NEW YORK STATE
MEDICAID PROGRAM

PHARMACY MANUAL

POLICY GUIDELINES

Table of Contents

Section I - General Pharmacy Policy

Required Prescribing Information

All prescriptions and fiscal orders must bear:

- The name, address, age and client identification number (CIN) of the patient for whom it is intended. If the CIN does not appear on the order, the prescription should only be filled if the CIN is readily available in the pharmacy records;
- The date on which it was written;
- The name, strength, if applicable, and the quantity of the drug prescribed;
- Directions for use, if applicable; and
- The name, address, telephone number, profession, DEA Number (if applicable) and signature of the prescriber who has written or initiated the prescription or fiscal order.

  If a pharmacist is certain that the prescription is from a legitimate prescriber and the prescriber's license number or eMedNY provider identification number is readily available in the records of the pharmacy, it is not necessary to record the license number or eMedNY provider identification number on the prescription or fiscal order.

For **non-controlled substance prescriptions**, the pharmacist may record on the prescription:

- The address, age and CIN of the Medicaid beneficiary,
- The address, telephone number and profession of the prescriber.

If the address, age or CIN of the Medicaid beneficiary are missing, the pharmacist is not required to enter any of these items on the prescription if the information:

- Is otherwise readily available in the records of the pharmacy and the pharmacist knows the person who is requesting that the prescription be filled, or
- The pharmacist is otherwise satisfied that the prescription is legitimate.

Prescriptions written for **controlled substances** must meet the requirements of Article 33 of the Public Health Law. In accordance with New York State Department of Health Rules and Regulations (Part 80), pharmacists are permitted to add or change only certain information on controlled substance prescriptions.

Prescription Drug Orders

Prescription drugs can be obtained by presenting a signed written order from a qualified prescriber.

Quantities for prescription drugs shall be dispensed in the amount prescribed, taking into consideration those drugs should be ordered in a quantity consistent with the health needs of the Medicaid beneficiary and sound medical practice.

> *A pharmacist may not fill an original prescription more than sixty (60) days after it has been initiated by the prescriber.*
>
> *For controlled substances, a pharmacist may not fill an original prescription more than thirty (30) days after it has been initiated by the prescriber.*

Non-Prescription Drug Orders

Non-prescription drugs, also known as over-the-counter (OTC) drugs, can be obtained by presenting a signed written order (fiscal order) from a qualified prescriber. The prescriber may use his/her prescription blanks to write fiscal orders.

If the ordering practitioner does not request a quantity that corresponds to the pre-packaged unit, the pharmacist may supply the drug in the pre-packaged quantity that most closely approximates the amount ordered.

> *A pharmacist may not fill an original fiscal order for a non-prescription drug more than sixty (60) days after it has been initiated by the prescriber.*

Medical/Surgical Supply Orders

Medical/surgical supplies can only be obtained by presenting a signed, written order (fiscal order) from a qualified prescriber.

If the ordering practitioner does not request a quantity that corresponds to the pre-packaged unit, the pharmacist may provide the item in the pre-packaged quantity that most closely approximates the amount ordered.

> *A provider may not fill an original fiscal order for medical/surgical supplies more than sixty (60) days after it has been initiated by the prescriber.*

Multiple Drug Orders

For drugs administered in a nursing home, multiple drug orders can be ordered on a single prescription document. The dispensing pharmacy must be employed by or providing services under contract to the nursing home.

> Pharmacies providing services under contract to nursing homes are not required to obtain separate prescriptions for non-controlled, carve-out drugs (i.e. select drugs which are paid on a fee-for-service basis).

All prescriptions written for controlled substance medications must be written **only** on an official New York State Prescription Form in order to be dispensed by a pharmacy.

Multiple drug orders are **not** allowable on prescriptions for controlled substances. Official prescriptions for controlled substances are limited to **one** controlled substance medication per official prescription form.

Refills

A prescription or fiscal order may not be refilled unless the prescriber has indicated on the prescription or fiscal order the number of refills. No prescription or fiscal order for a drug or supply may be refilled 180 days after it has been initiated by the prescriber.

All refills of prescription drugs must bear the prescription number of the original prescription. Refills of non-prescription drugs and medical/surgical supplies must also be appropriately referenced to the original order by the pharmacy. No more than five (5) refills are permitted for prescriptions or fiscal orders.

Reimbursement will not be available for refills associated with Schedule II Controlled Substances or benzodiazepines, which cannot be refilled under the federal and State controlled substance laws.

> *Automatic refilling of prescriptions for prescription drugs, or fiscal orders for non-prescription drugs, medical surgical supplies or enteral products is not allowed under the Medicaid Program.*

Faxed refill authorization requests are not allowed under the Medicaid Program.

Delivery/Automatic Refills

Prescriptions, over-the-counter medications, supplies or durable medical equipment (DME) shall be prepared in accordance with instructions provided on the prescription or fiscal order.

All shipping and/or delivery costs shall be the responsibility of the provider of service. The pharmacy or DME provider must first contact the beneficiary or caregiver to ensure that a delivery is needed. Confirmation of needed delivery shall be maintained in the patient record. Automatic refills will not be permitted.

The beneficiary or caregiver must receive delivery. Electronic signatures for receipt of product are permitted only if retrievable and kept on file by the pharmacy or DME provider. If a pharmacy or DME provider utilizes a delivery service, the pharmacy or DME provider will remain responsible for delivery of product to the intended beneficiary or caregiver. Replacement of lost, stolen or mis-delivered medication, supplies and DME is the sole financial responsibility of the pharmacy or DME provider. The Medicaid Program will not reimburse for replacement supplies of lost, stolen or misdirected medication or DME deliveries.

The pharmacy or DME provider must also guarantee appropriate delivery of intact, usable product (i.e., if product requires refrigeration, the provider must ensure delivery under appropriate product storage conditions).

Unused Medication

Nursing home pharmacy services providers are required to reimburse or credit the nursing home or purchaser of such drug products for the unused medication that is restocked and redispensed (Title 10 New York Codes, Rules and Regulation (NYCRR) 415.18(f)).

Drugs listed on the Medicaid Nursing Home Carve-Out List must be credited back to the Medicaid Program. The Carve-Out List is available online at:

http://www.nyhealth.gov/health_care/medicaid/program/carveout.htm.

Nursing homes and pharmacies providing pharmacy services to nursing homes are encouraged to review their protocols to assure these requirements are met:

- Drug products returned must be sealed in unopened, individually packaged, units and within the recommended period of shelf life for the purpose of redispensing.
- Drug products returned should show no obvious sign of deterioration.

- Drug products packaged in manufacturer's unit-dose packages may be returned provided that they are redispensed in time for use before the expiration date, if any, indicated on the package.

Drug products repackaged by the pharmacy into unit-dose or multiple-dose "blister packs" may be returned for redispensing provided that:

- The date on which the drug product was repackaged, its lot number and expiration date are indicated clearly on the package;
- Not more than 90 days have elapsed from the date of the repackaging;
- A repackaging log is maintained by the pharmacy;
- Partially used blister packs may be redispensed only as returned.
- Partially used blister packs may not be emptied and repackaged.
- Additional units of medication may not be added to partially used blister packs.
- No drug product dispensed in bulk in a dispensing container may be returned.
- No medication or drug product defined as a controlled substance in Section 3306 of the Public Health Law may be returned.

The vendor pharmacy to which such drug products are returned shall reimburse or credit the nursing home or purchaser of such drug products for the unused medication that is restocked and redispensed and shall not otherwise charge any individual resident or the State, if a resident is a Medicaid beneficiary or beneficiary of a State-funded program, for unused medication or drug products returned for reimbursement or credit.

Quantity/Frequency Limits

Prescription, non-prescription drugs and medical/surgical supplies may have fixed limits in the amount and/or frequency that can be dispensed.

For certain medical/surgical supplies, if the limit on an item is exceeded, prior approval must be requested with accompanying documentation as to why the limit needs to be exceeded. Quantity and frequency limits are available in the Pharmacy Fee Schedule online at:

http://www.emedny.org/ProviderManuals/Pharmacy/index.html.

Questions may be referred to the Division of Provider Relations and Utilization Management at:

(518) 474-8161.

Generic Drug Substitution Policy

All Medicaid pharmacy providers must comply with all State requirements adopted pursuant to NYS drug substitution laws.

A pharmacist shall substitute a generic drug when listed in the FDA approved drug products (Orange Book) whenever available unless the prescriber writes "DAW" (Dispense As Written) in the appropriate manner on the prescription.

For certain brand name Medicaid prescriptions to be eligible for reimbursement of the Estimated Acquisition Cost (EAC), prescribers must also certify that the brand name drug is required by writing directly on the face of the prescription "brand necessary" or "brand medically necessary" in their own handwriting (see Basis of Payment section of this Manual).

A rubber stamp or other mechanical signature device may not be used.

Additionally, as a result of the Medicaid Mandatory Generic Drug Program, prior authorization must be obtained for most brand-name drugs with an “A-rated” generic equivalent before dispensing.

Prescription Drug Prior Authorization

The Medicaid Program requires prior authorization for certain drugs through the Preferred Drug Program (PDP), Mandatory Generic Drug Program, and the Clinical Drug Review Program (CDRP).

Prescribers ordering a drug that requires prior authorization must complete the approval process.

Prescribers are required to initiate the prior authorization process by responding to questions related to the patient’s condition, justifying the use of the drug.

Prior authorization does not ensure payment.

Even if a service has been prior authorized, the provider must still verify a Medicaid beneficiary’s eligibility via the Medicaid Eligibility Verification System before service is provided and the claim must be otherwise payable in accordance with the requirements as found in each related section of the provider manual.

Prior authorization must be obtained from the Department of Health before certain drugs will be reimbursed.

Prescribers

- Prescribers, or in certain circumstances their agents (i.e., employee of the prescriber), are responsible for obtaining the prior authorization number by contacting the prior authorization system and answering questions regarding the prescription.

- Prescribers are required to respond to a series of questions that identify the prescriber, the patient and the reason for prescribing the drug.

- A prior authorization number may be issued following completion of the process. The prior authorization number must be entered on the face of the prescription.

- The Medicaid beneficiary's medical record maintained by the prescriber must include documentation of the rationale for requesting the drug requiring prior authorization.

Pharmacists

- The completed prescription may be filled at any New York State Medicaid-enrolled pharmacy that stocks the drug.

- Pharmacists should assure that the prescription contains all information necessary to fill the prescription, including the prior authorization number.

- A prescription may not be filled unless the pharmacy provider contacts the prior authorization system and submits the necessary information.

- Pharmacists must respond to a series of questions identifying the prior authorization number, pharmacy provider number, category of service and drug.

  The pharmacy will get an error message that directs them to contact the prescriber if the pharmacy enters information that does not match the prescriber input.

- The prior authorization number must be entered on the claim to receive payment. Only the prior authorization number is required in the prior authorization field.

Note: Prescriptions for non-preferred drugs will carry a prior authorization number ending with a "W". The "W" alerts pharmacy providers to select the non-preferred drug option when calling the prior authorization phone line to validate the prior authorization number. The "W" should not be included in the prior authorization field when submitting

a claim. If the pharmacy is billing manually, only the prior authorization number is required in the prior authorization field.

- Prior authorization does not guarantee payment. Payment is subject to patient eligibility and other Medicaid guidelines.
- The prior authorization number must be included on claims for refills.
- Each new prescription for a drug that requires prior authorization must include a prior authorization number.
- Prior authorization cannot be used to obtain:
  - Early refills,
  - Refills for lost or stolen drugs,
  - Extended or vacation supplies, or
  - Extension of drug quantity limits.

Preferred Drug Program

The Preferred Drug Program (PDP) promotes the prescribing of less expensive, effective prescription drugs when medically appropriate.

For selected categories of drugs where there are multiple drugs with similar efficacy, preferred and non-preferred drugs are identified.

Prior authorization is not required for preferred drugs.

For non-preferred drugs, prescribers initiate the prior authorization process, providing information about the patient's medical need for the non-preferred drug.

Pharmacists validate the prior authorization number prior to submitting the claim.

Prescriptions for non-preferred drugs will carry a prior authorization number ending with a "W". The "W" alerts pharmacy providers to select the non-preferred drug option when calling the prior authorization phone line to validate the prior authorization number.

The "W" should not be included in the prior authorization field when submitting a claim. If the pharmacy is billing manually, only the prior authorization number is required in the prior authorization field.

Additional information, detailed instructions and updates can be accessed at:

https://newyork.fhsc.com/providers/PDP_about.asp.

Clinical Drug Review Program

The Clinical Drug Review Program (CDRP) is an expanded prior authorization program for specific drugs that require intervention to assure appropriate utilization.

Under the CDRP, certain drugs require prior authorization because the Medicaid Program has one or more of the following concerns with a particular drug:

- Specific safety issues;
- The potential for fraud and abuse;
- General health concerns;
- The potential for significant overuse or misuse; and
- Significant costs when a more appropriate therapy has the same efficacy.

A list of drugs subject to the CDRP and guidelines on how to obtain prior authorization can be accessed at:

https://newyork.fhsc.com/providers/cdrp_about.asp/.

Mandatory Generic Drug Program

With the exception of drugs subject to the Preferred Drug Program, State statute excludes coverage of brand-name drugs in the Medicaid Program when the Food and Drug Administration (FDA) has approved a generic product, unless a prior authorization is received.

All prescriptions for brand-name drugs, where an A-rated generic equivalent is available, are subject to prior authorization. The Commissioner of Health has the authority to exempt specific brand-name drugs that have a generic equivalent from this requirement.

Ongoing Maintenance
The Medicaid Program continues to monitor, evaluate and amend the mandatory generic process to assure effectiveness and efficiency. When the FDA approves new generic drugs, the DOH allows the equivalent brand-name drug to be dispensed for a

period of six months, without prior authorization, to assure that there is an adequate supply of the new generic readily available.

Guidelines on how to obtain prior authorization for brand name drugs with an A-rated generic equivalent, including worksheets and step-by-step instructions for both prescribers and pharmacists can be accessed at:

http://www.health.state.ny.us/health_care/medicaid/program/mandatory_generic/index.htm.

Enteral Formula

Prior authorization for enteral formula ensures that only medically necessary enteral formulas are ordered, dispensed and reimbursed. Enteral formula policy guidelines are available in the Durable Medical Equipment Policy Manual at:

http://www.emedny.org/ProviderManuals/DME/index.html.

Service Limits

Selected items of medical/surgical supplies have limits in the amount and frequency that can be dispensed to an eligible Medicaid beneficiary. If a Medicaid beneficiary exceeds the limit on an item, prior approval must be requested with accompanying documentation as to why the limits need to be exceeded.

Requests for prior approval should be initiated by the ordering practitioner, who completes fields 1-17 of form eMedNY-361501. The provider then completes the remaining fields on the form and submits to the Medicaid eMedNY Contractor. The Prior Approval Guidelines and form eMedNY-361501 are available at:

http://www.emedny.org/ProviderManuals/DME/index.html.

Prior approval will be granted only for a specified period of time.

The supplier must obtain a prior approval number before dispensing the following:

- Any medical/surgical supply ordered in quantities larger than five units or the quantity indicated in the Medical/Surgical Supplies section of this Provider Manual.
- Any medical/surgical supply for which a procedure code is not listed in the OTC and Supply Fee Schedule, using an appropriate miscellaneous or unlisted procedure code.
- Whenever the procedure code is underlined in the List of OTC Categories and Supply Codes and OTC and Supply Fee Schedule section.

- When the dispenser attempted but could not gain authorization for the Medical/Surgical supply through DVS or the Voice Interactive Telephone Prior Authorization System.

Prior Approval

Prior Approval is the process of evaluating the aspects of a plan of care which may be for a single service or an ongoing series of services in order to determine the medical necessity and appropriateness of the care requested.

- Requests for prior approval of medical/surgical supplies when quantity limits are exceeded must be accompanied by the invoice with all discounts clearly noted. The invoice must be retained with the patient record.

- Prior approval is also required for payment of medical/surgical supplies not specifically listed in the Medicaid Provider Manual.

Prior approval guidelines may be accessed at:

http://www.emedny.org/ProviderManuals/DME/index.html.

Dispensing Validation System

The Dispensing Validation System (DVS) is an automated approval process for selected items of medical/surgical supplies, durable medical equipment, orthotics, prosthetics, enteral products, and orthopedic footwear.

- Payment for those items listed in the medical/surgical supply section of the Pharmacy manual, where the product description is preceded by a "#", is dependent upon obtaining a dispensing validation number through a Medicaid Eligibility Verification System (MEVS) transaction on the dispense date.

- MEVS DVS will verify whether the patient has already received, or is currently eligible to receive, the particular product being ordered, based upon limits in the amount and frequency that can be dispensed to an eligible Medicaid beneficiary.

Medicaid/Medicare Reimbursement

Pharmacies enrolled in the *Medicaid* Program are required to demonstrate participation in the *Medicare* Program. Medicaid pharmacy enrollment information can be accessed online at:

http://www.emedny.org/info/ProviderEnrollment/index.html.

For a service with both Medicare and Medicaid coverage, all charges for services must first be billed to Medicare. Only after Medicare payment information is received, may a claim be submitted for Medicaid reimbursement.

The pharmacist must maintain all Medicare payment information when Medicaid is billed on file for six years following the date of payment for audit purposes. All Medicare benefits must be maximized prior to billing Medicaid.

Medicare Part A

Medicare Part A covers inpatient care, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). It also covers hospice care and some home health care. Beneficiaries must meet certain conditions to receive these benefits.

Medicare Part B

Medicare Part B covers doctor's services, outpatient care and some other medical services that Part A does not cover. Medicare Part B also covers certain drugs such as:

- those used in chemotherapy and with organ transplants;
- medical supplies, such as diabetic and ostomy supplies; and
- enteral products under certain circumstances.

Further information on Medicare Part B drug coverage and billing issues can be accessed at:

http://www.cms.hhs.gov/Pharmacy/Downloads/partsbdcoverageissues.pdf.

- Medicaid will pay the **Medicare deductible** on claims where Medicare is the primary payer.
- When Medicare's payment exceeds the Medicaid fee, Medicaid will pay 20% of the Medicare coinsurance amount due. This amount will be considered payment in full. The beneficiary has no financial responsibility beyond this payment..
- When Medicare's payment is **less than or equal to** the Medicaid fee, Medicaid will pay the full Medicare coinsurance. With Medicaid/Medicare crossover claims, even for a procedure that would have required Medicaid prior approval, prior approval is not required since Medicare approved and paid for a service and/or procedure.

Medicare Part D

Medicare beneficiaries who also have Medicaid (dual-eligibles), in most circumstances, must be enrolled in a Medicare Part D prescription drug plan in order to maintain their Medicaid coverage. Beneficiaries and their prescribers must work together to find an appropriate drug that is covered by the Part D plan or, if necessary, use the Part D plan's exception and appeals process to obtain coverage for necessary prescriptions not listed on the plan's formulary.

Medicaid will continue to cover products excluded from coverage under Medicare Part D in the four drug categories below:

- benzodiazepines,
- barbiturates,
- certain non-prescription drugs, and
- select prescription vitamins.

All claims for dual-eligibles submitted to Medicaid are subject to Medicaid rules, including prior authorization.

For more information regarding Medicare Part D benefit, refer to the DOH website at:

http://www.health.state.ny.us/health_care/medicaid/program/medicaid_transition/index.htm.

Home Infusion

The New York State Medicaid Program does not provide a bundled payment to cover drugs, supplies and services associated with home infusion treatments. Home infusion drugs and supplies must be billed as pharmacy services.

The list of Medicaid reimbursable drugs may be accessed at:

http://www.emedny.org/info/formfile.html.

The Centers for Medicare and Medicaid Services (CMS) requires coverage of home infusion drugs under Medicare Part D that are not currently covered under Parts A and B of Medicare. Although the Medicare Part D benefit does not cover equipment, supplies and professional services associated with home infusion therapy, it does cover the ingredient costs and dispensing fees associated with infused covered Part D drugs.

Further information describing the payment obligations under Medicare for home infusion therapy can be accessed at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/HomeInfusionReminder_03.10.06.pdf.

Monitoring

Federal regulations require that pharmacy providers be monitored in order to assure that reimbursement for drugs is made at the lowest possible level, consistent with accurate cost information. This monitoring will consist of on-site reviews to verify that the pharmacy is submitting accurately priced claims.

Standards of Quality

Standards of quality of drugs provided under Medicaid must conform to standards in the United States Pharmacopoeia where applicable. In accordance with Section 6808 of the State Education Pharmacy Law, pharmacists are responsible for the strength, quality and purity of the drugs dispensed.

Section II - General Guidelines

Who May Dispense

Drugs and medical/surgical supplies may be dispensed to Medicaid beneficiaries by pharmacists/pharmacies which are licensed and currently registered by the New York State Board of Pharmacy, New York State Education Department, and which are enrolled in the New York State Medicaid Program.

Drugs may also be provided by a prescribing practitioner under certain circumstances.

Medical/surgical supplies may also be provided by a home health agency or durable medical equipment dealer.

Out-of-State Pharmacy Providers

Out-of-state pharmacies, which provide drugs to New York State Medicaid beneficiaries, must be properly registered and/or licensed by the appropriate authority in the state in which the pharmacy is located.

Out-of-State pharmacy providers must enroll in the New York State Medicaid Program in order to be reimbursed by the Program.

The New York State Education Department requires certain pharmacies located outside of New York State to register with the New York State Board of Pharmacy. For more information on this requirement, please refer to:

http://www.op.nysed.gov/part63.htm.

Who May Prescribe

Physicians, certified nurse practitioners (CNPs), midwives, dentists, podiatrists, registered physician's assistants (RPAs) and New York State Education Department certified optometrists may order prescription drugs, non-prescription drugs, and medical/surgical supplies, within their "scope of practice".

Prescriptions and fiscal orders written by RPAs, CNPs, midwives or certified optometrists must meet the following requirements:

- RPAs may write prescriptions and fiscal orders when delegated by the supervising physician. The Medicaid beneficiary must be under the care of the physician responsible for the supervision of the RPA.

- Once registered by the DEA as a "mid-level practitioner", RPAs may write for schedule III, IV and V controlled substances in the outpatient setting, subject to any limitations imposed by the supervising physician and/or clinic or hospital where such prescribing may occur.

- The prescription form must include:

  ► the imprinted name of the RPA;

  ► the name of the supervising physician;

  ► the practice address and telephone number;

  ► the RPA's signature followed by the designation RPA;

  ► the RPA's New York State Registration number; and

  ► the supervising physician's license number or eMedNY provider identification number (except when readily available in the pharmacy records).

- *RPAs are not authorized to issue prescriptions for Schedule II controlled substances.*

- RPAs must use their supervising physician's eMedNY provider or license number when requesting prior authorization for drugs or supplies.

➢ CNPs and midwives may write prescriptions (including Schedule II, III, IV and V controlled substances) and fiscal orders.

Such certified nurse practitioners and midwives are identified by a six-digit license number preceded by the letter "F".

- The prescription form must include:

  ► the name of the CNP or midwife;

  ► the office address and telephone number;

  ► the CNP's signature;

  ► the CNP's license number (except when readily available in the pharmacy records); and

  ► the DEA number when prescribing controlled substances.

- Certified optometrists may write prescriptions and fiscal orders limited to those agents as defined in Section 7101-A of the New York State Education Law.
  - The prescription form must include:
    - the name of the optometrist;
    - office address and telephone number;
    - the special privilege letter U, V and/or T that precedes their six-digit license number; and
    - license number (except when readily available in the pharmacy records).

Free Choice

The choice of which provider will fill the prescription or order for drugs, rests with the Medicaid beneficiary. The prescribing practitioner should give the written prescription or fiscal order to the Medicaid beneficiary in order to allow the Medicaid beneficiary to exercise his or her freedom of choice. Further information may be accessed at:

http://www.emedny.org/ProviderManuals/AllProviders/index.html.

Record-Keeping Requirements

General Requirements

In addition to the record keeping requirements in the general information section of this manual, pharmacies must keep on file the signed prescription or fiscal order for which Medicaid payment is claimed. These signed prescriptions and fiscal orders must be kept on file for six years.

Where original records are required (e.g., fiscal orders for supplies or durable medical equipment), providers may store them off-site and maintain copies (paper or electronically imaged) on-site. The original records must be accessible, made readily available upon a lawful request, and the location of the original records must be maintained in writing at the service location site (pharmacy).

Electronic imaging of prescriptions and fiscal orders must result in an exact reproduction of the original order and may be required to be authenticated.

For electronic prescriptions and fiscal orders, pharmacies are not required to generate and keep a hard copy of electronic prescriptions and fiscal orders. Original orders received in electronic format may be securely stored electronically.

Telephone Orders

Prescribers may telephone prescriptions and fiscal orders for drugs directly to a pharmacy unless otherwise prohibited by State or federal law or regulations.

The pharmacist is responsible to make a good faith effort to verify the prescriber's identity and validity of the prescription if the prescriber is unknown to the pharmacist.

- A telephone order must be reduced to writing, either through written communication or electronic record, indicating the time of the call and initials of the pharmacist.
- The format used to record the telephone order must conform to requirements of the NYS Education Law with regard to permitting substitution or dispensing as ordered.
- Prescriptions for multi-source brand drugs requiring “dispense as written” and "brand necessary" may be ordered over the telephone.
- When a pharmacy obtains a prescription over the telephone, it is the responsibility of the ordering prescriber to notate in the Medicaid beneficiary’s medical record in his/her own handwriting that the drug is “brand medically necessary”, the reason that a brand name multi-source drug is required, and the prior authorization number for the drug. See Mandatory Generic Drug Program section of this Manual.
- A follow-up hardcopy of a Non-Controlled telephone order is not required.
- A follow-up hardcopy of a Controlled telephone order is required by State and Federal law.

Faxed Orders

Prescribers may fax prescriptions and fiscal orders for drugs directly to a pharmacy unless otherwise prohibited by State or federal law or regulations.

The pharmacist is responsible to make a good faith effort to verify the validity of the prescription and the prescriber’s identify if the prescriber is unknown to the pharmacist.

- A faxed order must originate from a secure and unblocked fax number. The source fax number must be clearly visible on the fax that is received.
- A faxed order must include the physician stamp **and** signature.

- Each faxed prescription or fiscal order may include only one (1) drug. Lists of drugs are not acceptable as faxed orders. Drugs ordered from a nursing home are exempt from this requirement.

- All orders received by the pharmacy as a fax must be on the Official New York State Prescription Form.

Electronic Orders

Prescribers may electronically transmit prescriptions and fiscal orders for drugs directly to a pharmacy unless otherwise prohibited by State or federal law or regulations.

Pharmacies are not required to generate and keep a hard copy of electronic prescriptions and fiscal orders. Original orders received in electronic format may be securely stored electronically.

The pharmacist is responsible to make a good faith effort to verify the validity of the prescription and the prescriber's identify if the prescriber is unknown to the pharmacist.

- Electronic imaging of prescriptions and fiscal orders must result in an exact reproduction of the original order and may be required to be authenticated.

Section III - Scope of Pharmacy Benefits

List of Reimbursable Drugs

The List of Medicaid Reimbursable Drugs has been established by the New York State Commissioner of Health. Only those prescription and non-prescription drugs which appear on the list are reimbursable under the fee-for-service Medicaid Program. The List also contains those non-prescription therapeutic categories which the Commissioner of Health has specified as essential in meeting the medical needs of Medicaid beneficiaries.

The entire List is available electronically at:

http://www.emedny.org/info/formfile.html.

The List includes the following information:

- National Drug Code (NDC).
- Maximum Reimbursable Amount (MRA Cost).
- Cost Alternate (ALT): identifies the EAC price for those brand name multi-source drugs affected by the brand name medically necessary override provision.
- Formulary Description (drug name and strength).
- PA CD (Prior Authorization/Approval Code): Value zero (0) indicates no PA required; values (1, 2, 3, 5, 8, A or B) indicate PA is required.
- Labeler (manufacturer).

Note: Non-prescription drugs are found at the end of the list. Prescription drugs are listed alphabetically by controlled drug schedule, legend drug, non-prescription drug and supply.

Drug Coverage Limitations

Medicaid only provides reimbursement for drugs included on the New York State List of Medicaid Reimbursable Drugs (unless provided by a facility which includes the cost of drugs in their all inclusive rate). The following are examples of drugs/drug uses which are not reimbursable by Medicaid:

- Amphetamine and amphetamine-like drugs which are used for the treatment of obesity;
- Drugs whose sole clinical use is the reduction of weight;
- Any item marked “sample” or “not for sale”;
- Any contrast agents, used for radiological testing (these are included in the radiologist’s fee);
- Any drug which does not have a National Drug Code;
- Drugs packaged in unit doses for which bulk product exists.
- Any drug regularly supplied to the general public free of charge must also be provided free of charge to Medicaid beneficiaries;
- Any controlled substance stamped or preprinted on a prescription blank;

Pharmacists may wish to display in their stores a notice to Medicaid beneficiaries explaining that Medicaid does not cover all drugs. The Notice, suitable for copying and display, has been included at the end of this Manual.

Medical/Surgical Supplies

Prescribing practitioners may order medical/surgical supplies which are listed in the Pharmacy Fee Schedule. If a medical/surgical supply does not appear in the Fee Schedule, the provider may request the supply through the prior approval process.

Dispensing Limitations for Items Provided by Residential Health Care Facilities

All New York State residential health care facilities have included in their Medicaid rates prescription drugs, non-prescription drugs and medical/surgical supplies. Residential health care facilities may:

- Operate an institutional pharmacy to provide these items; or
- Contract with Medicaid enrolled community pharmacies to provide these items to Medicaid beneficiaries. The pharmacy must be reimbursed by the facility for these items.

Residential health care facilities with inclusive Medicaid rates for drugs and supplies may dispense these items to Medicaid beneficiaries regardless of the refill, quantity, and prior authorization/approval limitations described in this Manual.

Only drugs specifically "carved out" of the Medicaid all-inclusive rate may be billed directly to the Medicaid Program. Drugs "carved out" and billed directly to Medicaid are subject to refill, quantity and prior authorization/approval requirements as described in this Manual. The Medicaid Nursing Home/Child (Foster) Care Drug Carveout List may be accessed online at:

http://www.nyhealth.gov/health_care/medicaid/program/carveout.htm.

Out-of-state residential health care facilities may or may not include prescription drugs, non-prescription drugs and medical/surgical supplies in their rates. Medicaid beneficiaries with both Medicare and Medicaid (dual eligible Medicaid beneficiaries) who have met their residency requirements in a residential health care facility will receive their prescription drug coverage from their Medicare Part D Plan. Additional information regarding the Medicare Part D Prescription Drug Program and residential health care facilities may be accessed at:

http://www.health.state.ny.us/health_care/medicaid/program/update/2006/jun2006spec.htm.

Smoking Cessation Policy

- Smoking cessation therapy consists of certain prescription and non-prescription agents.
- Two courses of smoking cessation therapy per Medicaid beneficiary, per year are allowed. A course of therapy is defined as no more than a 90-day supply (an original order and up to two refills), even if less than a 30 day supply is dispensed in any fill.
- If a course of smoking cessation therapy is interrupted, it will be considered one complete course of therapy. Any subsequent prescriptions would then be considered the second course of therapy.
- Multiple smoking cessation therapies using different routes of administration are allowed (e.g. bupropion and nicotine patches may be used concomitantly if warranted).
- Duplicative use of any one agent is not allowed (i.e., same drug/same dosage form/same strength).
- For all smoking cessation products, the prescriber simply writes a prescription or fiscal order and gives it to the patient to present to the pharmacy.

Emergency Contraception Drug (Plan B) Policy

In August 2006, the U.S. Food and Drug Administration approved Plan B, an emergency contraception drug, as an over-the-counter drug (OTC) for women 18 years of age and older. For Medicaid payment, OTC drug products require a fiscal order; however, to ensure that there is no delay in treatment, a fiscal order will not be required to support payment for Plan B when provided to women 18 years of age and older. For women under the age of 18, a prescription will still be required.

For women of all ages, Plan B is limited to 6 courses of therapy in any 12 month period for any prescription and non-prescription combination.

For more information, please go to:

http://www.health.state.ny.us/health_care/medicaid/program/update/2007/2007-03.htm#eli.

Section IV - Basis of Payment

Prescription Drugs

Pharmacy reimbursement for prescription drugs under the New York State Medicaid Program is established in law. Current information regarding pharmacy reimbursement, including the Federal Upper Limit (FUL), Sole or Multi-Source drugs, Multi-Source generic drugs, Specialized HIV Pharmacies and State Maximum Acquisition Cost (SMAC) can be accessed at the Department of Health Website:

http://www.nyhealth.gov/health_care/medicaid/program/docs/pharmacy_reimbursement.pdf.

State Maximum Acquisition Cost (SMAC)

A SMAC will be applied when determining the Estimated Acquisition Cost (EAC) of multi-source generic drugs unless a FUL price is available.

The Bureau of Pharmacy Policy and Operations will receive all requests from providers concerning the validity of a SMAC price. The SMAC Research Request Form is posted on the eMedNY web site at:

http://www.emedny.org/ProviderManuals/Pharmacy/PDFS/SMAC_Research_Request_Form.pdf.

Questions from providers concerning the validity of a SMAC price can be referred to the Bureau of Pharmacy Policy and Operations at (518) 486-3209 or by e-mail at:

PPNO@health.state.ny.us.

Non-Prescription Drugs

Reimbursement for each covered **non-prescription drug** is restricted to the **lower** of:

- The usual and customary price charged to the general public on the date of provision of service, not to exceed the lower sale price, if any, in effect on that date; or
- The price established by the Commissioner of Health as shown on the New York State List of Medicaid Reimbursable Drugs for that generic category and strength in the package size nearest to that ordered.

Multiple Source Drugs

Reimbursement is only available for those multiple source drugs contained on the List of Medicaid Reimbursable Drugs.

For certain brand name prescriptions to be eligible for reimbursement at the EAC price, prescribers must certify that the brand name drug is required by writing directly on the face of the prescription "Brand Necessary" or "Brand Medically Necessary" in their own handwriting in addition to the "DAW".

A rubber stamp or other mechanical signature device may not be used.

Prior authorization must also be obtained for certain brand name drugs.

In order to dispense a brand name drug when the prescriber indicates "DAW" and "Brand Necessary" or "Brand Medically Necessary" on the face of the prescription, the pharmacist may indicate a "yes" in the brand necessary field of the paper claim form or a "1" when billing electronically.

For more information, refer to:

http://www.emedny.org/ProviderManuals/Pharmacy/ProDUR-ECCA_Provider_Manual/1_20/ProDUR-ECCA%20Provider%20Manual.htm#_Toc49591638.

Compounded Prescriptions

A Compounded Prescription is one in which two or more ingredients are mixed by the dispensing pharmacist.

In order to qualify for Medicaid payment a compounded prescription must include:

- A combination of any two (2) or more legend drugs found on the list of Medicaid Reimbursable Prescription Drugs,
- A combination of any legend drug(s) included on the list of Medicaid Reimbursable Prescription Drugs and any other item(s) not commercially available as an ethical or proprietary product(s), or
- A combination of two (2) or more products which are labeled "*Caution: For Manufacturing Purposes Only*."

The reconstitution of a commercially available drug is NOT regarded as a compounding procedure. For example, intravenous prescription products that require reconstitution,

further measurement, dilution and/or instillation into a suitable device (i.e. minibag, IV reservoir or syringe) for administration are not considered to have been compounded.

Billing for Individual Components by NDC Number (Option 1)

- Each ingredient must have a unique prescription number.
- Each drug ingredient payable by New York State Medicaid will be reimbursed as described in Basis of Payment.
- Payment will only be made for National Drug Codes (NDCs) covered on the List of Medicaid Reimbursable Drugs.

Billing for a Compound as a Single Entity (Option 2)

- The entire prescription must have one unique prescription number.
- Enter NDC Code using all “9’s” (99999-9999-99).
- A value of “1” must be entered in the Quantity Field.
- Reimbursement for each compound prescription is restricted to the usual and customary price charged to the general public for the total sum of the ingredients, up to the maximum reimbursable amount ($50.00), plus a dispensing fee ($3.50) and a compounding fee ($0.75).
- There is no co-payment assessed using this option.
- The pharmacy must retain the prescription and documentation of ingredients, amounts and costs.

For billing see the Procedure Code and Fee Schedule section at:

http://www.emedny.org/ProviderManuals/Pharmacy/index.html.

Medical and Surgical Supplies

Reimbursement for each covered medical/surgical supply will be the lower of:

- The price as indicated on the New York State List of Medical/Surgical Supplies; or
- The usual and customary price charged to the general public.

"Covered Supplies" are those on the list of Allowable Medical and Surgical Supplies found in the Procedure Codes and Fee Schedule section of the DME manual, located at:

http://www.emedny.org/ProviderManuals/DME/index.html.

For supplies not on that list, only those supplies for which the pharmacist has obtained prior approval are covered.

Co-payments for Drugs and Medical Supplies for Medicaid and Family Health Plus

The New York State Medicaid and Family Health Plus Program charges co-payments for many drug and medical supply items.

Health care providers have an obligation to provide services and goods regardless of a Medicaid and Family Health Plus enrollee's ability to pay co-payments. A provider may not deny services to an eligible Medicaid and Family Health Plus enrollee based on a Medicaid and Family Health Plus enrollee's (or his/her agent's) statement that he/she cannot afford the co-payment.

- Providers may not refuse services to otherwise eligible Medicaid and Family Health Plus enrollees who cannot afford to pay the co-payment. ***To refuse to provide services is an unacceptable practice.***

- Providers may:

  - request the co-payment each time a Medicaid and Family Health Plus enrollee is provided services or goods;

  - ask a Medicaid and Family Health Plus enrollee for outstanding co-payments the next time he/she comes in;

  - send the Medicaid and Family Health Plus enrollee bills; or

  - use other legal means to collect the co-pay due.

- Providers must not reduce the amount charged on a Medicaid and Family Health Plus claim by the co-payment that is collected from a Medicaid and Family Health Plus enrollee. Each claim that requires a co-payment will have the co-payment ***automatically deducted*** from the final payment when the claim is approved for payment.

Medicaid Co-payments:

- Some Medicaid enrollees become eligible for Medicaid by spending part of their monthly income on medical care. Since co-payments paid or incurred can be used toward satisfying the spend-down (overage) in the following month,

itemized bills or receipts for co-payments should be provided to Medicaid enrollees when requested.

- There is a maximum amount per Medicaid enrollee for all co-payments incurred per year. The co-payment year starts April 1 and ends March 31.
  When a Medicaid enrollee reaches the annual co-pay maximum, they will receive a letter confirming the date on which the co-pay maximum was met and exempting the Medicaid enrollee from a co-payment until the end of the current co-payment year.

- Co-payment amounts are as follows:

  - $3.00 for non-preferred Brand Name Drugs;
  - $1.00 for Generic Drugs; or preferred Brand Name Drugs
  - $0.50 for Non Prescription (over the counter) Drugs;
  - $1.00 for Medical/Sickroom Supplies.

- Co-payment is not required for certain Medicaid enrollees and service categories which include:

  - Family planning (birth control) services including birth control pills, Plan B, and condoms
  - FDA approved drugs to treat tuberculosis
  - FDA approved drugs to treat mental illness (psychotropic drugs)
  - Medicaid enrollees younger than 21 years old
  - Medicaid enrollees during pregnancy and for the two months after the month in which the pregnancy ends
  - Residents of Adult Care Facilities licensed by the New York State Department of Health (DOH)
  - Residents of nursing homes
  - Residents of Intermediate Care Facilities for the Developmentally Disabled (ICF/DD)
  - Residents of Office of Mental Health (OMH) or Office of Mental Retardation and Developmental Disabilities (OMRDD) certified residences
  - Enrollees in Comprehensive Medicaid Case Management (CMCM) or Service Coordination Programs

- Enrollees in OMH or OMRDD Home and Community Based Services (HCBS) Waiver Programs and

- Enrollees in a DOH HCBS Waiver Program for Persons with Traumatic Brain Injury (TBI).

Family Health Plus Co-payments for Drugs and Medical Supplies:

Family Health Plus enrollees access their pharmacy benefit through the Medicaid Program using a Common Benefit Identification Card (CBIC) effective October 1, 2008. Prescriptions for Family Health Plus enrollees will be subject to all Medicaid program requirements. Providers may need to obtain prior authorization from Medicaid for certain prescription drugs.

- There is no maximum amount per Family Health Plus enrollee for all co-payments incurred per year.

- Family Health Plus co-payment amounts are as follows:

  - $6.00 for Brand Name Drugs;
  - $3.00 for Generic Drugs;
  - $1.00 for Diabetic Supplies, Hearing Aid Batteries and Enteral Formulae,
  - $0.50 for Non Prescription (over the counter) Drugs.

- The following Family Health Plus enrollees are exempt from making co-payments:

  - Family Health Plus enrollees obtaining prescription birth control, and Plan B.

  - Family Health Plus enrollees under 21 years if age

  - Family Health Plus enrollees during pregnancy and for the two months after the month in which the pregnancy ends

  - Family Health Plus enrollees who are permanent residents of a Nursing Home or community based residential facility

  - Family Health Plus enrollees who are residents of Adult Care facilities licensed by the New York State Department of Health (DOH) are not required to make pharmacy co-payments.

  - Family Health Plus enrollees who are residents of an Intermediate Care Facility for the Developmentally Disabled (ICF/DD), also residents of an Office of Mental Health (OMH) or Office of Mental Retardation and Developmental Disabilities (OMRDD) certified residence.

Section V - Utilization Management Programs

Eligibility

Providers of Medicaid services are required to verify the eligibility of the Medicaid beneficiary. There are three methods available for utilization:

1) The Automated Response Unit (ARU or telephone);

2) The Veri-Fone POS terminal; and

3) The ePACES web-based application.

These systems enable providers to quickly verify eligibility and facilitate electronic submission of claims.

Card Swipe

The Department may designate providers, based on various criteria, to become a mandatory "swiper". Providers designated as such are required to swipe the Medicaid beneficiary's Medicaid card in a substantial number of instances. This can only be accomplished by using the Veri-Fone POS terminal. If a provider is designated as a mandatory swiper, the terminal will be supplied to the provider at no cost.

Information about the Veri-Fone terminals is available online at:

http://www.emedny.org/HIPAA/SupportDocs/Omni.html.

DOH staff monitors the level of transactions that are swiped. Should the percentage of swipes fall below expectation, the provider will be contacted in an attempt to identify the reason for the diminished percentage. If the Department determines that no valid reason exists for the low percentage of card-swipe transactions, the Department may withhold payment of claims equivalent in dollar value to the percentage of non-swiped claims, pending an audit or review of the claims submitted and the provider's service and claiming practices.

The Department may treat unjustified provider failure to swipe as an unacceptable practice under 18 NYCRR Part 515.

Recipient Restriction Program (RRP)

Medicaid beneficiaries who have been assigned to a designated pharmacy are required to receive all pharmacy services from the selected provider. All claims from other pharmacies will be denied.

Medicaid beneficiaries who are restricted to a primary Durable Medical Equipment (DME) dealer must receive all DME and prosthetic and orthotic appliances from the provider.

All primary pharmacy providers must maintain a patient profile for each restricted Medicaid beneficiary. The profile must contain, at a minimum, the name, and the date the drugs or supplies were dispensed. These profiles must be made readily available to the New York State Department of Health or its agents, upon request.

When a Medicaid beneficiary is restricted to an ordering provider (physician, clinic, inpatient hospital and/ or dentist), all pharmacy services must be ordered by the primary medical provider (clinic or MD) with the Medicaid beneficiary's restriction type.

The primary provider may refer the restricted Medicaid beneficiary to another provider with that category of service and that servicing provider may also order services. In either case, the primary provider's Medicaid identification number must be written on the order/prescription form or must be readily available in the pharmacy's record and should be used by the dispensing pharmacy when accessing the Medicaid Eligibility Verification System (MEVS) as well as when submitting claims.

Medicaid beneficiaries may have durable medical equipment restrictions separate from pharmacy restrictions.

Utilization Threshold

The Utilization Threshold (UT) Program requires providers to obtain an authorization from MEVS to render services for physician, clinic, laboratory, pharmacy and dental care. This authorization to render services will be given unless a Medicaid beneficiary has reached his/her utilization threshold limits.

It is necessary for an ordering provider to submit a Threshold Override Application form in order to obtain additional services. In certain special circumstances, such as emergencies, providers do not have to receive authorization from MEVS.

Arrangements have also been made to permit a provider to request a service authorization on a retroactive basis.

In requesting a retroactive service authorization there is a risk that a request may be denied if the Medicaid beneficiary has reached his/her limit in the interim. After receiving an authorization the claim may be submitted for processing. The regulation requiring claims to be submitted within 90 days of the date of service still applies.

Pharmacy providers may not submit a request for an increase in or pharmacy services. Such requests are to be submitted by the ordering provider only.

- Pharmacies encountering urgent or emergency situations should see the override instructions in the Provider Manual located at:

http://www.emedny.org/ ProviderManuals/Pharmacy/ProDUR-ECCA_Provider_ Manual/index.html.

Those limited laboratory services which can be rendered by a physician or podiatrist in private practice to his/her own patients do not count toward the laboratory utilization threshold.

Utilization Thresholds will not apply to services otherwise subject to thresholds when provided as follows:

- "Managed care services" furnished by or through a managed care program, such as a health maintenance organization, preferred provider plan, physician case management program or other managed medical care, services and supplies program recognized by the Department to persons enrolled in and receiving medical care from such program;

- Certain services otherwise subject to prior approval or prior authorization;

- Family planning services including: diagnosis, treatment, drugs, supplies and related counseling furnished or prescribed by or under the supervision of a physician. They also include medically necessary induced abortions, screening for anemia, cervical cancer, glycosuria, proteinuria, sexually transmissible diseases, hypertension, breast disease and pregnancy and pelvic abnormalities;

- Child/Teen Health Plan services;

- Services provided by or under the direction of a primary provider under the Medicaid beneficiary Restriction Program;

- Methadone maintenance treatment services;

- Services provided by private practitioners, with the exception of podiatrists, on a fee-for-service basis to inpatients in general hospitals and residential health care facilities;

- Hemodialysis services;
- School health project services; and
- Obstetrical services provided by a physician, hospital outpatient department, or free-standing diagnostic and treatment center.

The numbers of visits, lab procedures, medical supplies, drugs, and other items for each provider type are found in the General Policy Section of the Provider Manual at:

http://www.emedny.org/ProviderManuals/AllProviders/index.html.

Post and Clear

Certain providers who are able to order medical care, services or supplies, may be designated by the Department to enter, via one of the three methods listed above, the number of pharmacy prescriptions and laboratory tests ordered ("posting").

Posting of the order establishes a record that the care, services or supplies have been ordered by a qualified provider. It also enables the Department to verify that the order has been legitimately requested prior to paying a provider who submits a claim for furnishing the service.

Orders entered by a designated provider must be "cleared" off the MEVS system by the laboratory or pharmacy rendering the service.

Utilizing the post and clear system helps to ensure that only the services and supplies requested by the posting provider are furnished. It aids in the elimination of fraudulent practices such as forged prescriptions, duplication of services and serves as an additional means of control to assure the validity of prescriptions or fiscal orders.

Pharmaceutical Management Programs

Overview

Drug Utilization Review (DUR) programs are intended to assure that prescriptions for outpatient drugs are appropriate, medically necessary and not likely to result in adverse medical consequences. DUR programs help to ensure that the patient receives the proper medicine at the right time in the correct dose and dosage form.

The benefits of DUR programs are reduced Medicaid costs, reduced hospital admissions, improved health for Medicaid beneficiaries, increased coordination of health care services, and reduced drug diversion. Information supplied to Medicaid

providers through the DUR programs enhances their ability to prescribe and dispense medication more appropriately.

The federal legislation requiring states to implement DUR programs also requires states to establish DUR Boards whose function is to play a major role in each state's DUR program. The Department of Health contains a DUR Board comprised of health care professionals with recognized knowledge and expertise. The Board consists of five physicians, five pharmacists, two persons with expertise in drug utilization review and one designee of the Commissioner of Health.

The two components of New York State's DUR program are Retrospective DUR (RetroDUR) and Prospective DUR (ProDUR). While the two programs work cooperatively, each seeks to achieve better patient care through different mechanisms.

Each of these programs is described in detail below.

RetroDUR

The Department of Health manages a RetroDUR program for Medicaid benficiarys. The RetroDUR program is designed to educate physicians by targeting prescribing patterns which need to be improved. Under RetroDUR, a review is performed subsequent to the dispensing of the medication.

The primary goal of RetroDUR is to educate prescribers and pharmacists through alert letters which are sent to providers detailing potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions and clinical abuse/misuse.

> It is expected that providers who receive alert letters identifying a potential problem relating to prescription drugs will take the appropriate corrective action to resolve the problem.

ProDUR

Medicaid enrolled pharmacies are required to perform in-house prospective drug utilization review. The Department of Health oversees a ProDUR program through the Medicaid Eligibility Verification System (MEVS).

The point-of-sale system allows pharmacists to perform on-line, real-time eligibility verifications, Electronic Claims Capture and Adjudication (ECCA) and offers protection to Medicaid beneficiaries in the form of point-of-sale prevention against drug-induced illnesses.

The ProDUR/ECCA system maintains an on-line record of every Medicaid beneficiary's drug history for at least a 90 day period. The pharmacist enters information regarding

each prescription and that information is automatically compared against previously dispensed drugs, checking for any duplicate prescriptions, drug to drug contraindications, over and under dosage and drug to disease alerts, among other checks.

In the event that this verification process detects a potential problem, the pharmacist will receive an on-line warning or rejection message. The pharmacist can then take the appropriate action; for example, contacting the prescribing physician to discuss the matter. The outcome might be not dispensing the drug, reducing the dosage, or changing to a different medication.

The ProDUR Program is administered by the Department's fiscal intermediary or its subcontractor. Use of the online DUR functions via MEVS by pharmacy providers, including those providers that are rate-based, is mandatory. Pharmacy providers are required to use personal computers or central processing units to access the online system either independently or through a switch company. Any data entered by the pharmacy provider is processed, including checking eligibility, third party coverage, Utilization Threshold, Post and Clear and Medicaid Recipient Restriction Program status before being passed to the DUR system.

The DUR system utilizes National Council on Prescription Drug Program (NCPDP) format version 5.1. NCPDP responses alert providers to the type of drug interaction, drug-disease conflict, therapeutic duplication or over-utilization problems, and the most recent fill dates for the potentially hazardous drug.

A maximum of three different codes/drug interactions per prescription per entry may be sequentially displayed for up to four prescriptions per entry.

All of the DUR messages are specified by the State DUR Board which is composed of doctors, pharmacists, and DUR experts in concert with the drug information contractors.

ProDUR Claims Submission

Pharmacy providers can submit most claims directly via the electronic claims adjudication system that was developed for the ProDUR system. If claim capture and adjudication is selected, the claim will be processed for eligibility verification, ProDUR, Utilization Threshold/Post & Clear and, if requested, Dispensing Validation System (DVS). If approved, the claim will be fully adjudicated and paid.

For claims over 90 days from the date of service, a "non-captured" transaction may be submitted for eligibility verification but the claim must be submitted on a paper claim form or via electronic batch.

Certification for ProDUR/ECCA

All Medicaid pharmacy providers are required to perform on-line prospective drug utilization review. Submitting claims via ECCA is optional. Under ProDUR, all pharmacies

must enter their transaction using the NCPDP formats via one of the MEVS access methods. NCPDP format specifications can be found at:

http://www.emedny.org/ProviderManuals/Pharmacy/ProDUR-ECCA_Provider_Manual/1_0/produr_manual.html.

PLEASE CONSULT THE MEVS DUR USER MANUAL FOR SPECIFIC INFORMATION RELATING TO PRODUR, ELECTRONIC CLAIMS CAPTURE AND ADJUDICATION SUBMISSION, AND MEVS ACCESS METHODS.

Section VI - Definitions

The following terms are defined for the purposes of Medicaid and are included to help clarify policies as provided in this Manual:

Bioavailability

The rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action.

For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

Bioequivalence

Bioequivalence is the pharmaceutical equivalent or pharmaceutical alternative products that display comparable bioavailability when studied under similar experimental conditions.

Dose

The exact amount of medication to be taken at one time or at stated intervals according to the prescriber's directions.

Estimated Acquisition Cost

The estimated acquisition cost is the average wholesale price of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the Department, less a certain percentage.

Federal Upper Limit

Federal upper limit is the maximum reimbursement amount for certain multi-source drugs that are provided by at least three suppliers as a result of federal regulations at 42 CFR §447.332 [2004].

Payments for these drugs must not exceed, in the aggregate, a reasonable dispensing fee plus and amount that equals 150 percent of the lowest published price of the drug listed in national pricing compendia.

Fiscal Order

A fiscal order is a request written by one of the following to provide non-prescription drugs or medical/surgical supplies:

- Physician,
- Certified Nurse Practitioner,
- Midwife,
- Dentist,
- Podiatrist,
- Registered Physician's Assistant (RPA), or
- New York State Education Department-Certified Optometrist.

General Public

The general public is defined as the group accounting for the largest number of non-Medicaid transactions from the individual pharmacy and does not include other third party payers.

Generic Equivalent

A generic equivalent drug product is one which:

- Has been certified or approved by the FDA as being safe and effective for its labeled indications for use, and a new-drug application or an abbreviated new-drug application is held; and
- The FDA has evaluated such drug product as pharmaceutically and therapeutically equivalent and has listed such drug product on the list of approved drug products with the therapeutic equivalence evaluations.

Labeler

Any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, labeling, re-labeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

Labeler is the entity holding legal title to or possession of the NDC number for the covered outpatient drug.

Medical and Surgical Supplies

Medical and surgical supplies include items for medical use other than drugs including prosthetic/orthotic appliances, durable medical equipment and orthopedic footwear.

These items are used to treat a specific medical condition and are usually consumable, non-reusable, disposable, for a specific purpose rather than incidental and generally have no salvageable value.

Medical and surgical supplies must be dispensed by a provider who is licensed/registered by the appropriate authority, if existing, in the state in which the provider is located.

Examples of medical or surgical supplies include:

- bandages,
- gauze pads,
- colostomy bags,
- family planning devices,
- catheters, and
- irrigating kits.

Medical/surgical supplies do not include items and supplies that are useful to persons in the absence of an illness or injury or that are primarily used to service needs other than health needs.

Examples of consumable and non-reusable supplies that are not included under the Medicaid benefit are:

- items of personal hygiene (soap, shampoo, baby wipes, disposable washcloths, skin moisturizers, etc.),
- feminine hygiene items (sanitary belts, sprays, etc.) and
- dental hygiene items (toothbrush, dentifrice, mouthwash, etc.).

Multiple Source Drug

A multiple source drug is a drug product marketed or sold by two or more labelers or sold by the same labeler under two or more different brand names.

> Multiple source drugs are pharmaceutically equivalent and shown to meet an appropriate standard of bioequivalence.

New York State List of Medicaid Reimbursable Drugs

A list consisting of the prescription and non-prescription drugs for which Medicaid will reimburse the enrolled provider. This is available online at:

http://www.emedny.org/info/formfile.html.

Non-Prescription Drug

A non-prescription drug, also known as an over-the-counter drug, is that for which no prescription is required by law or regulation.

Non-prescription drugs may be obtained in the Medicaid Program only upon a fiscal order from a prescriber.

Pharmaceutical Equivalent

The pharmaceutical equivalent is a drug product which contains the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or dosage form, or concentration.

Pharmaceutically equivalent drug products are formulated to contain the same amount of active ingredient in the same dosage form and to meet the same or compendial or other applicable standards (i.e. strength, quality, purity, and identity), but they may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration time and within certain limits, labeling.

Prescribing Practitioner

A prescribing practitioner includes:

- Physicians,
- Certified Nurse Practitioners,
- Midwives,
- Dentists,
- Podiatrists,
- Registered Physician's Assistants, or
- New York State Education Department-certified optometrists licensed by law and currently registered to prescribe prescription drugs.

Interns and residents may prescribe drugs (under the supervision of a licensed physician or dentist) as part of their official duties as members of a hospital staff.

Prescription Drug

A prescription drug includes any drug for which a prescription from a qualified licensed practitioner is required under Section 6810 of the New York State Education Law.

Prescription drugs are subject to the requirements of the Federal Food, Drug and Cosmetic Act and those stipulated by the State Commissioner of Health.

All controlled substances are prescription drugs.

Single Source Drug

A single source drug is a drug which is produced or distributed under an original new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

This product is not generic, nor is it available as a generic.

State Maximum Acquisition Cost

This is a reimbursement amount established for any drug for which two or more A-rated therapeutically equivalent, multi-source, non-innovator drugs with a significant cost difference exist.

The State Maximum Acquisition Cost (SMAC) will be determined taking into account drug price status, marketplace status, equivalency rating, and relative comparable pricing.

Therapeutic Equivalent

A drug product which is expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

Usual and Customary Charge

This is the price which a pharmacy charges to the general public.

NOTICE TO MEDICAID BENEFICIARIES CONCERNING DRUG COVERAGE

Medicaid is a federal and State-funded health insurance program that helps many people, who can't afford medical care, pay for some or all of their medical bills.

Medicaid Does Not Cover All Drugs

Items which may be excluded from coverage:

- **Agents used for Weight loss or weight gain**
- **Agents used to promote fertility**
- **Agents used for cosmetic purposes or hair growth.**

Medicaid covers an extensive number of medically necessary drugs. However, not all drugs are covered. Check with your pharmacist if you are not sure if a drug you were prescribed is covered by Medicaid.