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BACKGROUND

West Virginia Medicaid offers a comprehensive scope of Pharmacy services to Medicaid members as an optional program, subject to medical necessity, appropriateness criteria, and prior authorization requirements. All covered drugs, whether legend or over the counter, must be prescribed by a practitioner qualified under state law within the scope of their license and in accordance with all state and Federal requirements.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) mandated major changes in coverage and reimbursement for Medicaid-covered outpatient drugs. West Virginia Medicaid reimbursement is limited to drugs whose manufacturers have entered into and have in effect a rebate agreement with the Secretary, US Department of Health and Human Services.

POLICY

518.1 COVERED SERVICES

Except for certain limitations and exclusions, West Virginia Medicaid will reimburse for the following:

- Outpatient legend drugs;
- Specific over-the-counter drugs;
- Compounded prescriptions;
- Drugs that require prior authorization, when approved by the Bureau for Medical Services (BMS);
- Family planning supplies, including certain over-the-counter supplies;
- Certain diabetic supplies;
- Influenza, pneumonia, Hepatitis A, Hepatitis B, human papilloma virus (HPV), tetanus, tetanusdiphtheria (Td), and tetanus- diphtheria-and-pertussis (Tdap) vaccines for adults 19 years of age and older administered by a pharmacist. Members up to 19 years of age have access to vaccines via the Vaccines for Children Program; and
- Herpes zoster vaccine for adults 50 years of age and older administered by a pharmacist.

Drugs covered under the Medicaid outpatient pharmacy program are those that have been approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act, when used for medically accepted indications.

Medically accepted indication means any use that is supported by one or more of the following official compendia:

- 1. The American Hospital Formulary Service Drug Information
- 2. The United States Pharmacopoeia Drug Information or its approved replacement
- 3. The DrugDex Information System

All covered drugs, whether legend or over the counter, must be prescribed by a practitioner qualified under state law within the scope of license and in accordance with all state and federal requirements.

The West Virginia Medicaid program follows the US Office of Inspector General's (OIG) guidelines in excluding prescribers from participating with West Virginia Medicaid who are barred from participating in federal health programs. Reimbursement of prescriptions issued by these excluded prescribers are denied.

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West Virginia Medicaid also excludes from reimbursement any prescription ordered by a prescriber who is not enrolled with West Virginia Medicaid.

518.1.1 Preferred Drug List (PDL)

The West Virginia Preferred Drug List (PDL) is a list of medications recommended to the BMS by the West Virginia Medicaid Pharmaceutical and Therapeutics (P&T) Committee and approved by the U.S. Secretary of the Department of Health and Human Resources. The P&T Committee is composed of actively practicing physicians, pharmacists, a nurse practitioner, and a physician's assistant. The P&T Committee meetings are held a minimum of three times per year and are open to the public.

The drugs that are designated as "preferred" have been selected for their clinical significance and overall cost efficiencies. All Medicaid-covered drugs noted as "non-preferred" continue to be available through the prior authorization process.

The PDL only contains drugs from certain drug classes. Some classes of drugs will not be reviewed for preferential agents because there are no, or limited cost savings associated with these classes. Drugs that meet the criteria for coverage and have no preferred status are considered covered drugs.

The PDL is updated at minimum annually and as needed. Newly released drugs in classes that are included in the PDL will be considered non-preferred until the new drug has been reviewed.

The complete PDL, criteria for coverage of non-preferred drugs, minutes of P&T Committee meetings, and other pertinent information are available on the <u>BMS website</u>.

518.1.2 Over-the-Counter Drugs

Certain over-the-counter (OTC) drugs are reimbursed for eligible Medicaid members when prescribed by a qualified practitioner. The OTC drugs must be manufactured by companies participating in the Federal drug rebate program and are limited to generic products when available. Any OTC drug available in packaging designed for OTC sale to the public must be dispensed in the original packaging. These products must be billed at the shelf price of the pharmacy. If a pharmacy is not accessible to, or frequented by the general public, or if the OTC drug is not on display for sale to the general public, then the product will be reimbursed at the same rate as legend drugs.

Nonprescription (over the counter or "OTC") drug coverage is limited to: Analgesics/antipyretics, antidiarrheals, antitussives, laxatives, hemorrhoidal preparations, topical antibacterial agents, topical and intravaginal antifungal agents, cough and cold preparations, contraceptives, topical acne agents, topical analgesics, antihistamines, topical antiviral agents, topical glucocorticoids, insulin, ophthalmic agents for allergic conjunctivitis, and pediculicides/scabicides.

The OTC drugs are not covered for residents of skilled nursing home facilities or intermediate care facilities for individuals with intellectual disabilities (ICF/IID) except for insulin. These drugs are included in the rates paid to these facilities.

A current list of covered OTC drugs is available on the BMS website.

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518.1.3 Diabetic Testing Supplies and Syringes/Needles

Certain supplies used by eligible diabetic Medicaid members are covered through the Outpatient Pharmacy program. A prescription issued by a licensed prescriber within the scope of their practice is required for coverage of these items. Verbal prescriptions that meet Federal and state regulations are permitted. Prescriptions must state the number of tests to be performed per day. Co-payments are not required on prescriptions for these items. Covered supplies include:

- Blood glucose testing strips;
- Urine testing tablets and strips;
- Lancets;
- Insulin syringe and needle combinations for the administration of insulin; and
- Needles for insulin pen systems

Needle and syringe combinations and disposable pen needles for insulin pens are reimbursed through the Pharmacy Point-Of-Sale (POS) program only for the administration of insulin.

Diabetic testing supplies and syringes/needles are not covered pharmacy services for members residing in skilled nursing or ICF/IID facilities.

The following limits apply for those members who have insulin dependent diabetes:

Urine and blood glucose testing tablets and strips	150 per 30 days
Lancets	200 per 30 days
Insulin syringe and needle combinations	100 per 30 days
Pen needles	100 per 30 days

The following limits apply for those members who have non-insulin dependent diabetes:

Urine and blood glucose testing tablets and strips	100 per 30 days
Lancets	100 per 30 days

Prescriptions for quantities greater than the above referenced amounts require prior authorization through the pharmacy prior authorization vendor.

Additionally, West Virginia Medicaid maintains a <u>Preferred Diabetic Supply List</u> for reference to currently preferred test strips and sensors.

Dual eligible members have coverage of diabetic supplies through Medicare. Medicaid will not cover these supplies for dual eligible individuals, except for amounts that may be reimbursed on Medicare Part B crossover.

518.1.4 Home Infusion Therapy Pharmacy Services

Drugs used for home infusion therapy services are covered under the West Virginia Medicaid Pharmacy program. These drugs require prior authorization and must be justified by the ordering practitioner, including why oral therapy is unsuitable for the patient. Dual eligible members have coverage of home infusion pharmacy services through their Medicare Part D plans.

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Total Parenteral Nutrition (TPN) supplies are considered Durable Medical Equipment (DME) and supplies and are not pharmacy POS covered services.

518.1.5 In-Home Parenteral Therapy (IHPT)

In-Home Parenteral Therapy (IHPT) is a Medicaid-covered service. Medicaid coverage for this service will include drugs and services that are:

- Medically necessary;
- Prescribed by a licensed physician;
- Administered through central line, peripheral line, infusion port, epidural, intrathecal or subcutaneous site;
- Provided by a licensed pharmacy enrolled with West Virginia Medicaid;
- Billed through electronic transmission according to standard guidelines or on the approved pharmacy paper claim form; and
- Prior authorized as directed by the BMS.

MEMBER REQUIREMENTS

Members receiving IHPT must meet the following requirements:

- The member must reside in either a private home or domiciliary care facility, such as an adult care residence. Members who are residents or patients of hospitals, nursing homes (including ICF/IID group homes), rehabilitation centers, and other institutional settings are not eligible for this service;
- The member must be under the care of a physician who prescribes the in-home infusion therapy and monitors the progress of the therapy;
- The member must have sites available for intravenous catheters or needle placement or have central venous access; and
- The member must be capable of self-administering or have a nurse or a caregiver who can be adequately trained, and is capable and willing to administer/monitor home infusion therapy safely and efficiently following appropriate teaching and adequate monitoring.

PRIOR AUTHORIZATION

All IHPT services require prior authorization. Requests must be made through the pharmacy prior authorization vendor. The approved <u>prior authorization forms</u> are available on the BMS website.

- Pre-Mixed Solutions or Products Requiring No Compounding: Pre-mixed solutions or products include those injectable items that do not require compounding by the pharmacist because a) the items are marketed as pre-mixed, thus requiring no dilution and/or compounding, or b) compounding is performed by the patient, the nurse or the caregiver. Commercially prepared products are mandated to be dispensed if available. Compounded products and related professional services shall not be reimbursed when the commercially prepared product is available.
- **Products Requiring Compounding:** Certain injectable products require compounding in order to meet the needs of the member and are not available commercially.

The request for prior authorization must include the diagnosis, duration of therapy, prescribing physician information, and appropriate documentation. The prior approval will be effective from the date of the physician's original order and continue for the specified length of therapy unless there is a change in

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prescription or level of care. Changes in therapy require new prior authorizations. Written requests for prior authorization must be submitted via fax or mail to the pharmacy prior authorization vendor on form IV-1. Signed physicians' orders for compounded IHPT medications must be provided to the pharmacy prior authorization vendor if reimbursement for compounding activities is requested.

Please refer to <u>Chapter 600 Reimbursement Methodologies</u> for further information on IHPT billing and reimbursement by POS.

518.1.6 Tobacco Cessation Program

West Virginia Medicaid, in partnership with the Bureau for Public Health (BPH), offers a tobacco cessation program, known as the <u>West Virginia Tobacco Quitline</u>, to assist members to discontinue use of tobacco products.

See <u>Chapter 519.18, Tobacco Cessation Services</u> for more information on the Quitline, covered cessation agents, and limitations.

Dual eligible members have coverage of legend drugs through their Medicare Part D plans, and coverage of over-the-counter drugs and tobacco cessation counseling services through Medicaid.

518.1.7 Buprenorphine-Naloxone/ Buprenorphine Coverage

Buprenorphine-naloxone and buprenorphine are covered through the Pharmacy program when written by any enrolled prescriber with a valid DEA on record. Other limitations may apply. <u>General coverage policy</u> is available on the BMS website and additional criteria for these agents, if applicable, may be found on the current <u>Medicaid Preferred Drug List</u> by searching for the desired product.

518.1.8 Bulk Chemicals

Per <u>CMS Medicaid Drug Rebate Program Release No. 155</u>, bulk chemicals are substances which when used in the manufacturing of a drug become the active ingredient of the drug product. As such they do not meet the definition of covered outpatient drugs as defined in section <u>1927(k)(2)</u> of the Social Security Act. However, bulk chemicals may be considered covered in rare circumstances if prescribed for a Food and Drug Administration (FDA) approved indication and/or medically accepted indication supported in official compendia. Prior authorization is required. All rules, regulations, limitations, and exclusions set forth in the Pharmacy Services manual apply also to bulk chemicals. A list of <u>covered bulk chemicals and criteria for coverage</u> is available on the BMS website.

518.1.9 Brand Name versus Generic Drugs

Brand name multi-source legend drugs that have therapeutic equivalents available will be denied for payment. Generic drugs must be substituted, if available. In certain instances, pharmacies may indicate brand name drug usage on submitted electronic and paper pharmacy claims by using Dispensed as Written (DAW) codes. The DAW codes that are recognized by West Virginia Medicaid and can be used by providers to explain the dispensing of a brand name product instead of a generic one are as follows:

DAW 1: Prescriber states that the brand name drug is "medically necessary". This information
must be supplied in writing by the prescriber via written prescriptions in his or her own handwriting,

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and must write on the prescription "Brand Medically Necessary". A checkbox or other methods to indicate that the brand should be dispensed shall not be accepted. Approval from the pharmacy prior authorization vendor help desk is required for the use of DAW 1 and appropriate justification must be provided.

- **DAW 4:** A generic equivalent is not available or not stocked at the time of dispensing. This code shall only be used when a generic drug is sold out or a generic drug is unavailable on a wide-spread basis. It shall not be used routinely to circumvent the mandatory generic program for other reasons. A call to the pharmacy prior authorization vendor help desk is required for the use of DAW 4 and appropriate justification must be provided. The brand name rate will be reimbursed when approved.
- **DAW 5:** Pharmacy uses this brand as a generic and realizes it will be paid at the generic rate.
- **DAW 6:** Pharmacy is dispensing a generic drug that has been identified by the drug database as a brand name drug due to pricing issues. These generic drugs have high Average Wholesale Prices (AWP) in relation to other generic drugs that are available. An effort shall be made to obtain lower-priced alternatives.
- **DAW 8:** Substitution not allowed generic drug not available in marketplace.
- **DAW 9:** Substitution allowed by prescriber, but plan requires brand.

For auditing purposes, documentation shall be made on the prescription to justify use of the DAW codes. All other DAW codes that are recognized by the National Council on Prescription Drug Programs (NCPDP) are not active in the West Virginia Medicaid program and will not affect the processing of claims, if submitted. The use of DAW codes is not permitted for non-preferred drugs included in the PDL program.

Completion of an FDA MedWatch form is required for the failure of a generic product to produce the same outcome as the equivalent brand name drug. The MedWatch form shall be sent by mail or fax to the pharmacy prior authorization vendor. The <u>MedWatch form</u> is available on the <u>FDA website</u>. Please note that some generic drugs may be classified as non-preferred by West Virginia Medicaid and require prior authorization. This occurs when brand name drugs are less expensive to Medicaid due to supplemental rebate negotiations. In this case, the pharmacy will be required to dispense the brand name drug instead of the generic equivalent.

518.2 PRIOR AUTHORIZATION

Prior authorization for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific prior authorization criteria are based on review of the most current clinical information, FDA-approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the BMS. These criteria then form the basis of acceptable drug therapy for members with Medicaid pharmacy benefits. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization is available on the BMS website. Drugs which require prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable unless, upon appeal by the prescribing provider, the Medicaid medical director determines that the drug meets the appropriateness and medical necessity criteria.

The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.

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Federal regulations state that Medicaid-covered drugs that require prior authorization must have a 24-hour decision turnaround. In emergent situations, a 72-hour supply of medication must be made available to members until the prior authorization process can be completed. No more than a 72-hour supply shall be dispensed. Submitting a quantity greater than a 72-hour supply constitutes an improper claim unless it is for a package that cannot be broken. If a product package cannot be broken, then the whole package may be dispensed, if necessary, to meet the member's needs. Documentation of this action shall be made on the prescription for auditing purposes. Repeated submissions of 72-hour supplies for the same patient and same drug to circumvent the prior authorization process constitute an improper billing method. This practice is subject to audit.

518.2.1 Process of Requesting Prior Authorization

The pharmacy prior authorization vendor is the agency contracted to provide prior authorization services to the West Virginia Medicaid Pharmacy program. Prior authorization may be initiated either by the dispensing pharmacist, the prescriber, or the prescriber's designee. Prior authorization requests from third party vendors or contractors will be denied. Requests may be made by telephone, fax, or mail. If all the necessary information is provided, requests will be addressed within 24 hours. It is the responsibility of the provider of the service, either the physician or pharmacist, to obtain the authorization before rendering the service. Requests for prior authorization after the service is rendered will be denied. In cases of back-dated eligibility, prior authorizations may be considered on a case by case basis using coverage policies in place on the dates the services were rendered. If the service is provided before prior authorization is obtained, the Medicaid member must be informed that they will be responsible for the bill. There is a maximum approval limit of one year.

Prior authorization requests shall include the following:

- Member name, address, and Medicaid identification number;
- Name of drug, strength, dosage, and duration of treatment;
- Diagnosis;
- Pertinent laboratory information;
- Justification for the use of the drug;
- Return fax number; and
- Signature of prescriber or pharmacist.

Prior authorization forms are available on the BMS website. These forms may be duplicated.

518.2.2 Prior Authorization Denial Appeals Process

If a prior authorization request is not approved, the prescriber may appeal the decision to the <u>Pharmacy</u> <u>Prior Authorization Vendor Appeals Department</u> in writing (first level appeal). Requests must include the following information:

- Member name, address, and Medicaid identification number;
- Name of drug, strength, dosage, and duration of treatment;
- Diagnosis;
- Pertinent laboratory information;
- Justification for the use of the drug, including any other treatments that have been tried;
- Supporting literature;

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- Return fax number; and
- Signature of prescriber.

Office and/or hospital notes, including signed ones, are not acceptable and do not constitute an appeal. The appeal decision will be returned to the fax number of the *prescriber* on record.

Appeals will be processed within three business days of their receipt. All appeals denied by the pharmacy prior authorization vendor will be sent to the BMS for physician review. Any denial resulting from physician review is final.

The Medicaid member is notified of this denial and of the right to request a fair hearing.

518.3 NON-COVERED SERVICES

The following list of drugs, drug products, and related services are not reimbursable. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with the Centers for Medicare and Medicaid Services (CMS);
- Agents used for weight loss, anorexia, or weight gain, including binge-eating disorder;
- Agents used for cosmetic purposes or hair growth;
- Drugs identified by the CMS as being less-than-effective (DESI);
- Agents used for fertility;
- Drugs used to treat erectile dysfunction;
- Drugs that are investigational or approved drugs used for investigational purpose;
- Drugs used for off-label indications that are not found in official compendia or generally accepted in peer reviewed literature;
- Drugs dispensed after their expiration date;
- The cost of shipping or delivering a drug;
- Herbal or homeopathic products;
- Drugs that result in therapeutic duplication, ingredient duplication, early refills, or other DUR events that are not medically necessary;
- Drugs that are not medically necessary;
- Covered outpatient drugs for 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;
- Nutritional supplements;
- Free pharmaceutical samples;
- Diagnostic agents;
- Vacation supplies;
- Allergenic extracts;
- Excipients except when used in compounded prescriptions containing a covered legend drug. Excipients must be eligible for Federal rebates in order to be eligible for reimbursement;
- Vaccines through the pharmacy POS, except for Influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, human papilloma virus (HPV), tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults 19 years of age and older administered by a pharmacist; vaccines and vaccine administration approved during a public health emergency declaration, and herpes zoster vaccine for adults 50 years of age and older administered by a pharmacist; and

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• Methadone for the treatment of opioid addiction/dependence is not covered as a pharmacy benefit. <u>See Chapter 504, Substance Use Disorder Services</u>.

Non-covered services are not eligible for a Department of Health and Human Resources' (DHHR) Fair Hearing. See <u>42 § 431.220 When a hearing is required</u> for more information.

518.4 SERVICE LIMITATIONS

Service limitations governing the provision of all West Virginia Medicaid pharmacy services will apply for eligible members as follows:

- Covered drugs are limited to their FDA-approved or medically accepted indications and dosing limits.
- When appropriate, PDL-preferred drugs must be tried before non-preferred drugs are approved.
- All covered outpatient drugs must be prescribed by a practitioner qualified under state law within the scope of their license and in accordance with all state and Federal requirements.
- Prescriptions may be written or verbal, and must meet all the Federal and state guidelines for legal prescriptions.
- Covered outpatient drugs are reimbursed up to a 34-day supply and may be refilled according to state and Federal Laws. Certain exceptions apply, for example, most oral systemic antibiotics are covered for a 14-day supply with one refill. Exceptions to this policy may apply if the only available package size of the product is one that exceeds the 34-day supply limit.
- Only those legend drugs for the symptomatic relief of cough and colds that appear on the approved BMS list are covered for this therapeutic indication. Certain over-the-counter cough and cold medications are also covered. This <u>list</u> is available on the BMS website. Dual eligible members have coverage of cough and cold medications through Medicaid if these products are not covered by their Medicare Part D or Part C plans.
- Barbiturates are not covered except for phenobarbital and mephobarbital, unless the barbiturate is in combination with another active ingredient. Dual eligible members have coverage of phenobarbital; mephobarbital; and butalbital, acetaminophen, and caffeine combination products through Medicaid if these products are not covered by their Medicare Part D plans. (Note: Combination products of butalbital, acetaminophen, caffeine, and codeine will be covered by Medicare Part D or Part C plans for dual eligible members.)
- Vitamins and minerals are limited to:
 - Legend vitamins A, D, K, folic acid, B-12 for injection, iron preparations, and niacin.
 - Minerals including calcium, iron, magnesium, fluoride, and additional mineral requirements for the treatment of End Stage Renal Disease.
 - Multivitamins for children through age 20.
 - Prenatal vitamins for women through age 45.
 - Legend fluoride preparations.
- Other drugs may be limited in quantity, duration, or based on gender. The <u>information regarding</u> <u>these drug products and their limitations</u> is available on the BMS website. Exceptions are considered on a case-by-case basis through the pharmacy prior authorization vendor.
- Additional drugs may have quantity limits to assure accurate billing of units.
- Limitations apply to diabetic testing supplies and insulin syringes/needles depending on the member's diagnosis, i.e. insulin dependent or non-insulin dependent diabetes. Medicaid does not cover diabetic supplies for dual eligible members, except for coverage of Part B deductibles and

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coinsurance amounts. These individuals have coverage for diabetic supplies either through Medicare Part B or Part D.

- Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:
 - Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions).
 - Over-the-counter medications.
 - Agents for the symptomatic relief of cough and cold symptoms.
 - Prescription vitamins and minerals.

518.5 DRUG UTILIZATION REVIEW (DUR)

The Omnibus Budget Reconciliation Act (OBRA '90) required that states establish a DUR program which consists of prospective and retrospective components as well as components to educate physicians and pharmacists on common drug therapy problems and assessments of whether usage complies with predetermined standards. In order to meet the requirements of the statute, the DUR program must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The two primary objectives of DUR systems are to improve quality of care and to assist in containing health care costs.

The establishment of a DUR Board was required by OBRA '90. This Board consists of local pharmacists, physicians, and other healthcare providers from around the state. The Board is charged with making recommendations for educational interventions to prescribers and pharmacists to identify and reduce, for both providers and patients, the frequency of patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care. Specific drugs or classes of drugs may be targeted in regard to:

- Therapeutic appropriateness
- Overutilization
- Under utilization
- Appropriate use of generic products
- Therapeutic duplication (same or different prescriber)
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage
- Incorrect duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse

The West Virginia Medicaid DUR Board meets quarterly to discuss methods of achieving the goals of assuring the appropriate use of drugs in the Medicaid program. These meetings are open to the public. The DUR Board also assists the BMS in defining criteria for coverage of drugs that require prior authorization.

The DUR Board meeting agendas, minutes, and other DUR information are available on the BMS website.

518.5.1 Prospective Drug Utilization Review (DUR)

Prospective DUR is conducted at the pharmacy POS before delivery of a medication by the pharmacist to

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the Medicaid member or caregiver. Prescription claims are screened to identify potential drug therapy problems of the following types:

- Therapeutic duplication
- Ingredient duplication
- Adverse drug-drug interactions
- Early refill
- Late refill
- High dosage
- Low dosage
- Incorrect duration of drug treatment
- Age/gender precaution
- Pregnancy precaution
- Breast feeding precaution

Dispensing pharmacists use the information provided by the pharmacy POS and their professional judgment to determine if the prescription shall be filled. The pharmacist determines the appropriateness of the prescribed therapy and intervenes with the prescribing physician and/or member in the event of a suspected problem.

Pharmacists may continue to process claims that contain prospective DUR messages by using DUR outcome and intervention codes. A call to the pharmacy prior authorization vendor help desk may be required in certain instances as determined by the BMS to obtain an edit override. Requests for edit overrides after the service is rendered will be denied, except in cases of back-dated eligibility. More detailed information regarding DUR may be accessed through the Health PAS-RX pharmacy POS <u>User</u> Guide found on the BMS fiscal agent's website.

518.5.2 Retrospective Drug Utilization Review (DUR)

Retrospective DUR is required in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid members, or associated with specific drugs or groups of drugs. West Virginia Medicaid conducts retrospective DUR with the assistance of a vendor. They provide patient profiles addressing drug use that may be inappropriate based on predetermined standards. A Retrospective DUR Committee, consisting of healthcare professionals, meets monthly to review these patient profiles that are used to generate letters to physicians and pharmacists relating to these issues.

518.5.3 Pharmacy Lock-in Program

Members who use pharmacy services excessively or inappropriately may be assigned to a single pharmacy provider where they receive their Medicaid-covered medications. The purpose of this program is to assist members in using pharmacy services appropriately.

As part of this program, the Retrospective DUR Committee reviews Medicaid member utilization profiles to determine if controlled substances are being used at a frequency or amount that results in a level that may be harmful or not medically necessary. Inappropriate utilization can include frequent use of multiple controlled substances, use of multiple prescribing physicians and/or pharmacies, overlapping prescription drugs within the same drug class and drug seeking behavior, i.e., doctor shopping.

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A series of letters is sent to prescribers and/or the member to seek information regarding their drug utilization or to warn that continued overutilization may result in restricting the member to a single pharmacy provider. If the pharmacy lock-in criteria are met, the member is given the opportunity to select a pharmacy, but pharmacy participation is voluntary. Pharmacists serving these members are requested to use their professional judgment in regard to filling prescriptions for controlled substances.

<u>Criteria for Lock-in Determination</u> is available on the BMS website. Members, upon discharge from a substance abuse program, or while receiving outpatient substance abuse treatment, will be locked into a single pharmacy provider. Upon admission to a facility for treatment of substance abuse or during the initial visit for outpatient substance abuse services, the member will be required to choose a pharmacy from which to receive all controlled substances.

518.6 PROVIDER PARTICIPATION REQUIREMENTS

Provider enrollment requirements in general are detailed in the BMS Manual <u>Chapter 300, Provider</u> <u>Participation and Requirements</u>.

518.7 CERTIFICATION

A pharmacy eligible to participate in Medicaid must hold a current permit from the West Virginia State Board of Pharmacy (BOP) and adhere to all state and Federal regulations. Pharmacies located out-of-state and filling prescriptions for West Virginia Medicaid members must be licensed by the state in which they are located. Pharmacies located out-of-state and which are shipping or mailing prescriptions into West Virginia, must be licensed by the state in which they are located <u>and</u> hold a permit from the West Virginia BOP. Pharmacies are required to file a copy of their current permits with the BMS annually. Failure to do so may result in the withholding of payments and/or enrollment termination.

When the current license and/or permit is not on file, the provider shall not be reimbursed by Medicaid until such time as the BMS Provider Enrollment Unit receives a copy of the current license and/or permit.

Out-of-state pharmacies may be enrolled under the following scenarios:

- The pharmacy must have a publicly accessible physical location located within a 30-mile radius of the state border at the time of enrollment. These pharmacies are eligible for full enrollment as if they were located within West Virginia; OR
- The pharmacy may be fully enrolled if they are operating under a business arrangement with an enrolled out-of-state residential facility. Please note that this enrollment does NOT permit the pharmacy to do mail order into West Virginia for members which are not residents of the out-of-state residential facility, OR
- The pharmacy is part of a limited distribution network. In this case, the pharmacy may be enrolled under a limited drug list agreement with WV Medicaid provided These out-of-state pharmacy providers shall be limited to the National Drug Codes (NDCs) for the limited distribution drugs (LDD) requested on their enrollment applications. The pharmacy applying for enrollment must submit a signed document with their application which clearly indicates the drug(s) for which they possess LDD rights, the manufacturer(s), and contact information for the manufacturer(s).

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518.8 DISPENSING PHYSICIANS

The BMS does not enroll dispensing physicians for reimbursement as a pharmacy provider type. Reimbursement for self-administered prescription drugs is limited to licensed and participating pharmacies.

518.9 IN-HOME PARENTERAL THERAPY PROVIDER REQUIREMENTS AND RESPONSIBILITIES

Pharmacies requesting reimbursement for IHPT compounding services must meet all state and Federal licensure and certification requirements. In order to participate in the West Virginia Medicaid program and receive payment from the BMS, IHPT providers must:

- Submit an IHPT Medicaid Provider Enrollment Form to the BMS; and
- Submit a copy of the provider's West Virginia BOP Sterile Compounding Permit or respective state Board of Pharmacy Sterile Compounding Permit.

Participating pharmacies that bill services for West Virginia Medicaid members shall be subject to the laws and regulations set forth by the West Virginia BOP that govern the requirements to hold a Sterile Compounding Permit.

518.10 PHARMACIES PARTICIPATING IN THE 340B PROGRAM

Pharmacies participating in the program established by Section 340B of the Public Health Services Act of 1992 dispense drugs with discounts generated from participation in the program. These drugs are not eligible for Federal drug rebates.

Actual acquisition costs must be submitted when billing Medicaid. Submission of invoices may be required for audit purposes.

All 340B pharmacy providers for West Virginia Medicaid are required to bill each pharmacy POS claim with the following NCPDP values:

- Claim Segment-Submission Clarification Code (420-DK) Use value 20 in Position 1 or 2 OR
- Pricing Segment- Basis of Cost Determination (423-DN) Use value 08

Per NCPDP guidelines, the value of "20" must be used to identify an <u>initial</u> claim as 340B, OR If a claim is submitted as <u>non-340B</u> and only later identified as 340B, then the provider must reverse and rebill using only the Pricing Segment- Basis of Cost Determination value of "08" to identify the claim as 340B.

Please note that the values of "20 and "08" are mutually exclusive and using them both will result in the denial of the claim.

These updates may be found on the updated West Virginia Medicaid Health PAS-Rx Point-of-Sale NCPDP Version D.0 Vendor <u>Specification Sheet.</u>

The NCPDP values above identify claims to be removed from the rebate file which avoids billing

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manufacturers for duplicate discounts. As per 42 USC 256b(a)(5) a manufacturer may audit and seek recoupment of the duplicate discount from covered entities found to be non-compliant with 340B requirements. In these instances, the rebate is due to the State and the duplicate discount will be recouped from the non-compliant covered entity.

The Health Resources & Services Administration (HRSA) maintains a current listing of participating providers who intend to bill Medicaid for 340B drugs on the <u>HRSA website</u>. It is the providers' responsibility to verify that the HRSA listing of their participation is current and accurate. Providers must report any changes in Medicaid 340B program participation to HRSA.

518.11 PHARMACY CHANGE OF OWNERSHIP

Change of ownership policy is addressed in the BMS Manual <u>Chapter 300, Provider Participation</u> <u>Requirements</u> and additional information may be found on the fiscal agent's website, see BMS Manual <u>Chapter 100, General Information</u>.

518.12 CASH PAYMENTS

Pharmacies are encouraged to report to the BMS when a member pays cash for prescriptions that would otherwise be covered by Medicaid or considered for reimbursement upon a call to the pharmacy prior authorization vendor, or when the pharmacy provider suspects overutilization by the member. The cash <u>waiver form</u> used for this reporting is available on the BMS website. Information collected through this process may be used for member lock-in consideration.

Medicaid reserves the right to deny coverage of controlled substances when the member has been found to be paying cash to bypass Medicaid's prior authorization and/or quantity limit requirements.

518.13 MEMBER COUNSELING

The OBRA '90 requires that pharmacists offer counseling to Medicaid members and must include the following:

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

The West Virginia Medicaid program relies on the West Virginia BOP to monitor these activities, but the BMS may audit these requirements through routine or special reviews. Should an audit be necessary, BMS will refer to all current state BOP regulations regarding maintenance of records.

518.14 DOCUMENTATION AND RECORD RETENTION REQUIREMENTS

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518.14.1 Tamper-Resistant Prescription Pad Requirement

All prescriptions written for West Virginia Medicaid members must be on tamper-resistant pads/paper which meet all three characteristics set forth in the guidelines from the CMS. The three characteristics to meet the tamper-resistant prescription requirement are:

- 1. Prevent unauthorized copying of a completed or blank prescription form;
- 2. Prevent the erasure or modification of information written on the prescription, and
- 3. Prevent the use of counterfeit prescription forms.

Written prescriptions must contain ALL of the following:

Feature	Description
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received by fax.
Uniform non-white background color – preferably green	Background is one color (preferably green), inhibits a forger from physically erasing written or printed information on a prescription form. If an attempt is made to erase copy – the consistent background color will look altered.
Quantity check off boxes	In addition to the written quantity on the prescription, quantities are indicated in ranges of 25's (or some other, similar range). Box MUST be checked for this feature to be valid.
Refill indicator	Refill indicator (circle or check number of refills or "NR"). Refill indicator must be used to be a valid feature.
Security features and descriptions listed on the front of the prescription	Listing of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the pads/paper.

Computer-generated prescriptions, electronic medical records (EMR), or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of tamper resistance, provided they contain the features listed in the table below. Prescribers are urged to contact their software companies to ensure that computer generated prescriptions have all requirements necessary for tamper resistance.

Computer-generated prescriptions must contain the following:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.

Feature	Description	
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received via fax. <i>This requires the purchase of special paper.</i>	

<u>OR</u>

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Feature	Description	
Micro print signature line	Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.	

2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

Feature	Description
Uniform non-white background color – preferably green	Background is one color (<i>preferably green</i>), inhibits a forger from physically erasing written or printed information on a prescription form. If someone tries to erase copy – the consistent background
OR	color will look altered.
"Toner-lock" paper for laser printed prescriptions, or plain bond paper for inkjet printed prescriptions	Toner-lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from the inkjet printers is absorbed into normal "bond" paper.
Quantity written and quantity with border characteristics for computer generated printed prescriptions	Quantity written, and Quantity surrounded by special characters such as asterisks to prevent modification, e.g. QTY Fifty ***50****.
Refill written and refill with border Characteristic for computer generated printed prescriptions	Refills written, and Refill surrounded by special characters such as asterisks to prevent modification, e.g. Five refills ****5 refills*****.

3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Feature	Description	
Security features and descriptions listed on the prescription	A complete list of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the paper.	

Prescriptions for West Virginia Medicaid members written by prescribers that reside outside of West Virginia may meet the Federal tamper-resistant prescription requirement if the prescription addresses the three distinct characteristics outlined above, and may contain the same or other features than those adopted by the BMS.

518.14.2 Prescriptions Returned to Stock

Claims for prescriptions which have been filled by the participating pharmacy, but not dispensed to the patient, shall be reversed. This shall be done on a timely basis, within 15 days. A log of these returns must be maintained by the pharmacy for a period of five years for auditing purposes.

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518.14.3 Nursing Home Returns

Drugs dispensed to nursing home residents that are not used by the member must be either returned to the dispensing pharmacy or destroyed according to applicable rules and regulations. Drugs that are returned unused by the Medicaid member and are available for re-dispensing, per West Virginia State BOP rules and regulations, must be credited to Medicaid. Claims for these returned medications must be reversed and resubmitted for the quantity used by the member.

518.14.4 Medication Dispensing/Shipping/Receiving

Providers shall take all necessary and prudent steps to prevent loss of medications in the shipping process and to assure that the member receives the shipment when needed, as Medicaid will not reimburse for medications not received by the member. In the case of a dispute, the only definitive proof of delivery accepted by BMS shall be a copy of the member's signature on the delivery log. Reimbursement shall be withheld should a dispute arise where proof of signature is not available from the pharmacy. It is recommended that a log of these signatures be maintained by the pharmacy for a period of five years should a dispute of delivery arise.

Claims for medications not received by the member in a timely manner, and which the member was compelled to obtain from a local pharmacy, may be reversed by the fiscal agent, if necessary, in order to allow for billing by a local pharmacy provider to meet the member's needs.

518.15 PHARMACY SERVICES FOR MEDICAID MEMBERS

Medicaid members eligible for pharmacy services have access to legend and over-the-counter drugs as defined in the State Plan filed with CMS. Any person requesting services shall be advised that they are responsible for furnishing proof of coverage to the provider prior to services being rendered. Eligibility may be verified through the Medicaid Voice Response System at 1-888-483-0801 or by sending an electronic NCPDP E-1 transaction through the pharmacy POS billing system.

518.15.1 Dual Eligible Members

Members eligible for both Medicare and Medicaid are called dual eligible members. Medicare is the primary payer for dual eligible members. Medicare, a Federal health insurance program for the aged and disabled, covers certain hospital (Part A), outpatient medical benefits and physicians' services (Part B) and prescription benefits (Part D) for participating individuals. Some dual eligible members may participate in Medicare Managed Care plans (Advantage or Part C plans) which include pharmacy services.

Dual eligible members have prescription drug coverage through Medicare Part D, or Part C if enrolled in a Medicare Managed Care plan. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Medicaid does not reimburse for Medicare Part D or Part C co-payments. Medicaid does not pay as the secondary payer on Medicare Part D or Part C covered drugs.

518.15.2 Medicaid Members Enrolled in Managed Care Organization Plans

Medicaid members enrolled in the managed care organization plans receive pharmacy benefits from the

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fee-for-service (FFS) pharmacy program. The FFS pharmacy program covers drugs which are submitted to pharmacies by written, telephonic, or electronic prescriptions.

Drugs that are billed with J Codes or Healthcare Common Procedure Coding System (HCPCS) Codes are covered by the managed care programs and cannot be billed to the fee-for-service program at the point of sale.

518.15.3 Medicaid Members with End Stage Renal Disease (ESRD)

Members diagnosed with End Stage Renal Disease (ESRD) may require <u>additional vitamin/mineral</u> <u>supplements</u> not usually covered by the pharmacy program. In order to accommodate these members, the prescriber must contact the prior authorization vendor (Rational Drug Therapy Program (RDTP)) by fax, phone or mail in order to confirm the ESRD diagnosis.

Once a member receives a kidney transplant, the member is no longer considered as having ESRD, and no longer qualifies for these additional supplements. To allow for clinical stabilization following transplant, a six-month extension of the ESRD coverage will be permitted before being terminated.

518.15.4 Qualified Medicare Beneficiary (QMB)

Qualified Medicare Beneficiary (QMB) members do not receive pharmacy coverage benefits through the Medicaid program. Medicaid does provide coverage of deductibles and co-insurance amounts for Medicare Part B covered drugs and other Medicare covered services with the exception of those covered under Part D.

518.15.5 Children in Foster and Adoptive Placement

Children in state custody and entered into foster, residential, or adoptive placements may be Medicaid eligible and receive a medical identification card. The eligibility number usually begins with "039." Drug claims may be submitted online through the pharmacy POS system or on the approved paper claim form. Medicaid coverage rules apply.

518.15.6 Incarcerated Members

Medicaid members who are incarcerated are restricted from coverage of pharmacy benefits until they are released from the correctional system. Claims submitted with dates of service during a period of incarceration will deny. If the member has been released before the restriction is updated, positive identification is required. A call to the pharmacy prior authorization vendor help desk must be made to request an override.

518.16 PHARMACY SERVICES FOR NON-MEDICAID INDIVIDUALS

Individuals who do not qualify for the Medicaid program may have pharmacy coverage under other Federal or state-funded programs. These individuals do not receive medical identification cards but may receive a letter or other form of eligibility authorization.

518.16.1 Limited Pharmacy Services or Ryan White Program

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The Limited Pharmacy Services program is funded under Part B of the Ryan White HIV/AIDS Treatment Extension Act in West Virginia, and claims are processed through the BMS claims processing system. The program assists eligible persons with HIV infection in obtaining drugs covered by the Limited Pharmacy Services <u>formulary</u>. To be eligible for the Limited Pharmacy Services program, a person must meet the following criteria:

- Be an HIV infected resident of West Virginia;
- Have family income less than 400% of the Federal poverty level (FPL);
- Not be eligible for other forms of reimbursement such as Medicaid or full insurance coverage; and
- Have completed the Limited Pharmacy Services and Medicaid application at their local DHHR county office.

Limited Pharmacy Services participants do not receive a medical identification card, but do receive a letter that verifies eligibility and includes their identification number with a prefix of "69." All claims except those for vaccines may be submitted online through the pharmacy POS system or by using the approved paper claim form. Covered drugs are limited to a 30-day supply. Claims must be submitted within one year from the date of service. Formulary drugs must be dispensed in generic form if available. Brand-name drugs that have generic equivalents require prior authorization. There are no co-payment requirements for this program. Limited Pharmacy Services program may cover co-pays for eligible residents who are covered by insurance or Medicare Part D. Claims for vaccines must be submitted on the approved pharmacy paper claim form and mailed to ATF, PO Box 6360, Wheeling, West Virginia 26003. Certain drugs may require prior authorization and emergency supplies of these drugs may not be dispensed. Please refer to the BMS website for the Limited Pharmacy Services formulary. More information regarding Limited Pharmacy Services is available at the DHHR Office of Epidemiology and Prevention Services website or by calling the local AIDS Task Force.

518.16.2 Children with Special Health Care Needs (CSHCN)

Pharmacy services are available for certain children under 21 years of age receiving medical care under the Children with Special Health Care Needs (CSHCN) program. Services are not limited to children of families receiving public assistance grants. Coverage is established by the CSHCN program. These members do not receive a medical identification card. An identification number with a prefix of "99" is assigned. Claims may be submitted online using the pharmacy POS system or by using the approved paper claim form. Policy questions regarding this program shall be directed to CSHCN.

518.16.3 Individuals Eligible for Immunosuppressant or Antipsychotic Medications

Certain individuals who are not eligible for Medicaid services may be eligible for coverage of immunosuppressant or antipsychotic medications using all state funds. Eligibility for these services is determined at the individual's local county DHHR office. A six-month eligibility period is established, and it is the member's responsibility to reapply for these services. No identification card will be issued. Medicaid receives a written communication from the Division of Family Assistance defining the drug(s) that will be covered for a particular individual. A letter including the services to be covered and the individual's identification number, prefix "39", will be forwarded to the pharmacy provider and the individual. Claims for these services may be submitted online through the pharmacy POS system or on the approved paper claim form. Medicaid coverage rules apply to these claims. Some individuals may also be eligible for coverage of immunosuppressant drugs by Medicare Part B. Medicare must be billed first. This state program will pay co-insurance and deductible amounts on Medicare Part B crossover claims only. All other

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Medicare eligible individuals must pursue coverage of immunosuppressant drugs and antipsychotic medications through their Part D plans.

518.16.4 James "Tiger" Morton Catastrophic Illness Fund

Certain individuals who are not eligible for Medicaid services may be eligible for coverage of selected medications using state funds through the James "Tiger" Morton Catastrophic Illness Fund. These individuals will not have an identification card and coverage will be communicated to the pharmacy provider on a case-by-case basis. Claims for these services must be submitted using the approved paper claim form.

518.16.5 Emergency Medical Assistance or Other State Programs

Certain individuals who are not eligible for Medicaid services may be eligible for emergency medical assistance or other pharmacy services using state funds. These individuals will present a letter to the pharmacy provider listing particular drug(s) to be covered. A prefix of "15" or "38" along with the respective county code will be noted on the authorization letter to identify the eligible individual. Claims for these services must be submitted using the approved paper claim form with a copy of the eligibility letter attached.

518.16.6 Juvenile Services

Incarcerated minors have pharmacy services coverage through Juvenile Services. A letter of eligibility will be presented to the pharmacy which includes the individual's identification number beginning with prefix "17". Claims for these services may be submitted through the online POS system or by using the approved paper claim form. Medicaid coverage rules apply.

518.16.7 Adult Family Care and Protective Services

Children and adults receiving protective services as a result of abuse and/or neglect or other individuals in need of assistance may be provided limited eligibility for state-funded services. A Special Medical Authorization Letter is issued as needed by the DHHR field staff. This letter specifies the individual, the medical provider authorized to provide services, the services authorized and the coverage period. An identification number for use in billing the services is also provided. Pharmacy claims for these individuals may be submitted online or on the approved paper claim form. Medicaid coverage rules apply.

518.17 DENIALS DUE TO ELIGIBILITY ISSUES

If an online denial occurs due to eligibility problems and the member presents a valid medical identification card or other proof of eligibility, the pharmacist should take the following steps:

- Dispense the prescription for valid and covered services,
- Obtain proof of eligibility, and
- Choose one of two options:
 - 1. Resubmit the claim online at a later date, using the original date of service; or
 - 2. Submit the claim on the approved paper claim form and attach a copy of the valid medical identification card or other proof of eligibility. Mail these claims to:

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Gainwell Technologies Pharmacy Claims Post Office Box 3765 Charleston, West Virginia 25327-3709

518.18 BILLING PROCEDURES

Claims for prescribed drugs dispensed to Medicaid members may be submitted electronically using the POS system or on paper claim forms. Claims must be filed within 12 months from the date of service.

Submitting claims via electronic media offers the advantage of speed and accuracy in processing. All claims, regardless of method of submission, are subject to DUR edits, prior authorization, and other Medicaid requirements.

Medications must be dispensed at the facility from which the drug products are prepared, and the services rendered.

Claims must accurately report the National Drug Code (NDC) dispensed, the number of units dispensed, days' supply, and other required data for claims processing. Use of an incorrect NDC or inaccurate reporting of a drug quantity will cause the BMS to report false data to drug manufacturers when billed for drug rebates. The BMS will recover payments made on erroneous claims discovered during dispute resolution with drug manufacturers or during claim reviews. Pharmacies are required to submit documentation for purchases of drugs reimbursed by the BMS upon request.

518.18.1 Point-of-Sale (POS) System

Currently, online processing for Medicaid pharmacy claims is available for all pharmacies using NCPDP Version D.0. The provider must complete and submit the provider trading partner agreement prior to use of POS submission for claims.

The Pharmacy POS User Guide provides complete billing instructions for the POS system. The Pharmacy POS NCPDP Version D.0 Vendor Specification Document provides specifications and information for switch vendors. These documents and other billing information are available on the <u>fiscal agent website</u>.

518.18.2 National Council on Prescription Drug Programs (NCPDP) Payer Sheet

West Virginia Medicaid accepts pharmacy POS claims submitted using NCPDP Version D.0 or Batch Version 1.1. According to the NCPDP accepted standards, some fields are required, optional, or conditional. The Pharmacy POS NCPDP Version D.0 Vendor Specification Document and the West Virginia Medicaid payer sheet are available on the <u>BMS website</u>.

518.18.3 Paper Claim Submission for Pharmacy Services

Pharmacies have the alternative of submitting a manual claim using a paper claim form, when necessary. The Universal Claim Form (UCF) provides a standard format for paper submission of drug claims to Medicaid. The UCF adheres to the data elements found in the NCPDP Telecommunication Standard and Data Dictionary. **Medicaid will not supply these forms to providers**.

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518.18.4 Claim Reversals

Pharmacy claims submitted by POS cannot be adjusted. To correct information submitted on a POS claim, the claim must be reversed online and then resubmitted using the corrected information. There is currently no paper reversal claim form. If a paper claim submission requires corrections, the pharmacy Help Desk must be contacted.

518.18.5 Pharmacy Identification Number

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the use of the National Provider Identifier (NPI) as the standard for identifying covered healthcare providers, including pharmacies. Pharmacies must use their NPI number on electronic submissions for reimbursement of pharmacy claims. NCPDP numbers will no longer be accepted on electronic claims. The NPI or NCPDP number will continue to be used on the approved paper claim form. For additional NPI information or to complete an NPI application, visit the <u>CMS website</u>.

518.18.6 Prescriber Identification Number

The NPI is required for the prescriber identification information on electronic POS claims. Either the DEA number or the NPI is allowed on the manual claim form. Only prescribing NPI entities are permissible. Claims submitted with non-prescribing NPI entities will be denied, including but not limited to pharmacies, laboratories, hospitals, and dialysis centers.

518.18.7 National Drug Codes (NDC)

All pharmacy claims submitted to West Virginia Medicaid must identify the 11-digit NDC printed on the stock container in which the drug was purchased. **Using the correct NDC is extremely important in order to avoid disputes with manufacturers for rebate payments**. For example, if a drug is purchased in a 5000-count bottle and repackaged in 100-count bottles prior to dispensing, submitting the NDC for a 100-count bottle is not permitted. Most drugs distributed by repackagers are not covered by Medicaid because the repackager has not signed a rebate agreement with CMS. A pharmacy may not dispense a repackager's drug and then bill Medicaid using the original manufacturer's NDC.

518.18.8 Decimal Units

The Medicaid pharmacy system is capable of accepting quantity amounts which contain decimal units. Pharmacy claims must be submitted using the standard units, including any decimal increments. Units must not be rounded up or down. Rounding results in over or under payments and creates inaccurate invoicing to manufacturers for the drug rebates owed to the state.

518.18.9 Days' Supply

For non-controlled substances, each Medicaid-covered prescription is limited to a <u>maximum</u> dispensed supply of 90 days, with some exceptions to accommodate packaging that cannot be broken.

All controlled substances are limited to a maximum supply of 34 days, with no exceptions.

If the member has coverage by a third party and is required to obtain up to a 93-day supply, coverage will

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be provided beyond the standard 90-day supply limit.

The pharmacist is responsible for submitting prescription claims up to the appropriate limit. Should a prescription be written for a quantity that is greater than the allowed limit, the pharmacist is responsible for notifying the prescriber of this limit and asking permission to reduce the number of units to be dispensed.

If the prescriber does not allow the prescription quantity to be reduced to the maximum Medicaid limit, the member shall be told that the cost of the prescription is their responsibility. The pharmacist must enter the actual day supply written on the prescription when attempting to fill a claim. Artificially adjusting the amount filled in order to meet Medicaid requirements when the prescription was written to last longer constitutes a false claim and is subject to recovery of the paid amounts.

518.18.10 Compounded Prescriptions

A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a covered legend drug. The covered legend drug must be the first NDC submitted on a compounded prescription claim. The Drug Efficacy Study Implementation (DESI) drugs or non-covered drugs **not appearing as the first NDC** in a compounded product will not cause the claim to deny, but those ingredients will not be included in the reimbursement. Over-the-counter ancillary products will be reimbursed provided the drug is manufactured by a company which participates in the Federal drug rebate program. A compound may contain up to 25 ingredients.

Products such as suppository molds and other items identified as supplies included in a compounded prescription will not be reimbursed by West Virginia Medicaid.

Billing compounded prescriptions follows NCPDP Version D.0 guidelines. For a compounded prescription, an additional \$6.00 will be added to the dispensing fee. Compounding is considered an integral part of the prescription services and must not be billed separately. More information can be found in the User Guide, located using the BMS link to the <u>fiscal agent website</u>.

518.18.11 Abuse and Inappropriate Utilization

The following practices constitute abuse and inappropriate utilization, and are subject to audit:

- Excessive fees (commonly known as prescription splitting or incorrect or excessive dispensing fees): Billing inappropriately in order to obtain dispensing fees in excess of those allowed by:
 - Supplying medication in amounts less than necessary to cover the period of the prescription; and/or
 - Supplying multiple medications in strengths less than those prescribed to gain more than one dispensing fee.
- Excessive filling: Billing for an amount of a drug or supply greater than the prescribed quantity.
- Prescription shorting: Billing for drug or supply greater than the quantity actually dispensed.
- Substitution to achieve a higher price: Billing for a higher priced drug than prescribed even though the prescribed lower priced drug was available.
- Automated refills and automatic shipments are prohibited. Medicaid does not pay for any
 prescription without an explicit request from a member or the member's responsible party, such as
 a caregiver, for each refilling event. The pharmacy provider shall not contact the member in an
 effort to initiate a refill unless it is part of a good faith clinical effort to assess the member's

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medication regimen. The possession, by a provider, of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription. Members or providers cannot waive the explicit refill request and enroll in an electronic automatic refill program. Any prescriptions filled without a request from a member or his or her responsible party will be subject to recovery. Any pharmacy provider with a policy that includes filling prescriptions on a regular date or any type of cyclical procedure will be subject to audit, claim recovery or possible suspension or termination of the provider agreement.

518.18.12 Lost/Stolen Medications

For members who report to the pharmacy that their medications have either been lost or stolen, the following procedure applies:

- The member must supply the pharmacy with a police report for stolen controlled substances; the pharmacy must retain a copy for audit purposes.
- The prescribing practitioner must agree that the lost or stolen medication shall be replaced.
- Lost/stolen medication approvals are limited to one occurrence per drug per year.
- In cases of natural disaster, the BMS will address the situation on a case-by-case basis.

518.18.13 Wasted Medication

Members who have wasted medication due to improper use or storage may have their medication replaced. This will be determined on a case-by-case basis. Members shall be properly instructed on the storage and use of their medications and any special delivery device used to administer their medications. Requests for replacement of wasted medications due to improper storage or delivery by the pharmacy or improper handling by the administrating provider will be denied.

518.18.14 False Claims

Pharmacies are prohibited from submitting false claims to test for drug coverage, member eligibility, or for other purposes. Claims of this type result in false member drug history records and may result in the member or prescriber being included in lawsuits or reviews in error. All claims submitted for reimbursement must be the result of actual prescription requests.

518.19 REIMBURSEMENT

Federal Medicaid regulations governing pharmacy services establish upper limits for payment; i.e., the payment shall be based on the lower of the allowable cost of the drug, plus a dispensing fee or the provider's usual and customary charge to the general public.

Reimbursement for outpatient drugs is limited to products manufactured by companies participating in the Federal Drug Rebate program.

If a provider accepts the member as a Medicaid patient, the provider must bill West Virginia Medicaid for covered services and must accept the Medicaid reimbursement amount as full payment. No charge may be billed to a Medicaid member for a covered service unless a co-payment is applicable by regulation. However, the provider may bill the member for services not covered by the West Virginia Medicaid program if the parties agree in writing to this payment arrangement before such services are rendered.

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Please refer to <u>Chapter 300, Provider Participation Requirements</u> for more information about billing Medicaid members.

518.19.1 Ingredient Cost

Reimbursement for covered outpatient drugs is based on the following methodology. Reimbursement for brand (single source) and generic (multiple source) drugs shall be **the lower of**:

- 1. **National Average Drug Acquisition Cost (NADAC) plus the professional dispensing fee.** The NADAC is based on the retail price survey of pharmacies and focuses on the average acquisition cost of retail community pharmacies. The NADAC represents the average acquisition cost of pharmacies surveyed and includes independent retail community pharmacies and chain pharmacies. The prices are updated and loaded into the West Virginia Medicaid Pharmacy POS claims system on a weekly basis. To view the NADAC weekly files and the NADAC Week to Week File Comparison, please visit the Pharmacy Drug Pricing Page on the CMS website.
- 2. If no NADAC is available, then Wholesale Acquisition Cost (WAC) plus 0% plus the professional dispensing fee.
- 3. The Federal Upper Limit (FUL) as supplied by CMS plus the professional dispensing fee. The FUL is calculated at no less than 175% of the weighted average (as determined on the basis of utilization) of the most recently reported monthly Average Manufacturer's Price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In situations where the FUL is less than the community pharmacies' average cost, the FUL is established using a higher multiplier so the FUL amount will equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. This methodology is codified in 42 CFR §447.514 (b)(1) and (2).

EXCEPTION: The FUL shall not apply in any case where a physician certifies in their own handwriting that, in their medical judgment, a specific brand is medically necessary for a particular patient. A notation like "brand medically necessary" written by the physician on the prescription above their signature is an acceptable certification. A procedure for checking a box on a form <u>will not</u> constitute an acceptable certification. All such certified prescriptions must be maintained in the pharmacy files and are subject to audit by the BMS.

4. The State Maximum Allowable Cost (SMAC) plus the professional dispensing fee. The SMAC rate is applied to all brand and generic drug products in each drug group. Non-AB rated drugs recognized by national drug information suppliers as comparable to a particular brand drug are subjected to the same SMAC rate applicable to the brand and "AB" rated generic drugs of the same chemical composition, package size, dose, and drug group.

The determination of which drugs will be part of the SMAC list will be designated by BMS. Drugs no longer available at SMAC prices are removed. New drugs will be added to the SMAC list as they are identified. The SMAC vendor on behalf of BMS will continually monitor pharmacies and industry information and make changes to the SMAC to reflect current pharmaceutical market conditions. The <u>SMAC list</u> may be accessed on the BMS website. Comments and questions regarding the SMAC list can be made to the vendor.

EXCEPTION: The SMAC shall not apply in any case where a physician certifies in their own

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handwriting that, in their medical judgment, a specific brand is medically necessary for a particular patient. A notation like "brand medically necessary" written by the physician on the prescription above their signature is an acceptable certification. A procedure for checking a box on a form <u>will not</u> constitute an acceptable certification. All such certified prescriptions must be maintained in the pharmacy files and are subject to audit by the BMS.

- 5. The submitted ingredient cost plus the professional dispensing fee.
- 6. The provider's usual and customary charges to the general public, including any sale price in effect on the date of dispensing.

518.19.2 Application of Dispensing Fee

- For covered legend and over-the-counter drugs, a professional dispensing fee of \$10.49 per prescription will be added to the NADAC (or WAC when NADAC is not available), FUL, SMAC, or submitted ingredient cost.
- Pharmacies participating in the 340B program will receive a dispensing fee of \$10.49 per prescription. These pharmacies are required to submit their Actual Acquisition Costs (AAC) to Medicaid.
- For a compounded prescription, an additional \$6.00 will be added to the dispensing fee. A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a legend drug. Compounding is considered an integral part of the prescription services and must not be billed separately.
- The dispensing fee may only be paid once every 30 days per drug entity for members residing in ICF/IID or nursing facilities.
- Claims paid on the basis of the usual and customary charge to the general public do not include an additional dispensing fee.

518.19.3 Co-Payments

A co-payment is required for each prescription with the exception of prescriptions for members excluded by regulation and/or those items specifically excluded from the co-payment requirement. The member copayment per prescription will be deducted from the allowed total charge to determine the amount payable for each prescription billed to the program. The deduction will apply as follows:

- If the allowed total charge is \$5.00 or less, there is no co-payment per prescription.
- If the allowed total charge is \$5.01 through \$10.00, the co-payment is \$.50 per prescription.
- If the allowed total charge is \$10.01 through \$25.00, the co-payment is \$1.00 per prescription.
- If the allowed total charge is \$25.01 through \$50.00, the co-payment is \$2.00 per prescription.
- If the allowed total charge is \$50.01 or more, the co-payment is \$3.00 per prescription.

The following populations and services are exempt from copays:

- Family planning services and supplies
- Members in long-term care facilities (i.e., nursing facilities or ICF/IID)
- Pregnant women including those with 12-month post-partum coverage
- Native Americans and Alaska natives
- Members under age 21

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- Members receiving Hospice services
- Members receiving Medicaid Waiver services, or covered through the Breast and Cervical Cancer Treatment program
- Three-day emergency supplies
- Diabetic testing supplies and syringes/needles
- BMS approved home infusion supplies
- POS-approved vaccines
- Agents for smoking cessation including nicotine replacement drugs, buproprion (Zyban) and Chantix

Please refer to <u>Chapter 600, Reimbursement Methodologies</u> regarding maximum quarterly out-of-pocket limits.

Members have been informed of co-payment requirements and the exclusions from co-payment. Federal regulations stipulate that no provider may deny services to an eligible individual in situations when the member is unable to pay co-payment charges. However, this does not preclude the member's liability for payment of the co-payment due the provider.

Providers may bill the member or refer the member to a collection agency, etc., in the same manner that the provider initiates collections from private pay customers.

Providers are prohibited from advertising or soliciting business by waiving members' co-payment responsibility. Members are responsible for applicable copays, and providers are prohibited from waiving the copay requirement to attract business from other providers.

518.19.4 Third-Party Liability (TPL) or Coordination of Benefits (COB)

Medicaid is the payer of last resort. The TPL ensures that Medicaid is the last payer to reimburse for covered Medicaid services. In particular, Medicaid participating providers must always seek reimbursement from other liable resources, including private or public insurance entities. Before submitting claims to Medicaid, providers must pursue all requirements of the primary insurer including, but not limited to prior authorization, brand name justifications, and DUR events.

Federal regulations require that state Medicaid administration identify any third-party resource available to meet the medical expenses of a member. The "third party" may be an individual, institution, corporation, or a public/private agency liable for all or part of the member's medical costs; e.g., private health insurance, United Mine Workers of America (UMWA) benefits, Veterans Administration benefits, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Medicare, Hospice, etc. Additionally, no Medicaid reimbursement may be made if the service is the responsibility of a public or private Workers Compensation Plan.

Medicaid covered drugs which currently require a prior authorization from BMS will continue to require a prior authorization if a primary insurer approves that service, and Medicaid reimburses any part of the cost. Medicaid co-payment is still required, if applicable, for claims considered by third party payers and reimbursed by the BMS. <u>Chapter 600, Reimbursement Methodologies</u>, of the BMS Provider Manual provides more detailed information regarding Third Party Liability.

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More information regarding the billing of COB for NCPDP Version D.0 can be found on the <u>fiscal agent</u> <u>website</u>.

518.19.5 Medicare-Covered Drugs and Supplies, Part B

Pharmacies are required to verify and pursue members' Medicare coverage and to submit pharmacy claims to Medicare for those pharmacy services covered by Medicare. Pharmacies can submit claims to Medicare Part B either on the acceptable paper claim form (CMS 1500) or electronically. Once the Medicare claim has been approved and processed, Medicare will automatically submit the balance of the claim as a "crossover" to Medicaid electronically, if the provider's Medicare number is on file with Medicaid. These claims should not be submitted to Medicaid separately if the claim crossed over from Medicare.

For Dually Eligible members and Qualified Medicare Beneficiary (QMB), if the service is covered by Medicare and Medicaid, Medicaid will pay the lesser of:

- The full coinsurance and deductible amounts due, based upon the Medicare allowed amount, or
- Medicaid's maximum allowable fee for that service minus the amount paid by Medicare.

For QMB, if the service is not covered or is denied by Medicare, Medicaid will not reimburse.

Drugs that are not covered by Medicare Part B may be covered by Medicare Part D. Medicaid does not reimburse for Part D co-payments.

518.19.6 Medicare-Covered Drugs, Part D

Dual eligible members have prescription drug coverage through Medicare Part D. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

- Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions)
- OTC medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

Medicaid does not reimburse for Medicare Part D co-payments. Medicaid does not pay as the secondary payer on Medicare Part D covered drugs.

518.19.7 In-Home Parenteral Therapy (IHPT) Billing and Reimbursement Via Pointof-Sale

Billing for IHPT claims is accomplished through NCPDP Version D.0 electronic or 1.1 batch (paper claim) system. Instructions for the processing of claims are found in the general pharmacy manual information. The active ingredient(s) for each prescription is/are to be billed using the NDC and its respective unit of use. The drug portion of IHPT will be reimbursed online according to the current reimbursement policy. The codes used for the reimbursement of compounding services are inclusive of, but not limited to, diluents for reconstitution, IV fluids, and other supplies used in the compounding process.

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Billing shall correspond to those items and fees reflecting therapy for a duration of a maximum of 34 days as prior authorized by the Pharmacy prior authorization vendor. If the order is discontinued, any billing for agents that have not been delivered to the member must be reversed.

- **Pre-mixed Solutions or products requiring no compounding:** After receiving prior authorization, prescriptions for items which are dispensed with no compounding requirements shall be submitted for payment via POS or approved paper claim form using the NDC number of the product and the quantity dispensed. Reimbursement will be made using the established retail reimbursement policy. Do not use the NCPDP compound indicator.
- IV Drugs Requiring Compounding: Products for IHPT requiring compounding involve billing in multiple parts. Drug components shall be submitted online or on the approved paper claim form using the actual NDC's that were used and quantity of each drug component, as approved by the Pharmacy prior authorization vendor. Use the NCPDP compound indicator when the product includes multiple agents. Please note: reimbursement for the diluting agent is included in the compounding fee and shall not be billed as a component of the compounded IHPT product if reimbursement for a compounding fee is requested.
- **Compounding Fee:** The compounding fee which includes all components of the prescription compounding, such as sterile water, alcohol swabs, IV fluids, needles/syringes, etc., and professional services shall be submitted online or on the approved paper claim form. The authorization for reimbursement of the compounding fee will be issued from the Pharmacy prior authorization vendor upon receipt of a copy of the signed order from the prescribing physician. Do not use the NCPDP compound indicator.
- Units Dispensed: Units are defined by First Data Bank product classification. In general, if a drug requires reconstitution, the units submitted will be the number of vials. For example, a 2-gm vial of cephazolin is submitted as a quantity of "1" for each vial. If the drug or component is available in solution, the units are submitted in milliliters. For example, a 2ml vial of gentamicin injection (80mg/vial) is submitted as "2" for each vial. The actual amount used in compounding shall be submitted. Wastage shall be kept to a minimum. The units dispensed must match the amount prior authorized by the pharmacy prior authorization vendor.

The pharmacy prior authorization vendor Help Desk is available to assist providers with questions regarding proper unit billing. In all cases, the amount and duration of therapy for which the BMS is billed must match those ordered by the physician and delivered to the member.

- **Brand Name Justification:** If a drug being dispensed is a product for which a generic equivalent exists, the generic must be dispensed. The use of brand name products must be justified, as referenced in the general pharmacy instructions.
- **Supplies:** Please refer to <u>Chapter 506, Durable Medical Equipment, Prosthetics, Orthotics and</u> <u>Supplies (DMEPOS)</u> for coverage policy and billing instructions for supplies associated with IHPT.

REFERENCES

West Virginia State Plan references pharmacy services at sections 3.1-A(12)(a), 3.1-B(12)(a), supplement 2 to attachments 3.1-A and 3.1-B(12)(a) and reimbursement at 4.19-B(12)(a). The Plan also references vaccine administration by a pharmacist (other licensed practitioner) at supplement 2 to attachments 3.1-A and 3.1-B(6)(d)(3) and reimbursement at 4.19-B(6)(d)(3), 4.18-A outlines required copayments.

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GLOSSARY

Definitions in <u>Chapter 200, Definitions and Acronyms</u> apply to all West Virginia Medicaid services, including those covered by this chapter. Definitions in this glossary are specific to this chapter.

340B Program: A Federal program administered by the Health Resources and Services Administration (HRSA) whereby certain designated facilities purchase prescription medications at deep discounts, allowing these facilities to offer some medications to their patients at greatly reduced prices.

Dispense As Written (DAW): A numerical value used by providers to explain the dispensing of a brandname product instead of a generic one.

Drug Efficacy Study and Implementation Program (DESI): Drugs determined by the Food and Drug Administration as lacking substantial evidence of effectiveness.

End Stage Renal Disease (ESRD): The stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

First Data Bank (FDB): A database company for drug pricing and drug utilization review (DUR) edits.

Federal Drug Rebates: Payments made by pharmaceutical manufacturers to the states for drugs dispensed to Medicaid members.

Federal Upper Limit (FUL): Maximum allowable cost established by CMS for certain prescribed drugs.

Home IV: Intravenous medications administered in the home, provided by specialized pharmacies, which require the services of a nurse or trained caregiver.

In-Home Parenteral Therapy (IHPT): The parenteral administration of fluids, drugs, chemical agents, or nutritional substances to members in the home setting.

Lock-In: Program administered through the retrospective DUR process to limit members to the use of one pharmacy provider.

Multi-Source Drugs: Drugs that are marketed or sold by two or more manufacturers or labelers.

National Provider Identifier (NPI): A standard unique healthcare provider identification number mandated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Parenteral: All routes of administration of substances other than gastrointestinal.

Pharmaceutical and Therapeutics Committee (P&T Committee): An advisory body that recommends drugs to West Virginia Medicaid for inclusion or exclusion relating to the PDL.

Pharmacy Prior Authorization Vendor: Agency designated by the BMS for prior authorizing prescription drugs.

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Qualified Medicare Beneficiary (QMB): A Medicaid program for beneficiaries who need help in paying for Medicare services. The beneficiary must have Medicare Part A and limited income and resources. For those who qualify, the Medicaid program pays Medicare Part A premiums, Part B premiums, and Medicare deductibles and coinsurance amounts for Medicare services.

Retrospective Drug Utilization Review (DUR): Review of member drug history records against predetermined standards to improve quality of healthcare and to educate physicians and pharmacists on common drug therapy issues.

Single-Source Drug: A drug that is available from only one manufacturer.

State MAC (SMAC): Maximum allowable cost for drug products or supplies established by the state Medicaid agency.

Supplemental Drug Rebate: A payment from a pharmaceutical manufacturer, negotiated by the state, in addition to the Federal rebate.

CHANGE LOG

REPLACE	TITLE	EFFECTIVE DATE
Entire Chapter	Pharmacy Services	October 1, 2015
Entire Chapter	Changes were made to: 518.1.9 Brand Name versus Generic Drugs 518.1.10 Pharmacies Participating in the 340B Program 518.15.2 Medicaid Members Enrolled in Managed Care Organizations 518.19.1 Ingredient Cost 518.19.2 Application of Dispensing Fee	July 20, 2018
Entire Chapter	Changes were made to: 518.1.6 Tobacco Cessation Program 518.1.7 Buprenorphine-Naloxone (Suboxone®) / Buprenorphine (Subutex®) Coverage (PA and Lock-In requirements were removed 518.3 Non-Covered Services 518.10 Pharmacies Participating in the 340B Program 518.12 Reporting of Cash Payments (also renamed to "Cash Payments")	December 1, 2020
Entire Chapter	Changes were made to: 518.15.3 Medicaid Members With End Stage Renal Disease (ESRD)	February 4, 2021
Entire Chapter	518.16.1 Limited Pharmacy Services or Ryan White Program claims updated.	July 28, 2021

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Entire Chapter 518.1.6 Tobacco Cessation. Added specific NRT and January 1, 2022 smoking cessation agents, added specific CPT codes covered for counseling, and formatted paragraphs. 518.1 Covered Services and 518.3 Non-Covered Services - Added HPV vaccine language 518.1.7 Buprenorphine-Naloxone / Buprenorphine Coverage - Removed brand names and added a link to the PDL. 518.1.3 Diabetic Testing Supplies and Syringes/Needles - Added hyperlink to the page where the Preferred Diabetic Supply List can be found. **Entire Chapter** 518.1.6 Updated Tobacco Cessation section March 16, 2023 518.1.7 Updated Buprenorphine-Naloxone / Buprenorphine Coverage 518.7 Certification – Updated out of state pharmacy enrollment policy. 518.10 Pharmacies Participating in the 340B Program added new billing requirements from CMS. 518.13 Member Counseling – Added clarification regarding audit policy. 518.19.3 Co-Payments – Updated post-partum coverage

CHAPTER 518 PHARMACY SERVICES