CONTENTS

GENERAL INFORMATION

This chapter describes the pharmacy services available under the Commonwealth of Virginia's State Plan for Medical Assistance (Medicaid). Pharmacy services are provided in accordance with the requirements of Social Security Act §1927 and are available to all categorically and medically needy individuals determined to be eligible for assistance. All medications and supplies must meet the pharmacy coverage criteria and the Virginia Administrative Code (VAC).

For the purpose of the Virginia Medical Assistance Program, a pharmacy provider is a Medicaid enrolled provider that is primarily engaged in dispensing prescription and over the counter medications and supplies outside of an institutional setting.

The policies described in this chapter apply to all enrolled providers of pharmacy services. Drugs, both legend and non-legend, covered by Virginia Medicaid will be dispensed through a licensed pharmacy or a dispensing physician, in accordance with Virginia State Board of Pharmacy procedures and licensure, if written on a tamper-resistant prescription pad/paper by a practitioner qualified to prescribe.

Virginia Medicaid Web Portal

The Virginia Medicaid Web Portal is the gateway for providers to transact all Medicaid and FAMIS (Family Access to Medical Insurance Security Plan) business via one central location on the Internet. The web portal provides access to Medicaid Memos, Provider Manuals, providers search capabilities, provider enrollment applications, training and education. Providers must register through the Virginia Medicaid Web Portal in order to access and complete secured transactions such as verifying Medicaid eligibility, service limits and service authorization or by submitting a claim. The Virginia Medicaid Web Portal can be accessed at: www.virginiamedicaid.dmas.virginia.gov.

Freedom of Choice

Virginia Medicaid individuals are free to choose a pharmacy provider enrolled in their fee-for-service or managed care plan when medications are a covered service. Provision of “free” items or incentives to Medicaid individuals as an enticement for their business may violate federal law and is prohibited. If a pharmacy provider is utilizing this practice, the Department of Medical Assistance Services (DMAS) may impose a civil money penalty sanction against the pharmacy provider.

Managed Care

Most individuals enrolled in the Virginia Medicaid program for Medicaid and FAMIS have their services furnished through contracted Managed Care Organizations (MCOs) and their network of providers. A provider eligibility check will occur during the submission of point-of-sale (POS) pharmacy claims, but all providers should check eligibility prior to rendering services that will be billed as medical claims to confirm which MCO the individual is enrolled in. The MCO may require a referral or prior authorization for the individual to receive services. All providers are responsible for adhering to this manual for Members enrolled in FFS, their provider contract with MCOs for Members enrolled in managed care and all relevant state and federal regulations.

There are several different managed care programs for Medicaid individuals (Medallion 4.0, Commonwealth Coordinated Care Plus [CCC Plus], Program for All-Inclusive Care for the Elderly

[PACE]). DMAS has different health plans participating in these programs. Go to the websites below to find which health plan participates in each managed care program in your area:

- Medallion 4.0: https://dmas.virginia.gov/for-providers/managed-care/medallion-40/
- CCC Plus: https://www.dmas.virginia.gov/for-providers/managed-care/ccc-plus/
- PACE: https://dmas.virginia.gov/for-members/for-adults/aged-blind-or-disabled/pace/

COVERAGE AND LIMITATIONS

GENERAL REQUIREMENTS

Medical Necessity

Only medications that are determined to be medically necessary may be covered for reimbursement by DMAS. The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary prescription orders shall be:

- Ordered by an authorized practitioner;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition; and
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational).

Prescription Requirements

Prescriptions may be written on a tamper-resistant pad or paper or may be transmitted to the pharmacy by any means which comply with the regulations of the Board of Pharmacy. If the prescription is not received as a written document, the information must be reduced to writing and filed sequentially by the pharmacy, as with any legend drug order. All legal requirements for storage and retrieval of documents must be observed. The drug must be labeled according to the prescriber's order and appropriate counseling must be offered to the member.

Automatic Refills and Shipments

Automatic refills and automatic shipments are not allowed for Fee-For-Service or Managed Care Members. Medicaid does not pay for any prescription (original or refill) based on a provider's auto-refill policy. 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 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 their responsible party may be subject to recovery. Any pharmacy provider who pursues a policy that includes filling prescriptions on a regular date or any type of cyclical procedure may be subject to audit, claim recovery or possible suspension or termination of their provider agreement.

Days' Supply Limitations

Covered drugs are covered for a maximum of a 34-day supply per prescription with the following exceptions:

- Select maintenance legend and non-legend drugs may be covered for a maximum of a 90-day supply per prescription per patient after two 34-day or shorter duration fills. Current list of qualified drugs may be found in Appendix E or on the DMAS pharmacy website at https://www.virginiamedicaidpharmacyservices.com/provider/documents.
- https://www.virginiamedicaidpharmacyservices.com/provider/documents.
- Routine contraceptives may be covered for up to a 12-month supply.

For prescription orders whose quantities exceed the allowed days' supply, refills may be dispensed in sufficient quantity to fulfill the prescription order within the limits of federal and state laws and regulations.

For unit-of-use drugs (i.e., inhalers, eye drops, insulin pen boxes) where the calculated days' supply exceeds the maximum allowed above, the entire unit should be dispensed for the maximum days' supply allowed for that medication.

Mandatory Generic Edit

The DMAS State Plan requires that prescriptions for multiple-source drugs be filled with generic drugs unless the physician or other licensed, certified practitioners certify in their own handwriting "Brand Medically Necessary" or if the brand name drug is listed on DMAS' PDL as the preferred product.

The prescription must be on file in the pharmacy and made available for review by DMAS Program auditors. This requirement also applies to telephone orders (the pharmacist should write "Brand Medically Necessary" on the telephoned order when instructed by the prescriber).

The Point-of-Sale (POS) system denies claims with a "substitute less costly generic" edit when a brand-name drug is dispensed without a "1" in the DAW field. For single-source drugs, providers should use a "0" in the DAW field when the prescriber does not designate "Brand Medically Necessary." If the pharmacist dispenses the brand name, because no generics are available in the marketplace (generic is not currently manufactured, distributed, or is temporarily unavailable), and the prescriber does not specify "Brand Medically Necessary," the pharmacist may enter a "9" or an "8" in the DAW field for proper reimbursement.

COVERAGE REQUIREMENTS

Requirements for Legend Drugs:

All legend drugs are covered with the following exclusions:

- OBRA '90 non-rebated drug products - Drugs distributed or manufactured by certain drug manufacturers or labelers that have not agreed to participate in the Federal Drug Rebate Program (See the Requirements for Rebatable Drugs section below)

- Agents used for anorexia or weight gain (an exception may be made for EPSDT members);

- Agents used to promote fertility;
- DESI (Drug Efficacy Study Implementation) drugs considered by the Food and Drug Administration (FDA) to be less than effective. Compound prescriptions, which include a DESI drug, are not covered;
- Drugs which have been recalled;
- Drugs used for hair growth;
- Drugs used for erectile dysfunction;
- Experimental drugs or non-FDA-approved drugs;
- Drugs used only for cosmetic purposes;
- Drug products dispensed after the labeled expiration date of the product.

Requirements for Rebatable (Legend or Non-Legend) Drugs

Virginia collects drug rebates on covered Medicaid prescriptions dispensed. These rebates are shared with the federal government on the basis of federal funds expended by Virginia Medicaid. Pharmacists must adhere to the following guidelines:

- The NDC code entered on the pharmacy claim must be the NDC code for the actual drug dispensed.
- The NDC code entered on the pharmacy claim must be the correct NDC code for the drug at the time of dispensing (Obsolete NDC codes do not capture rebates).
- Drug use data must be well documented (pharmaceutical manufacturers will not pay Virginia drug rebates on products if data are not well documented. Manufacturers can request program audits to determine what specific products have been dispensed).
- Drugs must be FDA approved.

Virginia Medicaid, Virginia Medicaid Managed Care Organizations, the Centers for Medicare and Medicaid Services (CMS), and the drug manufacturers may all request audits of provider records.

Requirements for Non-Legend Drugs

Virginia Medicaid covers certain FDA approved over-the-counter (OTC) drugs when used as therapeutic alternatives to more costly legend drugs. This policy allows the use of cost-saving alternatives in the Pharmacy program. Therefore, these products should only be prescribed for outpatients when the provider otherwise would have used a more expensive legend product. The choice of whether or not to use these additional products is to be determined by the member's prescribing health care provider. This expansion of OTC coverage in the outpatient population does not affect the current coverage standards for categories of drugs included for OTC coverage in the nursing facility environment.

Requests for OTC drugs are handled in the same manner as legend drugs (see the General Requirements section above). Drugs covered under this program must be supplied by companies participating in the CMS Medicaid rebate program.

Coverage of over-the-counter drugs is described below:

- Family planning drugs and supplies, insulin, and insulin syringes and needles are covered for all members except those residing in nursing facilities.

- Diabetic test strips are covered for members under 21 years of age only.

- Select drugs in the following specific therapeutic categories are covered when used as less costly alternatives to prescription drugs:
    - Analgesics
    - Antacids
    - Anti-Diarrheals
    - Anti-Emetics
    - Anti-Vertigo
    - Anti-Inflammatory Agents
    - Anti-Itch, topical
    - Antibiotics, topical
    - Antiflatulents
    - Antifungals, topical
    - Antihistamines (loratadine and various others)
    - Antivirals
    - Contraceptives
    - Dermatological Agents – various
    - Eye and Ear Preparations
    - Hemorrhoid Preparations
    - Iron Supplements
    - Laxatives, Cathartics, Bulk Producers, Stool Softeners
    - Mineral Supplements (calcium and various others)
    - Pediatric Electrolyte Solution
    - Pediculicides
    - Scabicides
    - Vitamins and Minerals (various)

- Non-legend Schedule V drugs are covered as legend regardless of the quantity dispensed.

- The Medicaid Pharmacy Program does not cover the following non-legend items:
    - Dietary items, such as sugar or salt substitutes;
    - Enteral nutrition products covered under Durable Medical Equipment (DME);
    - Supplies, including (but not limited to) antiseptics (e.g., hydrogen peroxide, merthiolate, tincture of iodine, mercurochrome, rubbing alcohol, antiseptic soaps, boric acid), first aid preparations (e.g., band-aids, gauze, adhesive tape), and miscellaneous supplies, such as cervical collar, asepto syringe, IV sets, and support stockings (certain supplies and items are considered to be DME);
    - Drug products dispensed after the labeled expiration date of the product;
    - Hair growth products;
    - Personal items, including (but not limited to) dentifrices, dental adhesives, toiletries, and other items generally classified as cosmetic; mouthwash and gargles; shampoos

(non-legend) and soaps; cough drops; depilatories, suntan lotion, and hair bleaches;
- Products used for cosmetic purposes;
- Non-FDA approved OTC medications; and
- Alcoholic beverages.

For OTC formulary coverage in Fee For Service:
https://www.virginiamedicaidpharmacyservices.com/provider/drug-lookup.

For members enrolled in Managed Care Organizations please contact the relevant MCO or review the relevant website.

See the Preferred Drug List (PDL) Program section for more information.

Requirements for Physician Administered Drugs (PADs)

Drugs which cannot be self-administered should be billed as a medical benefit to Virginia Medicaid by the physician or provider administering the drug. For details on coverage requirements under the medical benefit, please refer to Chapter IV of the Physicians Manual. Claims submitted for drugs deemed non-self-administered are denied and the message returned is "Medical Benefit: Provider to Bill as Medical Claim= (DMAS Edit Code = 394 or NCPDP Edit Code = 70.

DMAS allows select physician administered drugs (PADs) to be billed by pharmacies. Only PADs on the DMAS PDL will be covered under the pharmacy benefit in the FFS program. DMAS will continue to cover physician/practitioner administered drugs and devices not on the DMAS PDL through the medical benefit. For Managed Care Members, please contact the relevant MCO.

Specific Requirements for Individual Legend Drugs

- **Atypical Antipsychotics in Children Under the Age of Eighteen (18)**
  The Department of Medical Assistance Services (DMAS) requires specific clinical criteria be met for atypical antipsychotics prescribed to new patients under the age of eighteen (18). This requirement applies to both Fee-For-Service and Managed Care Members. DMAS has established the following service authorization (SA) criteria:
  - The drug must be prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation AND,
  - The member must have an appropriate diagnosis, as indicated on the attached SA form AND,
  - The member(s) must be participating in a behavioral management program AND,
  - Written, informed consent for the medication must be obtained from the parent or guardian

  Service Authorizations will be authorized for six (6) months, after which a new SA will need to be obtained. If the SA criteria listed above are not met, a thirty (30) day emergency fill will be allowed and the SA request will be reviewed by a board certified Child and Adolescent Psychiatrist. A copy of the Service Authorization form may be found at https://www.virginiamedicaidpharmacyservices.com/asp/authorizations.asp.

- **Weight Loss Drugs**

Drugs approved by the FDA for weight loss may be covered for members who meet specific criteria in the FFS program. For information on coverage for Managed Care Members, please contact the relevant MCO. Such coverage shall be provided only when a service authorization has been approved based on a certificate of medical need and the supporting documentation. Providers should consider the following factors in determining the need for the use of anti-obesity drugs:

- Conformity of the member's condition to the Social Security Administration (SSA) definition of obesity as a disability as found in Disability Evaluation Under Social Security (SSA Publication 64-039), Part III, § 9.09, which requires a weight in excess of 100 percent of the SSA-defined desired level and a concurrent condition defined in the same section of SSA definitions relating to impairment by virtue of endocrine systems and obesity;
- Presence of a life-threatening condition, documented by the treating physician; compliant with General Regulation 18 VAC 85-20-90, Pharmacotherapy for weight loss as set forth by the Virginia Board of Medicine, as delineated in its Board Briefs, Newsletter #52 (Spring 1997);
- The manufacturer's directions for the specific drug's therapy;
- Assessment of the risk-benefit ratio related to the member's commitment to compliance in treatment.

Documentation presented for consideration should include, but is not limited to:

- Physical evaluation, including age, height, eight, body mass index (BMI);
- Psychiatric or psychosocial evaluation;
- Documented medical record evidence of functional disability;
- Documented medical evidence of previous conservative medical management;
- Documentation that other causes of obesity have been ruled out (for example, hypothyroidism);
- Documentation of the extent of concurrent medical problems; and
- Documentation of the attending physician certifying the determination that the member's life is at risk due to obesity.

PREFERRED DRUG LIST PROGRAM (PDL)

DMAS' PDL Program provides clinically effective and safe drugs to its members in a cost-effective manner. The PDL is a list of preferred drugs by select therapeutic class for which the Medicaid program allows payment without requiring service authorization (SA) except where medically necessary. The PDL applies to all Medicaid and FAMIS Members enrolled in both fee-for-service (FFS) and managed care (MCO).

Based on reviews by the DMAS P&T Committee, medication classes may be added to the PDL as either closed or open classes, or may be excluded from the PDL. Medicaid Members may access preferred products on the PDL without meeting any service authorization criteria, unless DMAS deems a clinical service authorization necessary for the safety of the member. To access non-preferred medications on the PDL, the Medicaid Member must meet the service authorization requirements. The FFS program will always cover the posted PDL exactly. MCO plans must cover closed classes identically to the posted PDL, whereas the MCO plans may add additional preferred products to their formulary in open classes. Non-PDL classes are managed separately by FFS and the MCO plans. Therefore, preferred products and requirements for accessing medications in non-PDL classes may vary across MCO plans.

The complete list of pharmaceutical products included on the Virginia Medicaid's PDL may be accessed at https://www.virginiamedicaidpharmacyservices.com/provider/preferred-drug-list. Comments regarding this program may be emailed to the P&T Committee at pdlinput@dmas.virginia.gov. Service authorization forms can be found on the DMAS web portal at https://www.virginiamedicaid.dmas.virginia.gov/wps/portal under the provider services drop down in the provider forms section, or at: www.virginiamedicaidpharmacyservices.com/provider/authorizations.

While Medicaid MCO plans are required to use the same service authorization criteria as the FFS program for drugs on the PDL, methods of submitting service authorizations may vary. Please contact the relevant MCO for any queries related to submitting service authorizations for Managed Care Members.

Step Therapy Criteria

The P&T Committee and DUR Board have approved step therapy criteria for several drug classes included on the PDL. Preferred drugs with additional step therapy criteria may require the submission of a service authorization. The drug classes with step therapy criteria can be viewed at https://www.virginiamedicaidpharmacyservices.com.

Process for Reviewing New Drugs in Classes Subject to the PDL

12VAC30-130-1000 requires the Pharmacy and Therapeutics (P&T) Committee to review any drug in a class subject to the Preferred Drug List (PDL) that is newly approved by the Food and Drug Administration (FDA) provided there is at least thirty (30) days notice of approval prior to the biannual meeting. As the FDA approves new drug products, the following process will be utilized to review for inclusion on the PDL:

1) If the new drug product belongs in a class of drugs that has been previously reviewed by the P&T Committee, the drug will immediately be classified as non-preferred and will require service authorization in order to be dispensed. Further determination of the status of the drug will be conducted by the P&T Committee.

2) A drug will be considered eligible for review if it meets one of the following criteria:

    - It is a "new brand" drug defined by the FDA as having the new drug application (NDA) approved which indicates that the product may be marketed in the United States. Once the new brand drug name appears on the FDA web site as approved it will be eligible for review.

    - It is a "new brand of an established generic" and has met the FDA definition above of "new brand".

    - It is deemed a "First Generic" on the monthly FDA update of "Generic Drug Approvals". First Generics are those drug products that have not previously been approved as generic drug products and are new to the marketplace.

3) New, non-branded generic drugs within an established generic drug class that have been previously evaluated by the P&T Committee will not be reviewed. These new generics will be deemed the same PDL status (preferred or non-preferred) as the existing generic drugs in the related class.

4) Product line extensions of drugs on the PDL, including strength and form, will be reviewed by DMAS and approved by DMAS' Director or his/her designee who will determine if a drug review by the P&T Committee is necessary.

5) The P&T Committee will evaluate the drug for clinical effectiveness and safety at the next scheduled annual review of the drug class. If the P&T Committee determines that the new drug represents a substantial breakthrough in therapy, the Committee can review the drug at its next scheduled meeting even if the annual review of the drug class is not being conducted.

6) The Committee will review appropriate studies and publications as part of the decision process. In addition, the Committee will be provided with information such as disease categories and demographics on the affected Medicaid population in order to assess the potential impact on the population. If the drug meets clinical efficacy and safety standards, the Committee will request applicable pricing information. Based on clinical information and pricing standards, the P&T Committee will determine if the drug will be included in the PDL.

7) If the new drug product does not fall within a drug class previously reviewed by the P&T Committee, the DMAS' Director or his/her designee will make the determination as to whether the drug requires P&T Committee review.

Service Authorization (SA) Process

A message indicating that a drug requires a SA is displayed at Point-of-Sale (POS) when a claim for a non-preferred drug is requested. Pharmacists should contact the member's provider requesting them to initiate the SA process. For FFS members, prescribers can initiate SA requests by mail, by faxing the SA form to 800-932-6651, or by contacting the Clinical Call Center at 800-932-6648 (available 24 hours a day, seven days a week). SA requests submitted by fax or mail will be responded to within 24 hours of receipt. SA forms for FFS members can be located on the DMAS web portal at https://www.virginiamedicaid.dmas.virginia.gov/wps/portal under the provider services drop down in the provider forms section or at: www.virginiamedicaidpharmacyservices.com/provider/authorizations.

For Medicaid Members enrolled in an MCO, please check with the appropriate plan for SA contact details and service authorization forms.

Preferred Drug List (PDL) – 72-Hour-Supply Processing Policy

The PDL Program provides a process where the pharmacist may dispense a 72-hour supply of a non-preferred, prescribed medication if the physician is not available to consult with the pharmacist, including after hours, weekends, holidays, and the pharmacist, in his/her professional judgment consistent with current standards of practice, believes that the member's health would be compromised without the benefit of the drug.

Any non-preferred drug (including both PDL and non-PDL classes) may be eligible if the pharmacist, in his/her professional judgement consistent with the current standards of practice, must believe that the Member's health would be compromised without the benefit of the drug. The pharmacy provider must contact the Clinical Call Center at 800-932-6648 to obtain the necessary information required for processing the 72-hour supply for Fee-For-Service (FFS) Members, or the appropriate Managed Care Organization (MCO) for Managed Care Members.

In FFS, the member will be charged a co-payment for this 72-hour supply (partial fill). However, a co-payment will not be charged for the completion fill. For correct copays, the prescription must be processed as a "partial" and "completion" fill.

For unit-of-use drugs (i.e., inhalers, drops, etc.), the entire unit should be dispensed for the 72-hour supply.

Preferred Drug List (PDL) – 72-Hour-Supply Dispensing Fee Process in FFS

Pharmacy providers are entitled to an additional dispensing fee (effective May, 2006) when filling the completion of a 72-hour-supply prescription for a non-preferred drug. To receive the additional dispensing fee, the pharmacist must submit the 72-hour supply as a partial fill, and when submitting the claim for the completion fill, enter “03" in the "Level of Service" (data element 418-DI) field. The additional dispensing fee is ONLY available (one time per prescription) to the pharmacist after dispensing the completion fill of a non-preferred drug when a partial (72-hour-supply) prescription was previously filled.

Any questions regarding the PDL process should be referred to the Clinical Call Center at 800-932-6648.

For the current dispensing fees, see 12 VAC 30-80-40: http://leg1.state.va.us/cgi-bin/legp504.exe?000+reg+12VAC30-80-40.

PDL/Service Authorization “Helpline” for FFS Members

The Clinical Call Center can be reached at 800-932-6648 (24 hours a day, seven days a week), to answer questions regarding the PDL and service authorizations. Providers can initiate an SA request by faxing the SA form to 800-932-6651, by contacting the Clinical Call Center at 800-932-6648 or via the internet. Information about the online SA process can be found at www.virginiamedicaidpharmacyservices.com. SA requests also can be mailed to:

Magellan Medicaid Administration
11013 West Broad Street
Glen Allen, VA 23060
ATTN: MAP Department/VA Medicaid

Please contact the relevant MCO for any questions on the service authorization process for Managed Care Members.

HOME INTRAVENOUS THERAPY

All information in this section applies to the FFS program only. Please contact the relevant MCO for any questions regarding Managed Care Members.

Home Infusion Therapy: Service Day Rate

Home infusion therapy is the intravenous administration of fluids, drugs, chemical agents, or nutritional substances to members in the home setting via intravenous (IV), central line or implanted pump/port. DMAS will reimburse for these services, supplies, and drugs only when they are determined to be:

- Medically necessary to treat a member's medical condition;
- In accordance with accepted medical practice; and
- Not for the convenience of the member or the member's caregiver.

For a provider to use the home infusion therapy service-day-rate method of billing, the member must:

- Reside in either a private home or a domiciliary care facility, such as an assisted living facility. Reimbursement for home infusion therapy for those in hospitals, nursing facilities, rehabilitation centers, and other institutional settings is not authorized;
- Be under the care of a physician who prescribes the home infusion therapy and monitors the progress of the therapy;
- Have body sites available for intravenous (I.V.) catheter or needle placement or have central venous access; and
- Be capable of self-administration or have a caregiver who can be adequately trained, is capable, and is willing to administer/monitor home infusion therapy safely and efficiently, and follow the appropriate teaching and adequate monitoring. In those cases where the member is incapable of administering or monitoring the prescribed therapy and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.

Provider Eligibility

Providers must have a National Provider Identification (NPI) to participate in the home infusion therapy program. Providers eligible to participate in this program are:

- Infusion. therapy providers;
- Home health agencies;
- Pharmacies;
- DME providers.

In addition to being a Virginia Medicaid provider, a participating provider must:

- Meet any state licensing and certification requirements;
- Render infusion therapy covered services;
- Use Medicaid-established billing guidelines; and
- Accept Medicaid reimbursement as payment in full.

Therapy Coverage

Medicaid has assigned a service-day-rate code and reimbursement rate for each of the covered therapies:

- Hydration Therapy;
- Chemotherapy;
- Pain Management;
- Drug Therapy;
- Total Parenteral Nutrition (TPN).

Service-Day-Rate Definition

This payment methodology provides a fixed amount for each day of infusion therapy. The service day rate (per diem) reimburses for all services delivered in a single day. This payment methodology will be mandatory for the reimbursement of all home I.V. therapy services, unless the member is enrolled in one of the waivered services outlined under "Special Considerations." Service day rates are based on an average day of service, and there will be no additional reimbursement for special or extraordinary services.

The service-day-rate payment will be in two service categories: Durable Medical Equipment (DME) and Pharmacy.

Durable Medical Equipment (DME):

- For (Service Day Rate) DME Per Diem - submit on a CMS-1500, with DME provider number and use the appropriate national codes (refer to Appendix B of the *DME* Provider Manual).

- Items in the DME service day rate include all supplies required to administer I.V. therapy, including but not limited to:
  - I.V. pump/pole rental/control devices;
  - Tubings, adapters, caps, needles, filters, cannulas, extension sets, and alcohol swabs;
  - I.V. start kits and central venous catheter dressing kits.

Refer to Appendix B of the *DME* Provider Manual for the S codes, which can be found on the DMAS website at https://www.virginiamedicaid.dmas.virginia.gov/wps/portal

Pharmacy:

- For (Service Day Rate) Pharmacy Per Diem, submit claims on the CMS-1500, with the Pharmacy provider number, the modifier "59" (in Block 24, field D under modifier), and use the appropriate S code.

- Pharmacy Per Diems are for services provided every 24 hours or less. For dosing schedules that are greater than 24 hours, the per diem should be billed separately for

each visit. (i.e. q72hrs should be billed using the corresponding S code for q24hrs on each day of service).

- Items in the pharmacy service day rate include the:
  - Diluents for the therapeutic agent;
  - Mixing and compounding;
  - Flush kits and solutions (heparin and saline);
  - Cassettes and bags/mini-bags.

Service day rates, by type of therapy, for basic components as delineated above are available on the DMAS web site. In order to determine if a procedure is covered, active or has special indicators (prior authorized, specialty forms, etc,) providers should go to the DMAS website located at http://dmasva.dmas.virginia.gov and look to the right of the page and click on the section that says "Procedure Fee Files"

The user will need to determine whether or not to use the CSV or the TXT format. The CSV is comma separated value and the TXT is a text format. The TXT version is recommended for users who wish to download the document into a database application. The CSV Version opens easily in an EXCEL spreadsheet file. Click on either the CSV or the TXT version of the file. Scroll until you find the code you are looking for. To determine whether a service is covered by DMAS you need to access the Procedure Rate File Layouts page from the DMAS Procedure Fee Files. Flag codes are the section which provides you special coverage and/or payment information. A Procedure Flag of "999" indicates that a service is non-covered by DMAS.

Drugs

Drugs providing the therapy's active ingredient are reimbursed according to Medicaid's payment methodology.

Dispensing fees shall be added to the drug cost when applicable. One dispensing fee per month per member per NDC will be allowed, and the member co-pay shall be deducted if applicable.

Multiple Therapies

Multiple drug therapies of the same type of therapy are included in one service day rate of reimbursement. For example, if a member receives two antibiotics under drug therapy on the same day, the provider may only bill one service day rate for the pharmacy services. The individual antibiotics may be billed separately as active ingredients on the Daily Pharmacy Drug Claim Ledger Form (DMAS-173 R6/03), Point-of-Sale (POS) online billing, or other approved electronic billing method.

In the event of incompatible drug administration, the provider should use separate HCPCS codes (See Appendix B of this Manual for the appropriate HCPCS codes to use) to allow for the rental of a second infusion pump and the purchase of extra administration tubing. When applicable, DMAS may be billed in addition to the service day rate codes for the rental of the second infusion pump and extra administration tubing. There must be documentation to support the use of these codes in addition to the service day rate on the I.V. Implementation Form (DMAS-354).

Multiple therapies of different therapies under DME will be reimbursed at 100% for the most expensive therapy and 50% for the second and each additional therapy. Bill for the active

ingredient on the Daily Pharmacy Drug Claim Ledger Form (DMAS-173 R6/03), Point-of-Sale (POS) online billing, or other approved electronic billing method.

Pharmacy

The service day rate for covered home I.V. services is explained below. The service day rate is billed on the CMS-1500 claim form. The rate for TPN therapy includes the usual components of this therapy. However, the service day rate does not include the fluids for hydration therapy or the active ingredient in chemotherapy, pain management, or drug therapies. Bill for these components separately as pharmacy claims on the Pharmacy Drug Claim Ledger Form (DMAS-173 R6/03), Point-of-Sale (POS) online billing, or other approved electronic billing method.

In this manner, the active ingredient is identifiable in the Drug Utilization Review (DUR) program, and the Center for Medicaid and Medicare Services (CMS) rebate program operated by the agency.

Hydration Therapy

Hydration therapy is the intravenous administration of fluids, electrolytes, and/or other additives.

The pharmacy service day rate includes, but is not limited to:

- Drug component: Electrolytes and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Claims must be billed on the CMS-1500 (8-05) Claim Form using the correct HCPCS codes.

The hydration solution is billed on the Daily Pharmacy Drug Claim Ledger (DMAS-173 R6/03), DMAS-174 R6/03, Point-of-Sale (POS) online billing, or approved electronic billing method.

Pain Management

Pain management is the intravenous administration of narcotics or other drugs to relieve pain.

The pharmacy service day rate includes, but is not limited to:

- Drug component: diluent, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Claims must be billed on the CMS-1500 (8-05) Claim Form using the HCPCS codes S9325, S9326, S9327, and S9328.

Chemotherapy

Chemotherapy is the administration of chemical agents designed to have a specific effect upon disease-causing cells or organisms.

The pharmacy service day rate includes, but is not limited to:

- Drug components: diluent, and flushes (heparin and saline); and

- Cassettes/bags/mini-bags, mixing, and compounding.

Claims must be bill on the CMS-1500 (8-05) Claim Form using the HCPCS codes S9329, S9330, and S9331.

Special Notes
- Hydration solutions may be billed separately (see "Hydration Therapy").

Drug Therapy

Definition: Drug therapy is the intravenous administration of antibiotics or other drugs.

The pharmacy service day rate includes, but is not limited to:

- Drug components: diluent, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Claims must be billed on the CMS-1500 (8-05) Claim Form using the HCPCS codes S9338, S9348, S9490, S9494, S9497, S9500, S9501, S9502, S9503, and S9504.

Total Parenteral Nutrition (TPN)

TPN is the administration of nutritional substances by intravenous infusion to nourish members who are malnourished or may develop malnutrition and who are not candidates for enteral support. DMAS will reimburse for TPN and related services and supplies only when all of the following conditions are applicable:

- The TPN is used as the sole source of nutrition;
- There is a physician's statement of medical necessity in the member record indicating the diagnosis with a brief clinical history;
- The short- and long-term plans for the requested service are given; and
- The name and address of the pharmacy supplying the prescriptions are given.

The pharmacy service day rate includes, but is not limited to, the:

- Drug components: diluent, electrolytes, nutritional additives, lipids, and flushes (heparin and saline); and
* Cassettes/bags/mini-bags, mixing, and compounding.

Claims must be billed on the CMS-1500 (8-05) Claim Form using the HCPCS codes S9364, S9365, S9366, S9367, and S9368.

Special Notes

* The pharmacy service allowance includes solutions, routine additives (such as potassium chloride (KCl), multivitamins (MVI)), and lipids (Insulin is an example of a medication that may be billed separately with TPN therapy).

Procedures for Documentation Related to Total Parenteral Nutrition (TPN) Services

Providers do not need to submit documentation of medical necessity to the Director of Medical Support Services at DMAS for TPN services provided by pharmacies.

Prescribers must document the prescription order in the member's medical record and verify the medical necessity by providing a description of the related clinical symptoms and diagnosis in the record. These documentation procedures should expedite the provision of services to Medicaid members. DMAS will use its post-payment utilization review to verify compliance with these requirements.

VALID PRESCRIBER IDENTIFICATION NUMBERS REQUIRED

Claims for prescription services submitted by pharmacies provide the basis of several Medicaid programs, including Drug Utilization Review, Member Medical Management, and Provider Review. Inaccurate or incomplete data related to prescriber identification may negatively impact the success of these programs. Pharmacists are requested to ensure that all required information is submitted on the appropriate claim medium.

Pharmacists are required to enter a valid NPI number on all pharmacy claims. Based on this requirement, an online alert will prompt pharmacists to use a correct NPI number on all POS transactions. The message will read: "PRESCRIBING PHYSICIAN NOT ON FILE".

Prescriber NPI numbers can be obtained in a searchable database from the **CMS/ NPPES Registry** at https://nppes.cms.hhs.gov/NPPES/.

When submitting real-time (Point-of-Sale) claims transactions, the 10-digit NPI for the Prescriber ID and Provider ID must be sent with the Qualifier '01'. Please see the following link for the NCPDP Companion Guide under the EDI support tab, which will provide instructions for submitting claims with the appropriate Qualifier: www.virginiamedicaid.dmas.virginia.gov.

PAYMENT FOR SERVICES

General Information

Medicaid participation is limited to providers who accept, as payment in full, the amounts paid by DMAS fee-for-service (FFS) program or contracted Managed Care Organizations (MCO)plus any deductible, co-payment, or co-insurance required by the State Plan to be paid by the individual. While payments by DMAS may be less than the provider's usual and customary charge, members may not be charged for the difference. Members are only responsible for the Medicaid co-payment as applicable.

Payments for services will not exceed the amounts indicated for payment in accordance with the policy and methods described in the *State Plan for Medical Assistance Services* and described in 42 CFR § 447.331.

All NDC numbers used for billing must be recent and accurate as to manufacturer, product code, and package size. For instance, do not bill the NDC of a 100-unit package if the drug was dispensed from a bottle of 1000. Use of the correct NDC may be audited. Payment adjustments or charges of billing fraud may occur if it is shown that excessive billings were presented as a result of incorrect NDC numbers being submitted.

Payment Methodology for Medicaid FFS

Payment methodology for drugs dispensed by Medicaid enrolled pharmacies is defined in VAC 12VAC30-80-40 at http://leg1.state.va.us/cgi-bin/legp504.exe?000+reg+12VAC30-80-40. Drug claims shall be reimbursed using the following methodology:

(1) For brand drugs, the lessor of:
   a. The National Average Drug Acquisition Cost Brand (NADACB) price as established by CMS
   b. The provider's usual and customary charge to the public, as identified by the claim
   c. The Federal Upper Limit (FUL) as established by CMS in 42 CFR § 447.332

(2) For generic drugs, the lessor of:
   a. The National Average Drug Acquisition Cost Generic (NADACG) price as established by CMS
   b. The provider's usual and customary charge to the public, as identified by the claim
   c. The Federal Upper Limit (FUL as established by CMS

(3) If a National Average Drug Acquisition Cost does not exist than the drug claim shall reimburse at the lessor of:
   a. The Wholesale Acquisition Cost (WAC)
   b. The provider's usual and customary charge to the public, as identified by the claim
   c. The Federal Upper Limit (FUL as established by CMS

(4) If neither a National Average Drug Acquisition Cost (NADAC) or a Wholesale Acquisition Cost (WAC) exists, than the claim will deny and return a message "Drug Cost Not On File".

Payments for drugs include the allowed drug cost plus only one dispensing fee per month per member for each specific drug entity with the exception of 72-hour emergency prescriptions for non-PDL drugs. For the current dispensing fees, see 12 VAC 30-80-40: http://leg1.state.va.us/cgi-bin/legp504.exe?000+reg+12VAC30-80-40. This reimbursement formula applies to all prescriptions dispensed to non-institutionalized members as well as to services for nursing facilities. Co-payments will be deducted where applicable.

Payment Methodology for managed care claims will vary. Please direct any questions to the relevant MCO.

Pharmacy Reimbursement for Drugs Purchased under the 340B Program

Pharmacies participating in the 340B program established by Section 340B of the Public Health Services Act must notify DMAS regarding their participation. Said participants must also be listed on the HRSA website, www.hrsa.gov/opa/. Drugs with discounts generated from participation in this program are not eligible for federal drug rebates and pharmacy claims from 340B providers

are not submitted to manufacturers for drug rebates. Pharmacies dispensing drugs purchased under the 340B program must submit **actual acquisition cost (AAC)** on FFS claims for a drug product and will be reimbursed AAC plus a dispensing fee where applicable. 340B entities are not required to report actual acquisition cost on claims submitted to Medicaid Managed Organizations (MCOs), but must indicate that a 340B drug was dispensed. 340B entities/providers who are enrolled with DMAS as a provider type other than pharmacy shall charge DMAS no more than their actual acquisition cost for the drug. For more information, please refer to the Frequently Asked Questions – 340B document, which may be found at:
https://www.virginiamedicaidpharmacyservices.com/provider/documents.

NCPDP Prescription Claims Processing 340B Identifier

Pharmacy providers submitting FFS claims through the point-of-sale (POS) for drugs purchased through the 340B program must identify the drug as a 340B purchased drug by populating the Submission Clarification Code (42Ø-DK) field with a value of "20" **and** the Basis of Cost Determination (42Ø-DN) field with a value of "08". In addition, the pharmacy must submit their actual acquisition cost (minus any discounts) for the drug claim using NCPDP field 409-D9 Ingredient Cost Submitted. The following NCPDP denial edits and/or Virginia Medicaid edits may be posted if the claim is not submitted correctly:

- **8R = Submission Clarification Code Not Supported.** (DMAS edit = 1621) The billing provider is not enrolled with Virginia Medicaid as a 340B entity.
- **34 = M/I Submission Clarification Code**. (DMAS edit = 1620)
- **DN = M/I Basis of Cost Determination**. (DMAS edits = 85)
- **DQ = M/I Usual and Customary Charge**. (DMAS edit = 1623). The submitted acquisition cost is greater than the Virginia Medicaid allowed amount and Submission Clarification Code = 20 and Basis of Cost = 8, the claim will deny. NOTE: Claims will continue to deny if the acquisition cost is missing or invalid for existing DMAS edit = 0014.

Pharmacy providers submitting managed care claims through the POS system for drugs purchased through the 340B program must identify the drug as a 340B purchased drug by population the Submission Clarification Code (42Ø-DK) field with a value of "20".

For outpatient medical claims, 340B providers must indicate the use of drugs purchased through the 340B program using one of the modifiers of UD or JG or TB.

Contract pharmacies may not submit claims to DMAS for drugs purchased through a 340B program. A 340B contract pharmacy MUST carve out Virginia Medicaid pharmacy claims from its 340B operation.

Nursing Facility Services

Payments for pharmacy services provided to FFS members residing in nursing facilities are described below:

- Payments are based on the lowest of the allowed amounts or the usual and customary charge as described above.

- Legend drugs
    - The allowed drug cost plus up to two dispensing fees per month per member for each specific drug. If refilled more than twice within the same calendar month, only the allowed drug cost is paid. This reimbursement formula applies to unit-dose and non-unit-dose dispensing.
    - For schedule II drug incremental fills, the dispense fee will be prorated to the equivalent of two dispensing fees, based on the percentage of the prescription dispensed.
    - CMS federal upper limits apply for unit-dose dispensing.
    - For institutional claims, the metric quantity reported on the claim is expected to reflect the quantity of the drug which has been administered to the member during the billing period.

- Non-legend drugs are paid in the same manner as Legend drugs

- Nursing facilities may bypass the early refill edits if required to supply medication for new patients, but must be registered as an LTC facility to do so. For more information, see the Nursing Facilities Provider Manual

For Managed Care Members, please contact the relevant managed care organizations.

Co-payments

The following members are always exempt from co-payments:

- Children under 21 years old;

- Individuals receiving long-term care services, hospice care; and

- Home and Community-Based Waiver members.

The following services are never subject to co-payments:

- Services delivered in the emergency room;

- Emergency services delivered in other settings;

- Pregnancy-related services; and

- Family planning services (including family planning drugs and methods). NOTE: Prescribing physicians should indicate "PREGNANCY" on the prescription form for prescriptions related to the women's pregnancies.

All other members are responsible for a co-payment for each prescription in the FFS program.

Co-payment amounts for fee-for-service members are:

- One dollar ($1.00) co-pay for generic drug; and
- Three dollars ($3.00) co-pay for single-source or "Brand Medically Necessary" drugs.

Members have been notified that the inability to pay the co-payment at a particular time does not relieve them of that responsibility.

Managed Care Organizations may not charge copays for Medicaid Members, but will charge copays for FAMIS Members.

IMMUNIZATIONS AND VACCINES

Eligibility and Coverage under Medicaid Fee-For-Service (FFS)

For Medicaid-eligible members, routine immunizations will vary depending on patient age and Medicaid program (I.e. whether Members are covered under Medicaid Expansion or traditional Medicaid).

For Members under the age of 21, immunizations are covered under Virginia Medicaid's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program based on the Advisory Committee on Immunization Practices (ACIP) recommendations by age. The federal Vaccines for Children Program (VFC) provides free vaccines for children up through the age of 18, therefore Medicaid children under the age of 19 are not eligible for vaccination through pharmacies. For children ages 19 and 20, reimbursement for vaccines will be made to any eligible provider as defined in § 54-3408 of the Code of Virginia. For more information on immunization coverage under the EPSDT program, see Supplement B of the Physician/Practitioner Provider Manual. For more information on the VFC program, see Chapter IV of the Physician/Practitioner Provider Manual.All Provider Manuals may be accessed under the Provider Services dropdown menu at: https://www.virginiamedicaid.dmas.virginia.gov/wps/portal.

Individuals covered by EPSDT or Medicaid Expansion may receive the following ACIP recommended vaccines (members $\geq$ 19 years of age) through the pharmacy:

- The pneumococcal vaccines
- The tetanus vaccines
- The HPV vaccines for members $\leq$ 26 years of age
- The influenza vaccines on a yearly basis
- The zoster vaccine for members between age 50 and 64

Pharmacy claims for immunizations for all other individuals are limited except for instances when:

* The immunization is necessary for the direct treatment of an injury, such as tetanus vaccinations.
* The immunization is a pneumococcal or influenza vaccination given as part of a plan of treatment

Medicaid Managed Care Organizations (MCOs) may cover additional immunizations for adults not covered by the FFS program through the pharmacy POS as a value-added service. Please contact the relevant MCO for coverage information.

Reimbursement for Vaccines for FFS claims

Medicaid enrolled pharmacies can submit claims for the influenza vaccines using the pharmacy POS claims processing system. Influenza vaccines will be reimbursed under the payment methodology described in the "Payment for Services" section above fore FFS claims, and under the relevant plan payment methodology for MCO claims.

Please note DMAS will not cover immunizations for Members age 65 and older, as these claims should be submitted to Medicare as primary payer. Medicaid does NOT act as secondary payer for Medicare claims. For members with any other third party coverage, immunization claims should be submitted to these payers as primary, with any copays submitted to Medicaid as secondary if needed.

POINT-OF-SALE (POS) PRESCRIPTION DRUG PROGRAM

The Point-of-Sale (POS) Prescription Program is available to Medicaid Pharmacy Providers for both the Fee-For-Service (FFS) program and the managed care (MCO) program. In addition to the POS system, Virginia Medicaid FFS and MCOs provide a Prospective Drug Utilization Review (ProDUR) Program. Instructions below refer to the FFS program and may vary by MCO. Please refer to the relevant MCO for any managed care claims.

Pharmacies submitting claims through POS must make necessary arrangements through their software vendors with regard to equipment, input lines, and testing. Providers will be notified when on-line access to POS is available to the provider.

Requirements for Submission of POS Claims

Virginia Medicaid requires that a pharmacy submitting POS claims use VersionD.0, a standard format developed by the National Council for Prescription Drug Programs (NCPDP). Software capable of producing claims in this format may be obtained from a number of vendors. DMAS' fiscal agent must certify the software before claims can be accepted. Arrangements for a switching company can be made directly or through the provider's software vendor. The switch or network serves as a communication link between the pharmacy and DMAS's fiscal agent.

How to Enroll as a FFS POS Pharmacy

The following steps must be completed prior to submitting Point-of-Sale claims: a Pharmacy Point-of-Sale Authorization Form must be completed by the provider; testing must be completed (see the "Exhibits" section at the end of this chapter for a sample form); and an authorized approval letter must be obtained from DMAS. Chain pharmacies must return their completed POS Authorization Form to their billing headquarters. All other pharmacies must return their completed POS Authorization Forms directly to:

Virginia Medicaid Provider Enrollment Services
P.O. Box 26803

Richmond, VA 23261-6803

Submission of POS claims may not take place until an authorized approval letter has been sent to the pharmacy by DMAS.

To enroll as a pharmacy in the managed care program, the pharmacy provider must enroll separately with each MCO. Contact the relevant MCO for more information.

Adjudication of FFS Claims

Since POS claims are processed online in a real-time environment, claims submitted through on-line POS will be either paid or denied. There are some claims that will be denied for PA due to high cost. These claims include the following:

- Charges greater than $4,999.99
- Compounds above $250 per claim or $499,99 per month (rolling)
- Certain service authorizations

With respect to the effects of the ProDUR Program on the adjudication of claims, refer to the information in the ProDUR section below.

THIRD PARTY LIABILITY (TPL) PROCEDURES FOR POS PHARMACY FFS CLAIMS

In order to conserve Medicaid dollars and as payer of last resort on pharmacy claims, DMAS uses a process of Coordination of Benefits (COB) for Third Party Liability (TPL) collections at the point of sale. For pharmacy claims having a service date on or after June 20, 2003, DMAS will send an online claim denial message to pharmacy providers submitting claims for which the member has other insurance coverage. The messages are shown in the table below.

VA Code	*Virginia Denial Message Text*	*NCPDP Code*	*NCPDP Reject Message Text*
313	Bill Any Other Available Insurance	41	Submit Bill To Other Processor Or Primary Payer
387	Primary Carrier Payment Needs Explanation	13	Missing/Invalid Other Coverage Code

DMAS requests that providers who receive either of these messages verify whether the member has additional coverage. If the member acknowledges such coverage, the pharmacist should submit the claim first to that third party. Once the other insurer adjudicates the claim, the claim may be resubmitted to DMAS using appropriate messages in NCPDP data element fields, "OTHER COVERAGE CODE" and "OTHER PAYER AMOUNT." These fields are included in existing payer specifications. In order to submit an override to the denial, the pharmacist must use the appropriate response in each field as shown below. In the case where a member denies having additional coverage, the responses to be used in these fields are also noted below.

The pharmacy TPL editing is based on the NCPDP "Other Coverage Code" standard values (Version 5.1). The allowed values and their definitions are as follows:

00 – Not specified
02 – Other coverage exists – payment collected
03 – Other coverage exists – this claim not covered
04 – Other coverage exists – payment not collected

If a member denies having other coverage, the pharmacist should call the call center at 1-800-932-6648 for FFS claims, or the relevant MCO for managed care claims. Pharmacists are requested to make every effort to capture TPL payments where possible in order to maximize the potential cost savings to the Medicaid program.

Virginia Medicaid, always the payer of last resort, will only pay claims to the maximum of the Virginia Medicaid Allowed Amount. The coordinated benefit payment of the TPL amount and any additional Medicaid payment will be equivalent to the appropriate payment allowed under DMAS payment rules. Therefore, the total payment may not appear to correspond to the submitted claim amount. The final adjudication under Medicaid will show the appropriate co-pay to be collected from the member. The member is only responsible for the applicable Medicaid co-pay.

PROSPECTIVE DRUG UTILIZATION REVIEW (PRODUR) SYSTEM

The ProDUR system functions in conjunction with the POS Program. As a pharmacy claim is being electronically edited for eligibility and claims adjudication, the claim may also be edited against selected drug-use criteria. Since this edit (review) occurs before the prescription is filled, it is a prospective system. In the FFS program, all ProDUR criteria have been reviewed, revised, and approved by the Virginia Drug Utilization Review (DUR) Board, a group of nurses, pharmacists, and physicians who oversee the DMAS DUR activities. Each MCO conducts a separate DUR Board, so specific criteria may differ by plan. If an exception to one or more ProDUR criteria is identified, a message will be transmitted on line to the pharmacist. The pharmacist has the opportunity to use the message as the focus of member counseling or prescriber communication. Among NCPDP-standardized messages, which the pharmacist may receive, are messages identifying drug interactions, age contraindication, drug-disease contraindication, pregnancy contraindication, excessive dose with/without an age qualifier, insufficient dose with/without an age qualifier, early refill, underutilization (late refill), and therapeutic duplication. Early refill and therapeutic duplication are denied and require intervention.

ProDUR implementation does not impact the claims adjudication edits, such as eligibility verification.

For POS transmission problems or POS set-up information for FFS claims, contact the Helpdesk at **1-800-932-6648**. For managed care claims, contact the relevant MCO Helpdesk.

ProDur Programs (Expanded)

In July 2007, Virginia Medicaid implemented expanded ProDUR programs for dose optimization and maximum quantity limits. Claim denials are made at point-of-sale for both dose optimization and maximum quantity limits when dispensing outside of established guidelines.

Dose Optimization

The dose optimization program identifies high cost drugs where all strengths have the same unit cost and the standard dose is one tablet per day. By providing the highest strength daily dose, the

number of units dispensed is minimized. Dose optimization edits are established for a small number of drugs in the FFS program, and are available at:
http://dmasva.dmas.virginia.gov/Content_atchs/forms/DMAS-171.pdf

For Managed Care Members, please contact the relevant MCO plan.

Maximum Quantity Limits

Maximum quantity limits involve identifying high cost products where a days supply is defined by a set number of tablets. This strategy establishes quantity limits based on commonly accepted clinical dosing practices. Maximum quantity limit edits are established for a small number of drugs. Please see https://www.virginiamedicaidpharmacyservices.com/provider/authorizations for the FFS program. Pharmacy providers will receive a claim denial when these quantity limits are exceeded. The Clinical Call Center can be reached at **1-800-932-6648** to answer questions regarding maximum quantity limits for FFS claims. Please contact the relevant MCO for managed care claims.

Early Refills and Therapeutic (Class) Duplication Edits on FFS claims

DMAS has an early refill denial edit and therapeutic (class) duplication edit as an enhancement of the Medicaid ProDUR activities requirement. These POS edits expand ProDUR activities to include the denial of unjustified requests for early prescription refills or therapeutic (class) duplicate products. A mechanism has been provided for override of the denial for therapeutic (class) duplicate products in unusual situations as identified below.

For legend drugs dispensed for 90 days or less, "early refill" is defined as "when a prescription refill is requested before 75% of the calculated days' supply has elapsed for the previously filled prescription." For all controlled medications and any contraceptives dispensed for greater than 90 days supply, an “early refill” is defined as “when a prescription refill is requested before 90% of the calculated days’ supply has elapsed for the previously filled prescription.” Providers must take extra care in verifying that a correct amount is shown for the "days' supply" entry for all prescriptions. Early Refill (ER) alerts that deny and require the pharmacist to enter an intervention code to override the denial, require a phone call for an override. The Pharmacist should call 800-932-6648 for the override for FFS claims. Managed Care Organizations may use different criteria for early refills. Please contact the relevant MCO for managed care claims.

The following table outlines the Early Refill (ER) Override Criteria.

Virginia Medicaid
ProDUR – Early Refill (ER) Override Criteria

Early Refill Approval Criteria:
- Dosage Adjustments - Incorrect days supply - Lost/Stolen/Destroyed - Vacation - Hospital kept Meds - Member Error* - Two meds needed - Nursing home in/out

*Member error will only be accepted as valid reason one time per drug per lifetime.

Approval Period: When the pharmacist calls he/she will receive a SA based on the approval criteria. The criteria will not allow more than ONE SA in 30 days, except in dosage adjustment cases.

Any questions regarding the Early Refill Edit can be referred to the Clinical Call Center. The Clinical Call Center can be reached at 800-932-6648, 24 hours, 7 days a week, to answer questions and provide SAs for Early Refill Alerts.

A denial edit for therapeutic duplication will occur when a product in the same therapeutic drug class as a concurrently utilized product (e.g., concurrent use of two calcium channel blockers) is billed. All covered drugs are subject to FDB ProDUR Therapeutic Duplication Edits.

An early refill claim or a therapeutic duplication within certain drug classes will be denied payment. The error code and message will appear on both the computer screen and the remittance advice.

The error codes and error message associated with the denial edits are:

Status Error Code	NCPDP Error Code	Message
418	**88**	**Early Refill/ProDUR**
942	**88**	**Therapeutic Duplication/ProDUR**

Although the error alert code and/or message appearing on the screen may vary in individual practice settings due to the configuration chosen by the software vendor providing POS access, the denial of payment will be shown by some combination of the error codes noted above with a message explaining the code. A payment denial code will require the provider to reverse the claim except in those cases where a valid reason can be documented for the need to override the denial. Overrides of the denial must be entered into NCPDP field 416 (PA/MC Code and Number). The provider should make sure that the software vendor verifies that this field is set up and active in the system.

Pharmacy providers are able to initiate an override in the POS system in cases where, according to specific parameters, the need for therapeutic duplication is justified. The valid reason for override must be documented in the system (NCPDP Field 416) and in the prescription records of the pharmacy. As with all documentation related to Medicaid claims, records of overrides must be maintained for a period of five years and must justify the override. The utilization of the override function by providers will be monitored.

In the following unusual circumstances, the pharmacist may override the denial. Pharmacists must exercise professional judgment before proceeding with the override function.

DMAS ProDUR Codes

ProDUR Reason for Service (Conflict Code) NCPDP Field 439	**Current Claims Disposition**	**New Claims Disposition**	**Professional Service (Intervention Code)** NCPDP Field 440 942	**ProDUR Result of Service (Outcome Code)** NCPDP Field 441
DD Drug-Drug	Message only	**Provider override**	AS = Member Assessment CC = Coordination of Care DE = Dosing Evaluation/ Determination MØ = Prescriber Consulted MR = Medication Review PØ = Member Consulted	1A 1B 1C 1D 1E 1F 1G 1H 1J 1K 2A 2B 3A 3B 3C 3D 3E 3F 3G 3H 3J 3K 3M 3N
MC Drug-Disease	Message only	**Provider override**	AS = Member Assessment CC = Coordination of Care DE = Dosing Evaluation/ Determination MØ = Prescriber Consulted MR = Medication Review PØ = Member Consulted	1A 1B 1C 1D 1E 1F 1G 1H 1J 1K 2A 2B 3A 3B 3C 3D 3E 3F 3G 3H 3J 3K 3M 3N
PG Pregnancy	Message only	**Provider override**	AS = Member Assessment CC = Coordination of Care DE = Dosing Evaluation/ Determination MØ = Prescriber Consulted MR = Medication Review PØ = Member Consulted	1A 1B 1C 1D 1E 1F 1G 1H 1J 1K 2A 2B 3A 3B 3C 3D 3E 3F 3G 3H 3J 3K 3M 3N
TD Therapeutic Duplication	Deny for 11 drug classes - provider	**Provider override – 11 Drug Classes* Anti-Ulcer Agents**	AS = Member Assessment	1A 1B 1C 1D 1E 1F 1G 1H 1J 1K 2A 2B

	override allowed	**ACE Inhibitors** **Angiotensn II Receptor Blockers** **Antidepressants** **Benzodiazepines** **NSAIDs (includes salicylates and COX-2s)** **Calcium Channel Blockers** **Thiazide Diuretics** **Loop Diuretics** **Potassum-Sparing Diuretics** **Narcotics** **Cardiac Glycosides-REMOVED** ***Note: some of these classes are included in the PDL**	CC = Coordination of Care DE = Dosing Evaluation/ Determination MØ = Prescriber Consulted MR = Medication Review PØ = Member Consulted	3A 3B 3C 3D 3E 3F 3G 3H 3J 3K 3M 3N

Outcome Code Definitions

1A	Filled As Is, False Positive	3A	Recommendation Accepted
1B	Filled Prescription As Is	3B	Recommendation Not Accepted
1C	Filled, With Different Dose	3C	Discontinued Drug
1D	Filled, With Different Directions	3D	Regimen Changed
1E	Filled, With Different Drug	3E	Therapy Changed
1F	Filled, With Different Quantity	3F	Therapy Changed - Cost Increase
1G	Filled, With Prescriber Approval	3G	Drug Therapy Unchanged
1H	Brand to Generic Change	3H	Follow-Up/ Report
1J	Rx to OTC Change	3J	Member Referral
1K	Filled With Different Dosage Form	3K	Instructions Understood
2A	Prescription Not Filled	3M	Compliance Aid Provided
2B	Not Filled, Directions Clarified	3N	Medication Administered

REIMBURSEMENT FOR MEDICATIONS SHOWING OBSOLETE NATIONAL DRUG CODE (NDC) NUMBERS

DMAS will consider current, active NDC (National Drug Code) numbers for reimbursement of drug charges. Claims for drugs bearing terminated NDC numbers will be denied. Numbers determined to be terminated are based on notification in quarterly updates from the CMS Drug Rebate Program. The Medicaid Drug Rebate Program is based on NDC-specific units billed and captures representative marketplace drug discounts based on accurate data invoiced each calendar year quarter to drug labelers. Incorrect/expired/terminated NDCs provide the basis for rebate disputes that delay drug rebate collections by the Commonwealth.

Regardless of the use of any commercial computer data updating service, each provider is personally responsible for submissions, which are correct in all details. Failure to maintain a complete, current record of product NDCs may result in payment delays as providers must resubmit corrected claims denied for terminated products. To be assured of proper, timely

reimbursement, providers should check each stock package used against the billing to be submitted. It is important to be sure that billings are made based on actual stock used.

MEDICARE PART D DRUG COVERAGE

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created a prescription drug benefit under the Medicare program, Medicare Part D, which began on January 1, 2006. It is a voluntary program available to all beneficiaries; however, the MMA mandates that Medicaid enrollees who are also Medicare eligible (dual eligibles) no longer have Medicaid prescription drug benefits, effective January 1, 2006.

Medicaid Coverage for Dual Eligible Members

Members with any form of Medicare coverage (either Medicare Part A or Part B) are eligible for Medicare Part D and are excluded from most Medicaid pharmacy benefits. Virginia Medicaid maintains records that dual eligible members are Medicare eligible and/or have eligibility for third party pharmacy benefits (other supplemental coverage); however, specific plan information will not be available. Medicaid pharmacy benefits for dual eligibles may be denied for any third party coverage. When submitting claims at POS, pharmacy providers will see the Medicaid coverage denial (rejected) reasons: "Verify Part D coverage." Virginia Medicaid is not responsible for reimbursement (full or partial) of any Medicare Part D drug.

There are specific drug classes that are excluded by law under the new Medicare Part D program. Medicaid continues to cover these medications within the currently established guidelines of its pharmacy benefit program. Coverage of these drugs is in accordance with existing Medicaid policy as described in Chapter 50 of the Virginia Administrative Code (12 VAC 30-50; "Amount, Duration, and Scope of Medical/Remedial Services"). Prescription drug claims processed for dual eligibles remain subject to Virginia Medicaid's PDL. Those drug classes that Medicaid continues to cover for dual eligibles are as follows:

- Medications for weight loss (SA required);
- Legend and non-legend medications for symptomatic relief of cough and colds;
- Prescription vitamins and mineral products (except prenatal vitamins and fluoride preparations);
- Over-the-counter medications (prescriptions are required);

Medicaid covers co-insurance and deductible for prescription drugs administered under Medicare Part B based on current coverage guidelines. Over-the-counter (OTC) drug claims processed for dual eligibles remain subject to Virginia Medicaid's PDL. Medicare Prescription Drug Plans (PDPs) cover compound drugs that include covered Part D drugs. Medicaid pays for compounded medications for Part D members when the active ingredients include only the above referenced medications.

Medicare Part D Prescription Drug Plan Information

Pharmacy providers are asked to contact the beneficiary's prescription drug plans with questions

regarding the plan's pharmacy benefits. For a listing and contact information for these plans, please visit the DMAS website at www.dmas.virginia.gov (under "Provider Services," then "Medicare Part D") or the CMS website through the following link: https://www.medicare.gov/plan-compare/

Pharmacies may contact the pharmacist(s) in the CMS regional office at 1-215-861-4186 with questions related to the administration of the Medicare Part D program. Pharmacy providers can also contact the DMAS Call Center at 1-804-786-6273 (available 8:30 AM to 4:30 PM, Monday through Friday) with questions specifically regarding Virginia Medicaid's pharmacy benefit policies for dual eligible members.

REIMBURSEMENT FOR INDIAN HEALTH SERVICE TRIBAL FACILITIES

Reimbursement for tribal health clinics is detailed in 12VAC30-80-26 and applicable sections are included below:

- Services provided by or through facilities of the Indian Health Services (HIS) are paid at the applicable HIS U.S. Office of Management & Budget (OMB) rate published annually in the Federal Register of Regulations by the HIS.
- The most current published HIS OMB outpatient per visit rate, also known as the outpatient all-inclusive rate, is paid for up to five outpatient visits per beneficiary per calendar day for professional services. Included in the outpatient per visit rate are Medicaid-covered pharmaceuticals or drugs. Each prescription dispensed is defined as a separate outpatient visit for the purpose of this calculation.
- Tribal facility prescriptions should be billed to Medicaid fee-for-service through pharmacy point of sale for both fee-for-service and managed care members to ensure correct reimbursement.
- The Virginia Medicaid Common Core Formulary does not apply to members obtaining prescriptions through tribal facilities reimbursed with the above methodology.