluation, and counseling components of pre-dispensed drugs.

Provider Responsibility

The MDCH has limited the number of messages in the POS system to providers concerning potential drug problems to those that are critical to quality of care and appropriate dispensing. It is the provider's responsibility to provide ProDUR screening and to meet beneficiary information and data collection requirements.

ProDUR Screening Requirement

Before prescriptions are filled or delivered, the pharmacist must review the consequences of the drug therapy based on the standards from the following:

- American Hospital Formulary Service Drug Information
- United States Pharmacopoeia-Drug Information
- > DRUGDEX Information System
- American Medical Association Drug Evaluations
- Peer-reviewed medical literature

The review must screen for potential therapy problems due to:

- Therapeutic duplication
- Drug-disease contraindications (to the extent diagnosis information is available)
- Drug-drug interactions (including interactions with known over-the-counter drugs)
- Incorrect drug dosage or duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse
- Under-utilization or over-utilization

ProDUR Alert Messages

The State's PBM POS system provides on-line assistance for the dispensing pharmacist. Incoming drug claims are compared to a beneficiary's pharmacy claims history file to detect potential therapeutic problems. ProDUR alert messages are returned to the pharmacist when significant problems are discovered by this review.



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SECTION TITLE

DRUG UTILIZATION REVIEW (DUR)

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RETROSPECTIVE DRUG UTILIZATION REVIEW (RETRODUR)

The Program will utilize pharmacy data for retrospective drug utilization as required by Federal law and the following compendia:

- American Hospital Formulary Service Drug Information
- United States Pharmacopoeia-Drug Information
- DRUGDEX Information System
- American Medical Association Drug Evaluations
- Peer-reviewed medical literature

RetroDUR is intended to be an educational tool to reduce pharmaceutical costs associated from drug-induced illnesses and hospitalizations.

Purpose

The purpose of retrospective drug utilization review is:

- To identify high-risk cases for drug-induced illness
- To communicate risk factors to prescribers and dispensing pharmacists for evaluation
- To improve patient healthcare outcomes and quality of care

The RetroDUR alerts providers to a beneficiary's medical condition and total drug usage from all prescribers and pharmacies.

MDCH's PBM reviews utilization data on a monthly basis and makes recommendations to the Michigan DUR Board for interventions and educational seminars.

Michigan DUR Board

The Michigan DUR Board is composed of physicians and pharmacists. Post review, the DUR vendor will send appropriate intervention letters to pharmacies and prescribers. Based on the DUR intervention information, prescribers may choose to modify therapy. However, prescribers or pharmacists also may choose to correct beneficiary negative patterns by counseling, or provide background for re-evaluation by the DUR vendor or the DUR Board.

As needed, the PBM or DUR Board follows up on re-occurring patterns that have not been justified. Provider education or academic detailing may be provided to address re-occurring patterns.

CLINICAL CONSULTATION

MDCH provides feedback to providers through its academic detailing program. Administered by First Health Services Corporation (FHSC), the program targets topics related to drug therapy where direct educational intervention to medical providers may prove beneficial in improving outcomes. The topics for academic detailing are approved by the Michigan DUR Board. The clinical consultants are Michigan-licensed pharmacists who are recruited and trained through the Michigan Pharmacists' Association under



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the direction of FHSC. Whenever possible, clinical consultants are assigned to call on medical providers who practice in the same geographical area as the detailing pharmacist to provide a personal and professional connection between the health care providers. Providers are encouraged to give the clinical consultants feedback on both topics presented and the overall program.

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BASIC PHARMACY INFORMATION

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PRIOR AUTHORIZATION

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PHARMACY BENEFITS MANAGER (PBM)

Prior authorizations are processed by the MDCH's contracted PBM. Refer to First Health's Pharmacy Claims Processing System for Michigan Medicaid for prior authorization procedures. Authorization to override denial edits must be obtained from the PBM.

Do NOT use the PBM's Call Centers for:

- Supplies billed by Provider Type 87, including enteral formula administered by tube and total Parenteral Nutrition, since these are only reimbursed to a Medical Suppler Provider Type 87. Contact the Review and Evaluation Division, Prior Authorization Line, at 1-800-622-0276.
- Contact the member's Medicaid Health Plan or Special Health Plan to obtain the plan's policies.

PRIOR AUTHORIZATION REQUIREMENTS

Prior Authorization is required for:

- Products listed with a # in the Michigan Pharmaceutical Product List. Pharmacies should review the
 information in the remarks, as certain drugs may have prior authorization only for selected age groups
 (e.g., over 17 years).
- Payment above the Maximum Allowable Cost (MAC) rate on products listed with an **EQ** in the Michigan Pharmaceutical Product List.
- Prescriptions that exceed the Program quantity or dosage limits.
- Medical exception for drugs not listed in the Michigan Pharmaceutical Product List.
- Medical exception for non-covered drug categories.
- Acute dosage prescriptions beyond Program coverage limits for Anti-Ulcer medications.
- To dispense a 100-day supply of maintenance medications that are beneficiary-specific and not on the maintenance list
- Enteral Formulas for Oral Administration.
- Selected pharmaceutical products included in selected therapeutic classes whose products have minimal clinical differences, the same or similar therapeutic actions, the same or similar outcomes, or have available multiple effective generics.

STATE MEDICAL PROGRAM & BENEFICIARY MONITORING PROGRAM

Some beneficiaries of the State Medical Program and Beneficiary Monitoring Program receive service authorization from the local Family Independence Agency caseworkers; however, this authorization does NOT replace pharmacy prior authorization.



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BASIC PHARMACY INFORMATION

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PRIOR AUTHORIZATION

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GENERAL PROCEDURES

Pharmacies

Pharmacies may call the PBM Technical Call Center for exceptions on:

- Quantity
- Payment for brand name over the Maximum Allowable Cost (MAC)
- Early refills
- 72-hour supply of medication for emergency needs only when the prescriber is not available to obtain P.A.

Technical Call Center

PBM's Technical Call Center: 1-877-624-5204

Hours: 24 hours per day 7 days a week

Prescribers

Prescribers or their designees may call the PBM's Clinical Call Center for <u>any</u> prior authorization, but <u>must</u> call for any request that falls outside the above four categories.

Clinical Call Center

PBM's Clinical Call Center: 1-877-864-9014

Hours: 8:00 a.m. to 10:00 p.m., M-F, pager after hours

Fax: 1-888-603-7696

Write: First Health Services Corporation

4300 Cox Road

Glen Allen, Virginia 23060

DOCUMENTATION REQUIREMENTS

For all requests for P.A. to override an edit, the following documentation is required:

- Pharmacy name and phone number
- · Beneficiary diagnosis and medical reasons why another covered drug cannot be used
- Drug name, strength, and form
- Other pharmaceutical products prescribed
- Therapeutic results of therapeutic alternative medications tried
- MedWatch Form (when requested)



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ADDITIONAL DOCUMENTATION

Depending on the specific drug being prescribed, additional medical documentation may be required. Provided below is the additional documentation required for the most common categories.

Brand Override

Documentation of the therapeutic trial and failure reasons of the generic

Anti-Ulcer Acute

- Dosage exception
- Documentation of GI testing, diagnosis, results, and date of testing
- Alternative Anti-Ulcer medications tried, including maintenance doses tried
- · Other medications prescribed
- · Health status of patient if testing cannot be done

Medication for Erectile Dysfunction

- · Documentation of all other diagnoses and medication prescribed
- Medical history and results of physical examination
- Results of laboratory testing for testosterone, glucose, leutenizing hormone, follicle stimulating hormone, thrytropin if underlying cause points to testicular atrophy, hypothyroidism, etc.
- Results of testing such as electrodiagnosis or nocturnal penile tumescence test, as indicated by the medical history and physical examination findings
- Summary of attempts to treat the discovered underlying causes, substitution of pharmaceuticals to treat
 hypertension, depression, from those agents suspected to have caused the dysfunction

Weight Loss Medications

- Current medical status, including nutritional or dietetic assessment
- Current therapy for all medical conditions, including obesity
- Documentation of specific treatments, including medications
- Current accurate BMI, height, and weight measurements
- Confirmation that there are no medical contraindications to reversible lipase inhibitor use, no malabsorption syndromes, cholestasis, pregnancy and/or lactation
- Details of previous weight loss attempts and clinical reason for failure (at least two failed attempts are required)



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PRIOR AUTHORIZATION

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PRIOR AUTHORIZATION DENIALS

A prior authorization will be denied if:

- the medical necessity is not established,
- if alternative medications are not ruled out,
- evidence-based research and compendia does not support,
- it is contraindicated, inappropriate standard of care,
- does not fall within MDCH clinical review criteria, and/or
- · documentation required was not provided.

ENTERAL FORMULA

Enteral formulas require prior authorization and coverage is extended to only those enteral formulas with a unique nutritional composition from which nutrients are not obtainable from food and represent an integral part of treatment of the specified diagnosis/condition.

Prior Authorization Criteria

Authorization is based on a case-by-case review including, but not limited to, factors such as:

- Medical conditions requiring intake of a unique nutrient or ratio of specific nutrients to address increased or restricted medical requirements for these nutrients, when comparable levels cannot be obtained from regular foods and beverages.
- Nutrient malabsorption associated with a specific diagnosed disease
- Supplementation to regular diet or meal replacement is only considered if there is failure to thrive when the beneficiary's <u>weight-to-height</u> ratio has fallen below the 5th percentile on growth grids (under the age of 21)
- Mechanical or physiological conditions precluding normal dietary intake (e.g., obstruction of the throat or esophagus)
- Temporary medical complications (e.g., nausea due to chemotherapy, post-operative healing complications) necessitating a short-term (less than two months) use of enteral formula.

Non-Covered Products

The Program does **NOT** cover products, nor are exceptions made for,:

- Standard infant/toddler formulas
- Weight loss products or 'lite' products
- Puddings/Bars
- Liquid thickeners
- Regular and Special Dietetic foods
- Sports drinks



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Products are not covered for the following reasons or conditions:

- · Regular and special dietetic foods or formulas that represent only a liquid form of food
- Refusal to eat or poor eating behavior
- Loss of appetite
- Non-compliance with specialized diet
- As a convenience issue or inability to prepare meals
- Food preferences
- Eating disorders from such conditions as Alzheimer, Developmental Disability, Bulimia, Anorexia.

Documentation Requirements

The information required to verify medical necessity for enteral formulas is:

- ✓ Specific diagnosis related to the beneficiary's inability to take or eat regular food
- ✓ The economic alternatives that have been tried
- ✓ Amount needed per day
- ✓ Duration of treatment
- ✓ Height, current weight, and recent weight loss
- ✓ Laboratory values for albumin or total protein
- ✓ Specific diet prescription identifying levels of an individual nutrient(s) that is required in increased or restricted amounts.

Billing Information for Enteral Formulas Taken Orally

Enteral Formulas taken orally may be billed by either a Pharmacy (Provider Type 50) or Medical Supplier (Provider Type 87). Policies for Medical Suppliers are listed in the Program's Medical Supplier Manual.

The following instructions apply to oral Enteral Formulas billed by a Pharmacy (Provider Type 50).

- Enteral Formulas are not individually listed in the MPPL, but are listed under the general descriptions of Dietary or Enteral Formulas.
- The Program's reimbursement and billing procedures for Enteral Formulas are the same as legend drugs and OTCs.
- Billing units must be based on metrics (e.g., grams for powders, milliliters for liquids).
- Enteral Formulas are included in the per diem rate paid to <u>long-term care facilities</u>. A pharmacy will not be paid directly by the Program for these products dispensed to long-term care beneficiaries. Reimbursement must be obtained from the long-term care facility.



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ANTI-ULCER DRUG POLICY

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Coverage for Anti-Ulcer medications is limited to a 102-day supply at the acute dosage levels. After the 102-day supply, maintenance dosage levels are covered. There is no duration limit for maintenance dosing.

A beneficiary may receive two acute 102-day courses of Anti-Ulcer drug therapy within a 365-day timeframe without requiring prior authorization if the two acute 102-day therapies are separated by at least 34 days.

EXTENSIONS FOR ACUTE DOSING OVER THREE MONTHS

Prescribers or the prescriber designees may request extensions for acute therapy over the 102-day supply through the PBM Clinical Call Center. The Clinical Call Center phone number is I-877-864-9014.

If an existing Prior Authorization (PA) is on file and current, a new PA is NOT required for changes in therapeutic agents.

H2 Antagonists and Pepsin Inhibitors (i.e. Sucralfate) may be dispensed at the same time. However, if the Program observes patterns of duplicate therapy (e.g., Zantac and Tagamet prescribed simultaneously), both the prescriber and pharmacy providers will be contacted by the Program's PBM. Providers must document the medical reason for the combination therapy.

Compliance with the Anti-Ulcer Drug Policy is monitored with Point of Sale (POS) and post-payment review.



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DISPENSING POLICY

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DAYS SUPPLY

Prescription quantities are limited to the units specified by the prescriber. The Program will cover up to a 34-day supply for acute medications, and up to a 100-day supply for maintenance medications.

The pharmacy must submit accurate days supply information. Submitting incorrect days supply information can cause false ProDUR messages and claim denials. It could also result in a pharmacy being targeted for a post-payment audit.

ACUTE & MAINTENANCE SUPPLIES

Providers must bill and dispense as follows:

For acute illness:

• The amount dispensed must be limited to the quantity required for the desired therapy during that episode of illness or up to a 34-day supply.

For chronic illness:

- Maintenance drugs must be dispensed in quantities to achieve optimum therapy and economy of dispensing, or up to a 100-day supply.
- If a prescription for a product on the maintenance list is for more than a month's supply and less than a 100-day supply, only one dispensing fee is allowed.
- A pharmacy will receive a maximum of one dispensing fee per prescription for the same drug entity per month.
- A maximum of thirteen (13) dispensing fees will be paid for the same drug dispensed to the same beneficiary within a 365-day billing period.

The PBM's First Health's Pharmacy Claims Processing System for Michigan Medicaid provides a list of maintenance medications. This list DOES NOT exclude medications from other standard therapeutic class codes from being supplied in maintenance quantities. Prior authorization is necessary when a maintenance quantity of other medications is required for specific beneficiaries.

REFILLS

Refills must conform to current State and Federal statutes, rules, regulations, and policies.



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DISPENSING POLICY

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RETURNED TO STOCK PRESCRIPTIONS

The Program does NOT reimburse for prescriptions filled but not dispensed to the beneficiary. For prescriptions returned to stock/not picked up prescriptions, pharmacies must claim adjust or reverse the claim for any payments received, including the dispensing fee. The pharmacy should reverse claims in a timely manner. However, Department policy allows claim adjustments or reversals to be submitted up to six months after the original date of service. For example, if the Program beneficiary does not pick up a prescription from the pharmacy within 14 calendar days from the date the prescription claim was submitted by the pharmacy, the prescription claim should be reversed on the 15th calendar day or, at a minimum, by the 180th day. For audit purposes, a record of processed reversals must be retained by the pharmacy for six (6) years.



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SECTION TITLE

QUANTITY AND BILLING UNITS

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METRIC

The Program uses standard metric billing units and the provider may not round fractions. For example, if the product is 2.5 ml, it must be billed as 2.5 ml, not 3 ml.

COMMON UNIT BASES

Program quantities are based on the amount dispensed for the unit of the product. Thus, quantity field entries must be based on the amount dispensed for the Unit specified in the Michigan Pharmaceutical Product List. The most common unit bases are EACH, ML, or GM. Following are examples.

Drug Name	Drug Strength	Dosage Form	Unit	Billing Quantity Based On:
Alphanate		Vial	EA	AHF Units
Amoxicillin Trihydrate	125mg/5 ml	Susp Recon	ML	Reconstituted ml's
Cefazolin Sodium	1gm	Vial	EA	Vials
Chemstrip BG		Strip	EA	Strips
Gentamicin Sulfate	40mg/ml	Vial	ML	Milliliters
Humulin-N	100U/ml	Vial	ML	Milliliters
Indocin 50mg Supp.	50mg	Supp Rect	EA	Suppositories
Prolastin		Vial	EA	Milligrams
Proventil Inhaler		Aerosol	GM	Grams in each canister
Zantac 300mg Tab	300mg	Tablet	EA	Tablets

QUANTITY LIMITS

Dispensing quantities will be limited according to accepted standards of practice, Food and Drug Administration (FDA)-approved manufacturer recommendations and the recommendations of the Michigan DUR Board. The Program's PBM and claims processing system monitors the validity of quantity entries for an individual claim line based on the Program's quantity limits, or the following guidelines.

Oral Solids, except Schedule II 300 Units Schedule II Oral Solids 180 Units Oral Liquids 2000 Mls

Condoms 12



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REIMBURSEMENT

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USUAL & CUSTOMARY CHARGE

Reimbursement is the lower of the Usual & Customary Charge or the Program's Product Cost Payment Limits and dispensing fee minus the beneficiary co-payment. If a beneficiary has other insurance or Medicare coverage, the related other insurance or Medicare payments are subtracted from the Program's payment.

Usual & Customary Definition

Usual & Customary (U & C) Charge is defined as a pharmacy's charge to the general public. The sum of charges for both the product cost and dispensing fee must NOT exceed a pharmacy's usual and customary charge for the same or similar service. Usual & Customary Charge must reflect all advertised discounts, special promotions, or other programs initiated to reduce prices for product costs available to the general public or to a special population.

If a pharmacy discounts prescriptions to an inclusive category of customers (e.g., over 60 years), the pharmacy must reflect this discount in its billings for Program beneficiaries in the same category.

OVER-THE-COUNTER DRUGS

The Usual & Customary Charge for *prescription-ordered* over-the-counter drugs may be different than the retail shelf price of the same product sold without a prescription, but not greater than the pharmacy's shelf price for the product, excluding the dispensing fee.

SALES TAX

Sales Tax must NOT be added to a pharmacy's Usual & Customary Charge. The Program does not reimburse for sales tax.

PROGRAM PRODUCT COST PAYMENT LIMITS

Product Cost Payment Limits are based on the National Drug Code (NDC) the pharmacy identifies as the product dispensed. Reimbursement for drug products is the lower of an Average Wholesale Price (AWP) minus discounts, a Maximum Allowable Cost (MAC), or the provider's charge. Misrepresentation of the product's NDC will result in denied payment and fraud/abuse sanctions subject to applicable Federal and State laws.

Entities or contracted pharmacies that participate in the Federal 340B program must bill the 340B price.



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Discounted Average Wholesale Price

The Program's discounted average wholesale price is as follows:

INFORMATION

Pharmacy Group	Discount Used for Payment
Pharmacies with 1-4 stores	AWP minus 13.5 %
Pharmacies with 5 or more stores	AWP minus 15.1 %
Pharmacies with no retail customers serving LTC beneficiaries	AWP minus 15.1 %

Maximum Allowable Cost (MAC)

MAC reimbursement levels are established by the MDCH and are generally applied to multi-source brand and generic products. However, where appropriate, MAC reimbursement may be applied to single source drugs. The provider should refer to MPPL for the specific pharmaceutical product MAC reimbursement level.

MAC reimbursement levels are reviewed on a monthly basis and published in the MPPL 30 days prior to the effective date. Provider questions or concerns regarding MAC reimbursement should be directed to:

Michigan Department of Community Health Quality Improvement and Customer Services Bureau Review and Evaluation Division P.O. Box 30479 Lansing, Michigan 48909-7979

Phone: 517-335-5265 Fax: 517-241-7813

MAC Overrides

Specific brand products have a MAC reimbursement level. To receive payment above the MAC reimbursement level, prior authorization is required.

DISPENSING FEES

Dispensing Fee is defined as the fee charged for filling a prescription and all related services performed by a pharmacy. The Program's dispensing fee is published in the MPPL.

Retail Price Exception (RTL)

Selected supplies are not paid a dispensing fee. Supplies indicated with an RTL in the MPPL are paid the lower of Retail Price or Retail-Based MAC price.



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State Medical Program

The State Medical Program (SMP) dispensing fee is 85% of the fee paid under Michigan Medicaid.

Compounded and Re-Packaged Unit Dose

Compounded and Pharmacy Re-Packaged Unit Dose prescriptions are paid dispensing fees higher than the standard fee.



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SECTION TITLE
SPECIAL PRODUCT COVERAGE

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AMPHETAMINE

Some drugs used to treat narcolepsy or hyperkinesis may be covered for beneficiaries over 17 years of age. The prescriber or designee must obtain prior authorization before the pharmacy dispenses these products.

ANTIHEMOPHILIC DRUGS

Billing quantities for antihemophilic drugs must be based on antihemophilic units. In the rare instance that over 100,000 antihemophilic units are prescribed, pharmacies need to fill out a paper claim to avoid exceeding the 99,999.99 unit field limit.

Infusion kits necessary for administration must be billed by a Medical Supplier (Provider Type 87). See the Medical Supplier section of this chapter for enrollment instructions.

Antihemophilic drugs are a Medicare Part B benefit. For beneficiaries who are eligible for both Medicare and Medicaid, the pharmacy must bill Medicare prior to billing Medicaid as explained in the Other Insurance Appendix.

ANTINEOPLASTIC DRUGS

Covered chemotherapeutic agents are listed in MPPL. Most injectable chemotherapy forms are not listed in the MPPL as reimbursement is made to the administering health care provider (e.g., physicians, outpatient hospitals). A dosage intended for parenteral infusion (continuous or intermittent), perfusion, or intracavity administration in an office, clinic, or outpatient hospital is not a reimbursable Medicaid benefit to a pharmacy. The pharmacy should bill the ordering provider of service.

Injectable chemotherapy and topical uses for these products may be reimbursed to a pharmacy (Provider Type 50) for home use. Some of these agents may require prior authorization. See the MPPL for verification of prior authorization requirements.

COMPOUNDED DRUGS

The Program defines a compounded drug as the combination of two or more ingredients not available from any manufacturer in the combination prescribed. Compounded prescriptions must contain at least one product manufactured by an approved manufacturer. The following compounded policies do not apply to infusion therapy.

Exclusions

Compounded drugs are NOT covered if active ingredients include:

- A non-covered legend drug or drug class (e.g., cough/cold, DESI)
- Only over-the-counter drugs (OTCs)
- Reconstitution of a product only

A compound prescription is NOT covered if it contains non-covered products and is prescribed solely to circumvent Program limitations.



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Dispensing Fees

Dispensing fees for compounded drugs are based on the schedule below. To receive the compounded fee, a prescription must involve extemporaneous compounding and dispensing prepared only when orders for specific beneficiaries are received.

The Program monitors its compounded drug policy on a pre- and post-payment basis.

Compounded Drug Dispensing Fee	Final Dosage Forms	
\$6.00	Creams, Emulsions, Nasal Drops, Ointments,	
	Ophthalmics, Otic Drops, etc.	
\$10.00	Capsules, Suppositories, Powder Papers	

CONDOMS

Condoms do not require a prescription. A pharmacy may provide condoms at the beneficiary's request. Both males and females are eligible to receive condoms. Condoms are not a covered benefit for participants in the Children's Special Health Care Services.

Payment Limit

Payment is the lesser of the pharmacy's retail price or the Maximum Allowable Cost listed in the MPPL. A dispensing fee is NOT paid for condoms.

Dispensing Limits

The following quantity requirements are monitored by pre- and post-payment reviews. A pharmacy will not be reimbursed for more than:

- 12 condoms at one time to a beneficiary
- 36 condoms in 30 days to a beneficiary

Documentation

Pharmacies are responsible for maintaining adequate documentation to substantiate which beneficiaries received condoms. Documentation can be collected on a prescription blank or a log entry. Both forms of documentation must contain:

- An assigned control number, e.g. Prescription number
- Beneficiary name
- Beneficiary Medicaid ID number
- brand name of condom dispensed
- · quantity dispensed
- date dispensed



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CLOZARIL

Clozaril may be billed in weekly cycles. A dispensing fee may be reimbursed each week when billed in accordance with other Program guidelines.

INFUSION THERAPY

Infusion therapy (except for TPN) used in the home setting is covered. If a specific drug is NOT listed in or listed with #, prior authorization must be obtained.

MEDICAL SUPPLIES & EQUIPMENT

Necessary expendable supplies and durable medical equipment, such as a pump or IV stand, must be billed by a Medical Supplier (Provider Type 87) in compliance with the guidelines and policies of the Medical Supplier Manual.

INHALERS

Depending on the beneficiary's condition, several inhalers per month may be necessary. If dispensing limitations allow <u>and</u> the physician writes accordingly, the beneficiary may obtain more than one inhaler per prescription.

METHADONE

Methadone is only covered when used as an analgesic for severe intractable pain such as that produced by some types of terminal illnesses.

ORAL CONTRACEPTIVES

Prescriptions for oral contraceptives may be dispensed for a 3-month supply when the prescriber writes accordingly.

OVER-THE-COUNTER (OTC)

Covered OTC drugs are listed in the MPPL. A prescription is required. The refill policy is the same as for legend drugs.

OTC Drugs for End Stage Renal Disease (ESRD)

Certain OTC drugs are covered only for ESRD (that is, prescribed for the treatment of a beneficiary with a kidney transplant or one undergoing maintenance dialysis).



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Documentation must be kept on file by the pharmacy to substantiate the beneficiary's ESRD condition and must include:

- The date of the transplant (month and year), or
- The name of the facility performing dialysis, or
- An indication that the beneficiary is on Chronic Ambulatory Peritoneal Dialysis (CAPD)

OTC Drugs for Long-Term Care (LTC)

If a covered OTC drug is included in the long-term care per diem, it is designated No LTC in the MPPL. These products and non-covered OTC drugs are included in the per diem rate paid to a long-term care facility. It is the responsibility of the long-term care facility to provide these products for its beneficiaries. Reimbursement must be obtained from the facility

Covered OTC drugs such as insulin and those not designated as No LTC are reimbursable to a pharmacy (Provider Type 50) for long-term care beneficiaries.

PEAK FLOW METERS

Peak flow meters may be billed by pharmacies (Provider Type 50). Coverage is limited to four (4) peak flow meters per year. These products are listed by brand name in the MPPL.

SPACERS, AEROCHAMBERS

Spacers and/or aerochambers may be billed by pharmacies (Provider Type 50). Coverage is limited to four (4) spacers and/or aerochambers per year. These products are listed by brand name in the MPPL.

UNIT DOSE

The Program only reimburses for unit dose packaging in three specific situations:

- When the drug entity is available only in unit dose packaging
- When the pharmacy cost of the unit dose packaged product is lower than Michigan Medicaid MAC
- The pharmacy is enrolled as a LTC pharmacy provider.

Unit dose for oral solids is encouraged for long-term care beneficiaries, but not mandated.



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Because of the uniqueness of pharmacy services provided in the long-term care setting, the Program has established separate billing policies. Other policies listed in this chapter also apply to long-term care beneficiaries.

LEVEL OF CARE

Long-term care (LTC) beneficiaries typically reside in a nursing home, hospital LTC unit, or county-operated medical care facility (MCF). The levels of care (see below) listed on their Medicaid ID card can identify LTC beneficiaries.

- 02 Beneficiary of nursing home services.
- 08 Developmentally disabled beneficiary in an intermediate care facility.
- 16 Beneficiary in a hospice.
- Services provided/billed by the long-term care facility are not covered. Services provided by the facility may be billed to the beneficiary. Services provided/billed by other providers are covered if Program guidelines are met.

UNIT DOSE POLICY

Unit dose for oral solids is encouraged for long-term care beneficiaries, but not mandated. The Program does NOT reimburse pharmacies for unit dose liquids or for ambulatory beneficiaries unless the drug entity is only available in unit dose packaging, or unless the Usual & Customary Charge (U & C) is less than the Program's fee screens. The Program monitors these policy requirements for unit dose and those listed below on a pre- and post-payment basis.

Unit dose pharmacies may be reimbursed for services rendered to beneficiaries in the above settings but only when the pharmacy:

- a. Bills for the **actual quantity consumed** by the beneficiary, not the quantity dispensed.
- b. Returns unit dose product dispensed but unused to the pharmacy's inventory for re-use.
- c. Maintains documentation of the quantity dispensed and consumed by the beneficiary, showing a credit to the Program for drugs not consumed.
- d. Bills for only beneficiaries with the following levels of care: 02, 08, 16 and 56.
- e. Has signed a *Unit Dose Pharmacy Agreement*. The PBM will enter a Unit Dose specialty and effective date on the pharmacy enrollment record. The Unit Dose Pharmacy Agreement can be obtained from the PBM:

First Health Services Corporation

By Phone: 1-804-965-7619
In Writing: 4300 Cox Road

Glen Allen, Virginia 23060

Web sites: www.mdch.state.mi.us/msa/mdch_msa/medicaid_data.htm

www.michigan.fhsc.com



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RE-PACKAGED UNIT DOSE

If a pharmacy re-packs traditional containers (bottles of 1000, 500, etc.) into unit dose packages, the Program will pay a flat unit dose fee of \$0.030 per capsule or tablet for long-term care beneficiaries. To qualify for this fee, in addition to the five guidelines under Unit Dose Policy, the re-packaged unit dose system used must:

- Include only capsules and tablets.
- Conform to the physical standards of the US Pharmacopoeia/National Formulary, FDA Current Good Manufacturing Practices and methods acceptable to the Michigan Board of Pharmacy.

CO-PAYMENT

Medicaid beneficiaries residing in long-term care facilities have no co-payment for pharmacy.

PHARMACY CONSULTANT SERVICES

Medication reviews and other pharmacy consultant services are the responsibility of the facility and are included in the facility's per diem rate by the Program. The pharmacy must make arrangements with the facility for reimbursement of such services.

PRODUCTS INCLUDED IN THE LTC PER DIEM RATE

The Program does not directly reimburse a pharmacy for items included in a facility's per diem rate. If provided, no additional or separate charges may be made to a beneficiary, a member of the beneficiary's family, or other beneficiary representative. If a pharmacy is requested to dispense any of the following, arrangements for payment must be between the pharmacy and the facility.

- Medical Supplies Examples of medical supplies included in the facility's per diem rate are insulin syringes, reagent strips, etc.
- Enteral Formulas Enteral Formulas are included in the facility's per diem rate.
- OTC Products Over-the-Counter (OTCs) listed in the MPPL NOT designated with No LTC may be paid directly to a pharmacy. OTCs designated with No LTC in MPPL and non-covered OTCs are included in the facility's per diem rate. Examples of OTCs in the per diem follow.

EXAMPLES OF OTCS REIMBURSED IN THE PER DIEM RATE

ORAL ANTISEPTICS Mouthwash

TOPICAL ANTISEPTICS Chlorhexidine Gluconate Wash

and Solution

TOPICAL ANTISEPTICS Hydrogen Peroxide

Isopropyl Alcohol

Povidone-Iodine Solution/Wash



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Acetaminophen **ANALGESICS**

Aspirin

Buffered Aspirin

Enteric-coated aspirin

COUGH/COLD PREPARATIONS Guaifenesin with and without Dextromethorphan

Pseudoephedrine/Chlorphen/Dextromethorphan

Pseudoephedrine/Chlorpheniramine

Pseudoephedrine HCI

OINTMENTS Vitamins A & D Ointment

White Petroleum

Zinc Oxide

Calcium Carbonate, Calcium Gluconate, Calcium Lactate VITAMINS/MINERALS

> Daily Multiple Vitamin with and without Minerals Oyster Shell Calcium with and without Vitamin D

Vitamin B1, Vitamin B6

All other OTC vitamins and minerals

MISCELLANEOUS Epsom Salts (external use)

Glycerin Suppositories

Milk of Magnesia

Mineral Oil or Emulsions of Mineral Oil

Povidone Douches Sterile Lubricant Vinegar Douches

Stool Softeners and stool softeners/laxative combinations



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PUBLIC HEALTH SERVICE & DISPORTIONATE SHARE HOSPITALS

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With enactment of Section 602 of the Veterans Health Care Act of 1992, Public Health Service (PHS) covered entities and selected disproportionate share hospitals became eligible for contract drug prices from manufacturers (340B Program).

ACTUAL ACQUISITION COST

In addition to these product cost discounts, entities participating in this contract drug program are required by federal policies to bill drugs covered in the PHS program using the <u>actual acquisition cost</u> for a drug plus a dispensing fee. Actual acquisition cost is defined as the actual invoice cost for a drug product to the pharmacy or company, organization, corporation, or affiliate with which it is associated.

Except for a 2% cash allowance, actual acquisition cost must reflect trade and quantity discounts, rebates, free goods, and price concessions.

The Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Finance Administration [HCFA]) provide a list of participating entities to State Medicaid agencies. On a post-payment basis, the Program will review billings from PHS participating entities to track compliance with this requirement.

PHS and contract pharmacies or disproportionate share hospital participating entities that are enrolled as Medicaid pharmacies (Provider Type 50) must contact the Review and Evaluation Division at the following address so their claims can be excluded from the Drug Rebates.

Michigan Department of Community Health Review and Evaluation Division Attn: Rebate Program Specialist P.O. Box 30479 Lansing, Michigan 48909-7979

Phone: 517-335-5078 Fax: 517-241-7813



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DRUG REBATE PROGRAM

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The drug rebate program was mandated by the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) and implemented on January 1, 1991. The rebate program requires pharmaceutical manufacturers to contract with the Department of Health and Human Services (HHS) to have their products covered under State Medicaid Programs.

The Program invoices pharmaceutical manufacturers for rebates. Invoicing is done on a quarterly basis from the pharmacy paid claims history. Pharmacies MUST bill the actual NDC for products dispensed. Pharmacies may be contacted periodically to verify product utilization and cost. Contact can include phone or written verification requests. Documentation requirements for verification can include, but are not limited to,:

- · Copies of the product invoice
- · Copies of original prescriptions
- Compounding records

APPROVED MANUFACTURERS

The Program only covers those drugs produced by manufacturers who have signed rebate agreements with the Department of Health and Human Services (HHS). Approved manufacturers are listed in the MPPL. Products distributed by companies or divisions whose manufacturers did not enroll, or did not enroll all their divisions, are not covered.

Approved manufacturers are listed on the MPPL and are identified by the specific five-digit labeler code (the first five digits of the NDC). Pharmacies must bill the actual NDC for the products dispensed.



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BENEFICIARY MONITORING

PROGRAM (BMP)

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The Beneficiary Monitoring Program's purpose is to monitor and control inappropriate utilization of prescribed drugs and emergency room services.

REPORTING SUSPECTED ABUSE

The Program appreciates and encourages your continued cooperation in reporting beneficiaries who you believe may be intentionally or unintentionally inappropriately utilizing Medicaid services. All providers may direct complaints regarding beneficiary abuse to the address or telephone number below:

Michigan Department of Community Health Program Investigation Section Attention: Beneficiary Monitoring Program P.O. Box 30479 Lansing, Michigan 48909-7979 Phone: 517-335-5239

...

LOCK-IN CONTROL

The Beneficiary Monitoring Program uses a lock-in control mechanism to assign a primary physician to monitor and control inappropriate utilization of prescribed drugs and emergency room services for Fee-for-Service beneficiaries.

The beneficiary's primary physician's name will be listed on the beneficiary's Medicaid ID card. Only those pharmacy claims written or authorized by the beneficiary's primary physician are a covered benefit. This authorization does not replace any additional prior authorizations required by the Program.

PRESCRIPTIONS NOT FROM PRIMARY PROVIDER

All non-emergency prescriptions must be ordered by the beneficiary's primary physician. If a prescriber other than the primary physician prescribes a drug product, the primary physician must be contacted for authorization. The primary physician will then order the necessary prescription.

EMERGENCY PRESCRIPTIONS

The Beneficiary Monitoring Program Lock-In does not affect emergency services. Emergency is defined as any condition for which a delay in treatment may result in the beneficiary's death or the permanent impairment of the beneficiary's health. Any pharmacy may dispense a covered product in accordance with other Program guidelines if an emergency exists.

When a prescriber orders an emergency prescription for a beneficiary in the Beneficiary Monitoring Program Lock-In:

- The prescriber must write 'Emergency Service' on the prescription.
- The Pharmacy must call the PBM's Technical Call Center for an emergency authorization for the date of service at 1-877-624-5204.
- Report any fraud and abuse to the PBM's Technical Call Center.



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PHARMACY AUDIT AND

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The following information serves as a <u>general</u> guide to the area of policy compliance that will be reviewed on a post-payment basis. Although the list provided is <u>not all-inclusive</u>, it covers a large proportion of discrepancies found through on-site audits, desk audits, and mail audits.

CHANGING CLAIM INFORMATION

The Claims Processing System recognizes and denies exact duplicates. Providers may not falsely alter the NDC number, date of service, prescription number, days supply, or any other claim requirement that would allow payment. The Program will recover inappropriate payments for billings found in violation of policy.

COMPOUNDS

The compounding of prescription products to gain coverage of non-covered OTC, non-covered legend drugs, or other non-covered categories is prohibited, e.g., the use of injectable Sodium Bicarbonate to compound a Sodium Bicarbonate foot irrigation. The program will recover inappropriate payments for billings found in violation of policy.

CSHCS ONLY

Pharmaceutical products must relate to the qualifying diagnosis. Payment will be recouped for billings for products not related to the qualifying diagnosis.

DAYS SUPPLY

Accurate days supply information is required. Altering days supply information for purposes of payment will be considered fraud and will be reported to the appropriate unit for investigation.

DISPENSING FEES

Pharmacies may not bill in a pattern that would lead to more than thirteen (13) dispensing fees in a year for the same drug entity. Splitting prescriptions to increase the number of fees paid will be considered fraud and reported to the appropriate unit for investigation. The program will recover inappropriate payments for billings found in violation of policy.

DRUG REBATE

Dosages outside the normal dosage range based on the days supply submitted may prompt a verification request of product usage on reported utilization.

HOSPICE

Pharmacies must **not** bill the Program for prescription services related to the terminal illness. The program will recover inappropriate payments for billings found in violation of policy.



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INACCURATE BILLING

The NDC number of the product actually dispensed must be billed.

The NDC number is package size and manufacturer specific.

Non-covered, repackaged products intentionally billed under the brand NDC constitutes fraud.

The program will recover inappropriate payments for billings found in violation of policy.

OTHER INSURANCE PAYMENTS

Pharmacies must bill other insurances before billing Medicaid. This also applies to Medicare Part B eligible beneficiaries.

Failure to bill Medicaid the total due less the amount paid by another insurance or by Medicare Part B may be construed as fraud under the Medicaid False Claim Act.

PRESCRIPTION DOCUMENTATION

For originals and all refills, accurate prescription documentation must be readily accessible and maintained for six (6) years. The program will recover inappropriate payments for billings found in violation of policy.

PRESCRIBER INFORMATION

Accurate prescriber information must be provided.

Per the Social Welfare Act MCL 400.111b (21), "In the interest of review and control of utilization of services, a provider shall identify each attending, referring, or prescribing physician, dentist, or other practitioner by means of a program identification number on each claim or adjustment of a claim submitted to the state department."

Submitting incorrect prescriber identification numbers can cause false ProDUR messages and claim denials. It could also cause a pharmacy to be targeted for post-payment audit. Pharmacies will be audited for inappropriate identification of prescribers. Pharmacies identified through the audit process as misidentifying prescribers will receive a warning letter. Continuation of incorrectly identifying prescribers will result in payment being taken back for those claims.

PUBLIC HEALTH SERVICE & DISPROPORTIONATE SHARE HOSPITALS

The actual acquisition cost must be billed. The program will recover inappropriate payments for billings found in violation of policy.

RETURN TO STOCK

Providers must reverse claims for products billed but not dispensed to the beneficiary. A record of the reversals log shall be maintained for audit purposes for six (6) years.



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SIGNATURE REQUIREMENT

Providers must maintain and have accessible the signature log indicating beneficiary's pick-up of prescription claims and acceptance or denial of beneficiary counseling. Missing signatures indicate the prescription was not picked-up or the beneficiary was not offered counseling as required. Pharmacies are required to maintain this log for six (6) years. The program will recover inappropriate payments for billings found in violation of policy.

UNIT DOSE

Pharmacies that serve nursing facilities must bill the actual quantity consumed by the beneficiary, not the quantity dispensed. The program will recover inappropriate payments for billings found in violation of policy.

USUAL & CUSTOMARY CHARGE

For specified products, the submitted charge will be compared to the cash price to the general public. The program will recover inappropriate payments for billings found in violation of policy.

Continued violations of Medicaid claims processing policies may result in recoupment and referral to the Michigan Attorney General's Office for investigation of fraud.



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MEDICAL SUPPLIER PROVIDER TYPE 87

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PROVIDER TYPE 87

Covered medical supply items payable to a Pharmacy (Provider Type 50) are listed in the MPPL. A prescription is required for medical supplies. Covered products include insulin syringes, reagent strips, alcohol swabs, etc.

The Program will not separately reimburse a pharmacy for medical supplies dispensed to beneficiaries in long-term care facilities, such as nursing homes, hospital long-term care units, or medical care facilities. These items are considered a part of the facility's per diem rate. If provided, no additional or separate charges may be made to a beneficiary, a member of the beneficiary's family, or other beneficiary representative. If a pharmacy is requested to dispense any of these items, arrangements for payment must be between the pharmacy and the facility.

Except for those items listed in the MPPL, medical supplies and equipment are covered only when billed by a Medical Supplier (Provider Type 87) or Orthotist/Prosthetist (Provider Type 85). These items include equipment (e.g., canes), orthotics (e.g., arch supports), prosthetics, oxygen dispensers, wound care dressings (e.g., transparent film, hydrocolloid absorptive dressings, alginate and gel dressing), splints, ace bandages, TPN, enteral for tube administration, etc.

Medical suppliers use an invoice and method of billing different than a pharmacy. When billing as a Provider Type 87 or 85, the pharmacy must consult the Medical Supplier Manual.

To enroll as a Medical Supplier, contact:

Michigan Department of Community Health Medicaid Payments Division Provider Enrollment Unit P.O. Box 30238 Lansing, Michigan 48909

Phone: 517-335-5492



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GLOSSARY OF TERMS

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Acute Illness is a condition of rapid onset, short course, and pronounced symptoms.

Average Wholesale Price (AWP) is the price of a product as published by First Data Bank.

Brand-name Drug is defined as a single-source drug, a cross-licensed drug or an innovator drug for which a lower-cost generic equivalent is available.

Chronic Illness is a lasting condition or ailment of long duration or of frequent recurrence.

"Compound" Prescription is any product for which two or more ingredients are extemporaneously mixed in usually accepted therapeutic doses. This requires the pharmacist's skill in weighing, measuring, levigating, etc., at the time of dispensing. The allowable compounding fee applies to the preparation of an individual prescription. It does not apply to prescriptions dispensed from a previously prepared stock supply (i.e., premaking a special lotion or ointment in gallons or pounds).

Controlled Substances are drugs that come within the scope of the Controlled Substances Act and are divided into five schedules- I, II, III, IV, and V.

Dispensing Fee is the payment for the pharmacist service in dispensing the prescribed drug.

Dispensing Physician is a duly-licensed physician who prepares, dispenses and instructs patients to self-administer medication on a regular basis.

Drug Efficacy Study Implementation (DESI) Drugs: FDA designations related to "substantial evidence" of effectiveness.

Drug Utilization Review (DUR) means a process designed to ensure that prescriptions shall be appropriate, medically necessary and not likely to result in adverse medical outcomes.

Drug Utilization Review Board (DUR Board) means an advisory board, comprised of physicians and pharmacists, to the State's Medicaid Program.

Estimated Acquisition Cost (EAC) is average wholesale price (AWP) minus 13.5% for non-chain pharmacies or 15.1% for chain pharmacies.

Federal Drug Rebate Program was established by OBRA 90, and requires manufacturers to sign a rebate agreement with the Health Care Financing Agency (HCFA) in order to have their products covered for Medicaid beneficiaries. State Medicaid agencies administer the program and collect rebates from the manufacturers.

First Health Services Corporation is referred to as First Health throughout this chapter. First Health is the contracted vendor to administer the Program's pharmacy benefit, prior authorization, pharmacy audit, and RetroDur.

Fraud is the deliberate, intentional, and willful act with the specific purpose of deceiving the Department with respect to any material fact, condition, or circumstance affecting eligibility or need.

Generic refers to a nonproprietary drug or class of drugs. The generic name refers to the official chemical composition of the drug as published in the latest edition of a national recognized pharmacopoeia or drug compendium. Generics do not refer to a particular brand name product.

Legend Drug is a drug bearing the statement: "Caution – Federal Law Prohibits Dispensing without a Prescription."



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Less-Than-Effective (LTE) is a drug not effective for some or all of its labeled indications as determined by the Secretary of Health and Human Services (HHS).

Long Term Care Facility Pharmacy refers to pharmacies specializing in provision of drugs and services in an institutional setting where drugs are dispensed based on unit dose.

Maximum Allowable Cost (MAC) is the maximum cost allowed by the Michigan Department of Community Health for certain multiple source drugs.

Medicaid Health Plan (MHP) is a health maintenance organization contracted to provide services to Medicaid beneficiaries.

Multiple Source Drug - A drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

National Council for Prescription Drug Programs (NCPDP) develops standards for electronic pharmacy transactions (Point of Sale claims transactions).

National Drug Code (NDC) is the eleven-digit code assigned to all prescription and over-the-counter products by the labeler/manufacturer of the product under Federal Drug Administration (FDA) regulations.

OBRA 90: Omnibus Budget Reconciliation Act of 1990 as amended.

Over-the-Counter (OTC) - A drug that can be purchased without a physician's prescription.

Pharmacist - A person licensed under Michigan statutes to provide services within the scope of pharmacy practice.

Pharmacy - An entity registered by the Michigan Board of Pharmacy.

Point-of-Sale (POS) refers to the real-time on-line adjudication of pharmacy claims to the PBM. Point-of Sale provides participating pharmacies real-time access to beneficiary eligibility, drug coverage, pricing information, guidelines for drug use, and dispensing fees.

Prescribed Drug - A drug, either legend or over-the-counter, that is ordered by a physician to be used by a patient to treat a disease or condition.

Program is the term used throughout this chapter to indicate, collectively, Medicaid, Children's Special Health Care Services, and the State Medical Program.

Prospective Drug Utilization Review (ProDUR) encompasses the detection, evaluation, and counseling components of pre-dispensing drug therapy screening. ProDUR is required at the point of sale before each prescription is delivered to a Medicaid beneficiary. ProDUR screening is the responsibility of each Medicaid participating pharmacy and is a requirement of participation in the Program.

Reimbursement is the amount of payment requested for a provided benefit service. It shall be the lesser of the provider's usual and customary charge or any amount the provider will accept from any other third party program or from the public in the form of discounts, special rebates, incentives, or coupons.

Retrospective Drug Utilization Review (RetroDur) program analyzes and interprets patterns of beneficiary drug usage through periodic examinations of claims data to identify patterns of fraud and abuse, gross overuse, and inappropriate or medically unnecessary care.



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Return to Stock refers to those prescriptions filled but not dispensed or picked up by the beneficiary.

Special Health Plan – A managed care organization contracted to provide services to CSHCS only or CSHCS/Medicaid beneficiaries.

Usual and Customary Charge is the reimbursement amount the general public is requested by the provider to pay for a good or service.



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