

MANUAL TITLE: PHARMACY MANUAL

CHAPTER 2, PROVIDER PARTICIPATION REQUIREMENTS REVISION DATE:
2/3/2023

CHAPTER II

PROVIDER PARTICIPATION REQUIREMENTS

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PARTICIPATION IN MANAGED CARE AND WITH THE FEE FOR SERVICE (FFS) CONTRACTOR

Most individuals who are eligible for Medicaid or Family Access to Medical Insurance Security (FAMIS) benefits are enrolled with one of the Department of Medical Assistance Services' (DMAS') contracted Managed Care Organizations (MCOs) and receive services from the MCO's network of providers. All participating providers must confirm the individual's MCO enrollment status prior to rendering services. The MCO may require a referral, prior authorization or other action prior to the start of services. All providers are responsible for adhering to state and federal requirements, their MCO provider contract(s) (as applicable), and the applicable DMAS provider manual.

Effective April 4, 2022 all newly enrolling providers seeking to participate with one or more of DMAS's MCO(s) or the FFS contractor must be screened and enrolled with DMAS prior to enrolling with the MCO(s).

For providers to participate with one of DMAS' contracted MCOs, they must also be credentialed by the MCO(s) and contracted in the MCO's network. Please visit the DMAS website at <https://www.dmas.virginia.gov> for more information on participation with the managed care programs and/or the DMAS FFS contractor.

After DMAS screens and approves a provider's enrollment application, it will be forwarded to the MCO(s) or Behavioral Health FFS contractor requested by the provider along with any required supporting documents. Any provider of services must be enrolled with DMAS prior to billing for services rendered to eligible individuals, including individuals enrolled with an MCO/Behavioral Health FFS contractor.

Carved-Out Services

Regardless of an individual's MCO enrollment, some services are "carved-out" of the managed care system and are paid directly by DMAS using fee- for-service methodology. Providers must follow the fee- for-service rules in these instances.

Individuals who receive services under one of the three 1915(c) Developmental Disabilities Home and Community-Based Services (HCBS) Waivers, including the Building Independence, Community Living, and Family and Individual Supports Waivers, are enrolled in managed care for their non-waiver services (e.g., acute, behavioral health, pharmacy, and non-waiver transportation services). The individual's waiver services benefits are carved- out and managed directly by DMAS.

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Provider Enrollment

A participating provider is a person who has a current, signed participation agreement with DMAS.

DMAS's online provider enrollment process may be accessed through the Provider Enrollment link located on the DMAS Medicaid Enterprise System (MES) Provider Resources site at <https://vamedicaid.dmas.virginia.gov/provider>.

As a part of the enrollment process, providers must complete a Participation Agreement applicable to their provider type. In the case of a group practice, hospital, or other agency or institution, the authorized agent of the provider institution must sign the agreement. For group practice, hospital, or other agency or institution, DMAS must receive prior written ratification of the identity of any designated authorized representative and the fact that a principal-agent relationship exists.

A National Provider Identifier (NPI) number must be obtained from the National Plan and Provider Enumeration System (NPPES) and provided with the enrollment application. An enrolled provider's NPI is used by MES to manage provider information across functions. For example, this number must be used on all claims submitted to DMAS.

Provider NPIs may be disclosed to other Covered Healthcare Entities pursuant to Centers for Medicaid and Medicare Services (CMS) regulations requiring the disclosure of NPIs as a part of HIPAA-compliant standard transactions. (Please reference the Healthcare Information Portability and Accountability Act (HIPAA) of 1996.)

If you have any questions regarding the enrollment process, please email Provider Enrollment Services at VAMedicaidProviderEnrollment@gainwelltechnologies.com or phone toll free 1-888-829-5373 or local 1-804-270-5105.

PROVIDER SCREENING REQUIREMENTS

All providers must undergo a federally mandated comprehensive screening as part of their enrollment process. An abbreviated screening is also performed on a monthly basis for any provider who participates with the Virginia Medicaid Program. The full screening is conducted at the time of revalidation, and providers are required to revalidate at least every 5 years.

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The requirement for screening is in response to directives in the standards established by Section 6401(a) of the Affordable Care Act in which CMS requires all state Medicaid Program agencies to implement the provider enrollment and screening provisions of the Affordable Care Act (42 CFR 455 Subpart E). These regulations were published in the Federal Register, Vol. 76, February 2, 2011, and were effective March 25, 2011. The required screening measures vary based on a federally mandated categorical risk level. Providers' categorical risk levels are defined as "limited", "moderate" or "high".

Limited Risk Screening Requirements

The following screening requirements apply to limited risk providers: (1) Verification that a provider or supplier meets any applicable Federal regulations and State requirements for the provider or supplier type; (2) Verification that a provider or supplier meets applicable licensure requirements; and (3) Verification that a provider or supplier has not been excluded from providing services in federally funded programs. The verification process includes a review of applicable federal and state databases checks and is completed on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

Moderate Risk Screening Requirements

In addition to the screening requirements applicable to the limited risk provider category listed above, unannounced pre-and/or post-enrollment site visits apply to moderate risk providers. The screening requirements listed in this section are to be performed at the time of initial enrollment and at the time of revalidation, which is at least every 5 years.

High Risk Screening Requirements

In addition to those screening requirements applicable to the limited and moderate risk provider categories listed above, providers in the high risk category may be required to undergo criminal background check(s) and submit fingerprints. These requirements apply to owners, authorized or delegated officials or managing employees of any provider or supplier assigned to the "high" level of screening.

Application Fees

Institutional providers may be required to pay a federally-required fee at the time of application for enrollment, re-enrollment or reactivation, and when adding new locations. If a provider is required to pay an application fee, it will be outlined in the provider enrollment application and/or revalidation notice.

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CMS determines the application fee each year. This fee is not required to be paid to DMAS if the provider has already paid the fee to another state Medicaid program or Medicare, or has been granted a hardship approval by Medicare.

Providers may submit a hardship exception request for CMS approval with their enrollment application. If CMS does not approve the hardship request, then providers have 30 calendar days from the date of the CMS notification to pay the application fee or the application for enrollment will be rejected.

An appeal of a hardship exception determination must be made to CMS pursuant to 42 CFR 424.514.

Out-of-State Provider Enrollment Requests

Prior to enrollment in DMAS, providers with a primary servicing address located outside of the Virginia border must have a site visit conducted by either their state's Medicaid program or by CMS due to their provider risk-level. Pursuant to 42 CFR 455 Subpart E, an application will be pended for proof of this information if it is received by DMAS prior to the completion of the site visit.

Revalidation Requirements

All participating providers are required to revalidate at least every 5 years. Providers are notified in writing of their revalidation due date and of any new or revised provider screening requirements. (Providers will indicate their preferred mode of notification, i.e., email or USPS, at the time of enrollment.) DMAS may rely on the enrollment and screening facilitated by CMS to satisfy the provider screening requirements if a provider is enrolled as a Medicare provider at the time of revalidation.

ORDERING, REFERRING, AND PRESCRIBING (ORP) PROVIDERS

42 CFR 455.410(b) states that state Medicaid agencies must require all ordering, or referring, and prescribing physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers.

The ACA requires ORP providers to enroll to meet new program integrity requirements designed to ensure that all orders, prescriptions or referrals for items or services for Medicaid members originate from appropriately licensed practitioners who have not been excluded from Medicare or Medicaid. There is one exception: the provider enrollment requirements do not apply to physicians who ordering or refer services for a Medicaid member in a risk-based managed care plan.

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If a provider does not participate with Virginia Medicaid currently but may order, refer or prescribe to Medicaid members they must be enrolled to ensure claims will be paid to the servicing provider who is billing for the service.

As a servicing provider, it is essential to include the National Provider Identifier (NPI) of any ORP on all claims to ensure the timely adjudication of claims.

PARTICIPATION REQUIREMENTS

Providers approved for participation in the Virginia Medicaid Program must perform the following activities, as well as any other activities specified by DMAS:

- Immediately notify Provider Enrollment Services in writing of any change in the information that the provider previously submitted to DMAS.
- Ensure freedom of choice to individuals who are eligible for medical assistance under the Virginia Medicaid Program (eligible individuals) in seeking medical care from any institution, pharmacy, or practitioner qualified to perform the required service(s) and participating in the Virginia Medicaid Program at the time the service was performed.
- Ensure the eligible individual's freedom to reject medical care and treatment.
- Provide services and supplies to eligible individuals in the same mode of delivery and of the same quality and as provided to the general public.
- Charge DMAS for the provision of services and supplies to eligible individuals in amounts not to exceed the provider's usual and customary charges to the general public.
- Accept as payment in full the amount established by DMAS to be reasonable cost or maximum allowable charge. 42 CFR 447.15 provides that a "State Plan must provide that the Medicaid agency must limit participation in the Medicaid Program to providers who accept, as payment in full, the amount paid by the agency." A provider may not bill an eligible individual for a covered service regardless of whether the provider received payment from the state. The provider may not seek to collect from an eligible individual, or any financially responsible relative or representative of that individual, any amount that exceeds the established Medicaid allowance for the service rendered. A provider may not charge DMAS or an eligible individual for missed or broken appointments.

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- Accept assignment of Medicare benefits for eligible individuals.
- Use DMAS-designated billing forms to submit claims.
- Maintain and retain business and professional records sufficient to fully and accurately document fully and accurately the nature, scope, and details of the health care provided. In general, such records must be retained for a period of not less than five years from the date of service or as provided by applicable state laws, whichever period is longer. However, if an audit is initiated within the required retention period, the records must be retained until the audit is completed and every exception resolved.
- Furnish to authorized state and federal personnel, in the form and manner requested, access to records and facilities.
- As requested by DMAS, disclose, as requested by DMAS, all financial, beneficial, ownership, equity, surety, or other interests in any and all firms, corporations, partnerships, associations, business enterprises, joint ventures, agencies, institutions, or other legal entities providing any form of health care services to eligible individuals.
- Hold confidential and use for authorized DMAS purposes only all medical assistance information regarding eligible individuals. A provider shall disclose information in his or her possession only when the information is used in conjunction with a claim for health benefits or the data are necessary for the functioning of DMAS. DMAS shall not disclose medical information to the public.

PROVIDER RESPONSIBILITIES TO IDENTIFY EXCLUDED INDIVIDUALS AND ENTITIES

In order to comply with Federal Regulations and Virginia Medicaid Program policy, providers are required to ensure that Medicaid is not paying for any items or services furnished, ordered, or prescribed by individuals or entities that have been excluded from participation in any state Medicaid Program or Medicare.

Payments cannot be made for items or services furnished, ordered, or prescribed by an excluded provider or other authorized person when the individual or entity furnishing the services either knew or should have known about the exclusion. This provision applies even when the payment itself is made to another provider, practitioner, or supplier that is not excluded, but is affiliated with an excluded provider. A provider who employs or

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contracts with an excluded individual or entity for the provision of items or services reimbursable by the Virginia Medicaid Program may be subject to overpayment liability as well as civil monetary penalties.

All providers are required to take the following three steps to meet Federal and Virginia Medicaid program Program integrity requirements:

- Screen all new and existing employees and contractors to determine whether any of them have been excluded from participation in Medicaid or Medicare. (Go to <https://oig.hhs.gov/exclusions/>)
- Search the Health and Human Services Office of the Inspector General (HHS-OIG) List of Excluded Individuals and Entities (LEIE) website monthly by name for employees, contractors and/or entities to validate their eligibility for Federal programs.
- Immediately report to DMAS any exclusion information discovered. Such information should be sent in writing and should include the individual or business name, provider identification number (if applicable), and what, if any, action has been taken to date. The information should be sent to:

DMAS

Attn: Program Integrity/Exclusions 600 E. Broad St, Suite 1300
Richmond, VA 23219

-or-

E-mailed to: providerexclusions@dmass.virginia.gov

REQUIREMENTS OF SECTION 504 OF THE REHABILITATION ACT

Section 504 of the Rehabilitation Act of 1973, as amended (29 U. S. C. §794), provides that no disabled individual shall, solely by reason of the disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal assistance. As a condition of participation, all Medicaid providers are responsible for making provisions for disabled individuals in their program activities.

As an agent of the federal government in the distribution of funds, DMAS is responsible for monitoring the compliance of individual providers. In the event a discrimination complaint is lodged, DMAS is required to provide the Office of Civil Rights (OCR) with any evidence regarding compliance with these requirements.

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REQUIREMENTS OF THE CIVIL RIGHTS ACT OF 1964

All providers of care and suppliers of services under contract with DMAS must comply with the requirements of Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. §§ 2000d through 2000d-4a), which requires that no person be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance on the basis of race, color, religion, sex, or national origin.

UTILIZATION OF INSURANCE BENEFITS

Virginia Medicaid is a "payer of last resort" program. Benefits available under Medicaid shall be reduced to the extent that they are available through other federal, State, or local programs; coverage provided under federal or State law; other insurance; or, third-party liability.

Health, hospital, workers' compensation, or accident insurance benefits shall be used to the fullest extent in meeting the medical needs of the covered person. Supplementation of available benefits shall be as follows:

- Title XVIII (Medicare) – The Virginia Medicaid Program will pay the amount of any deductible or coinsurance up to the Medicaid limit for covered health care benefits under Title XVIII of the Social Security Act for all eligible persons covered by Medicare and Medicaid.
- Workers' Compensation - No payments shall be made for a patient covered by Workers' Compensation.
- Other Health Insurance - When an eligible individual has other health insurance (such as CHAMPUS/TRICARE, Blue Cross-Blue Shield, or Medicare), the Virginia Medicaid Program requires that these benefits be used first. Supplementation shall be made by the Virginia Medicaid Program when necessary, but the combined total payment from all insurance, shall not exceed the amount payable under Medicaid had there been no other insurance.
- Liability Insurance for Accidental Injuries - DMAS will seek repayment from any settlements or judgments in favor of eligible individuals who receive medical care as the result of the negligence of another. DMAS should be notified promptly if an eligible individual is treated as the result of an accident, DMAS should be notified promptly so action can be initiated to establish a lien as set forth in the Code of

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Virginia §8.01-66.9. In liability cases, providers may choose to bill the third-party carrier or file a lien in lieu of billing DMAS.

In the case of an accident in which there is a possibility of third-party liability or if the eligible individual reports a third-party responsibility (other than those cited on his Medical Assistance Identification Card), and whether or not Medicaid is billed by the provider for rendered services related to the accident, the physician is requested to forward the DMAS-1000 to the attention of the Third-Party Liability Casualty Unit, Department of Medical Assistance Services, 600 East Broad Street, Richmond, Virginia 23219. The form can also be sent electronically to TPLcasualty@dmass.virginia.gov

DOCUMENTATION REQUIREMENTS

The Virginia Medicaid Program provider participation agreement requires that medical records fully disclose the extent of services provided to all Medicaid members. Medical records must clearly document the medical necessity for covered services. This documentation must be written at the time the service is rendered and the description of the services rendered must be clear. All documentation must be signed (name and title) and dated (month, day, year) on the date of service delivery.

ELECTRONIC SIGNATURES

An electronic signature that meets the following criteria is acceptable for clinical documentation:

- Identifies the individual signing the document by name and title;
- Assures that the documentation cannot be altered after the signature has been affixed by limiting access to the code or key sequence; and
- Provides for nonrepudiation; that is, strong and substantial evidence that will make it difficult for the signer to claim that the electronic representation is not valid.

Use of the electronic signatures for clinical documentation purposes shall be deemed to constitute a signature and will have the same effect as a written signature on a document. Providers shall have written policies and procedures in effect regarding use of electronic signatures. In addition to complying with security policies and procedures, providers who use electronic signatures shall sign a statement assuring that they alone will have access to and use the key or computer password. The policies and procedures and statements of exclusive use shall be maintained and available at the provider's location.

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Additionally, the use of electronic signatures shall be consistent with the applicable accrediting and licensing authorities and the provider's own internal policies. These requirements for clinical documentation apply only to Medicaid claims, and do not preclude other state or federal requirements.

An original written signature is still required on provider enrollment forms and for medical consents. This clarification does not apply to electronic claims submission or the electronic sharing or transmission of clinical records.

TERMINATION OF PROVIDER PARTICIPATION

The provider participation agreement is time-limited with periodic renewals required. DMAS will request a renewal of the Participation Agreement prior to its expiration.

A participating provider may terminate participation in Medicaid at any time; however, written notification must be provided to DMAS 30 days prior to the effective date. The written notification should be sent to the following address:

DMAS Provider Enrollment Services
PO Box 26803
Richmond, Virginia 23261-6803

DMAS may terminate a provider's participation agreement. DMAS must provide written notification 30 days prior to the termination's effective date. Such action precludes further payment by DMAS for services provided to customers subsequent to the date specified in the termination notice.

Pursuant to §32.1-325 (D) of the Code of Virginia, the DMAS Director of Medical Assistance Services is authorized to:

Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

Appeals of Provider Termination or Enrollment Denial: A provider has the right to appeal in any case in which a Virginia Medicaid Program provider agreement or contract is terminated or denied pursuant to Virginia Code §32.1-325(D). The provider may appeal the decision in accordance with the Administrative Process Act (Code of Virginia §2.2-4000 et seq.) and the Provider Appeals regulations (12 VAC 30-20-500 et seq.). Such a

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request must be in writing and must be filed with the DMAS Appeals Division within 15 calendar days of the receipt of the notice of termination or denial.

APPEALS OF ADVERSE ACTIONS

An appeal is a request for a review of an adverse decision taken by DMAS, a DMAS contractor, or another agency on behalf of DMAS. There are two types of appeals – a provider appeal, which may be filed by a provider or their authorized representative, and a client appeal, which may be filed by an individual or an authorized representative on the individual's behalf. The provider appeals process is described below. The client appeals process is described in Chapter III.

PROVIDER APPEALS

Definitions

Administrative Dismissal –the dismissal of a provider appeal that requires only the issuance of an informal appeal decision with appeal rights but does not require the submission of a case summary or any further informal appeal proceedings.

Adverse Action – means, for services that have already been rendered, the termination, suspension, or reduction in covered benefits or the denial or retraction, in whole or in part, of payment for a service. An adverse action may also include the denial or termination of enrollment as a DMAS participating provider.

Appeal – means:

1. A request made by an MCO provider (in-network or out-of-network) to review the MCO's reconsideration decision of an adverse action in accordance with the statutes and regulations governing the Virginia Medicaid appeal process. After a DMAS-enrolled provider exhausts the MCO's reconsideration process, Virginia Medicaid affords the provider the right to two administrative levels of appeal (informal appeal and formal appeal) in accordance with the Virginia Administrative Process Act at Code of Virginia § 2.2-4000 *et seq.* and Virginia Medicaid's provider appeal regulations at 12 VAC 30-20-500 *et seq.*; or
2. For fee-for-service ("FFS") services, a request made by a provider to review DMAS' adverse action or a DMAS Contractor's reconsideration decision of an adverse action in accordance with the statutes and regulations governing the Virginia Medicaid appeal process. If an adverse action requires reconsideration before appealing to DMAS, the provider must exhaust the reconsideration process, after which Virginia Medicaid

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affords the provider the right to two administrative levels of appeal (informal appeal and formal appeal) in accordance with the Virginia Administrative Process Act at Code of Virginia § 2.2-4000 *et seq.* and Virginia Medicaid's provider appeal regulations at 12 VAC 30-20-500 *et seq.*

Reconsideration – means a provider's reconsideration request of an adverse action. The MCO's or DMAS Contractor's reconsideration decision is a pre-requisite to a provider filing an appeal to the DMAS Appeals Division.

Transmit – means to send by means of the United States mail, courier or other hand delivery, facsimile, electronic mail, or electronic submission.

Non-State Operated Provider

The following procedures will be available to all non-state operated providers when an adverse action is taken that affords appeal rights to providers. Many adverse actions require a provider to request reconsideration with DMAS or the DMAS Contractor before appealing to the DMAS Appeals Division. Read the denial notice carefully to determine if reconsideration is required, as the reconsideration process is a pre-requisite to filing an appeal with the DMAS Appeals Division. Failure to exhaust a required reconsideration process will result in the appeal to the DMAS Appeals Division being deemed premature.

If the provider chooses to exercise available appeal rights, a request for reconsideration must be submitted if the action involves a DMAS claim under the EAPG payment methodology or involves a ClaimCheck denial. For EAPG and ClaimCheck actions, the request for reconsideration and all supporting documentation must be submitted within 30 days of the receipt of written notification of the underpayment, overpayment, and/or denial to the attention of the Program Operations Division at the following address:

Program Operations Division
Department of Medical Assistance Services
600 East Broad Street,
Richmond, Virginia 23219

DMAS will review the documentation submitted and issue a written response to the provider's request for reconsideration. If the adverse decision is upheld, in whole or part, as a result of the reconsideration process, the provider may then appeal that decision to the DMAS Appeals Division, as set forth below.

Internal reconsideration rights with an MCO must also be exhausted prior to appealing to DMAS if the individual is enrolled with DMAS through a Virginia Medicaid MCO. A reconsideration may also be required by other DMAS contractors before appealing to

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DMAS.

For services that have been rendered and any applicable reconsideration rights have been exhausted, providers have the right to appeal adverse actions to DMAS.

Provider appeals to DMAS will be conducted in accordance with the requirements set forth in the Code of Virginia § 2.2-4000 *et seq.* and the Virginia Administrative Code 12 VAC 30-20-500 *et seq.*

Provider appeals to DMAS must be submitted in writing and **within 30 calendar days** of the provider's receipt of the DMAS adverse action or final reconsideration decision. There are two case types that have other timeframes to file appeals: (1) provider appeals of a termination of the DMAS provider agreement that was based on the provider's conviction of a felony must be appealed **within 15 calendar days** of the provider's receipt of the DMAS adverse action; and (2) providers appealing adjustments to a cost report are required to file the informal appeal within **90 calendar days** of the provider's receipt of the notice of program reimbursement.

The provider's notice of informal appeal is considered filed when it is date stamped by the DMAS Appeals Division. The notice must identify the issues from the adverse action being appealed. To ensure that the appeal is efficiently processed, include: the provider name, national provider identification number (NPI), recipient name(s) and Medicaid ID# *[if applicable]*, date(s) of service *[if applicable]*, claim or service authorization number *[if applicable]*, and the reason for the appeal. Also include a copy of the adverse action and a contact name, phone number, and address for appeal correspondence.

Failure to file a written notice of informal appeal within the prescribed timeframe or that does not identify the action being appealed will result in an administrative dismissal of the appeal.

The appeal must be filed with the DMAS Appeals Division through one of the following methods:

- Through the Appeals Information Management System ("AIMS") at <https://www.dmas.virginia.gov/appeals/>. From there you can fill out an informal appeal request, submit documentation, and follow the process of your appeal.
- Through mail, email, or fax. You can download a Medicaid Provider Appeal Request form at <https://www.dmas.virginia.gov/appeals/>. You can use that form or a letter to file the informal appeal. The appeal request must identify the issues being appealed. The request can be submitted by:

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- Mail or delivery to: Appeals Division, Department of Medical Assistance Services, 600 E. Broad Street, Richmond, VA 23219;
 - Email to appeals@dmass.virginia.gov; or
 - Fax to (804) 452-5454.

The Department of Medical Assistance Services normal business hours are from 8:00 a.m. to 5:00 p.m. Eastern time. Any documentation or correspondence submitted to the DMAS Appeals Division after 5:00 p.m. will be date stamped on the next day the Department is officially open. Any document that is filed with the DMAS Appeals Division after 5:00 p.m. on the deadline date will be untimely.

Any provider appealing a DMAS informal appeal decision must file a written notice of formal appeal with the DMAS Appeals Division **within 30 calendar days** of the provider's receipt of the DMAS informal appeal decision. The notice of formal appeal must identify each adjustment, patient, service date, or other disputed matter that the provider is appealing. Failure to file a written notice of formal appeal within 30 calendar days of receipt of the informal appeal decision will result in dismissal of the appeal. The notice of appeal must be transmitted through the same methods listed above for informal appeals.

The provider may appeal the formal appeal decision to the appropriate circuit court in accordance with the APA at the Code of Virginia § 2.2-4025, *et seq.* and the Rules of Court.

The provider may not bill the member for covered services that have been provided and subsequently denied by DMAS.

Repayment of Identified Overpayments

Pursuant to § 32.1-325.1 of the *Code of Virginia*, DMAS is required to collect identified overpayments. Repayment must be made upon demand unless a repayment schedule is agreed to by DMAS. When lump sum cash payment is not made, interest shall be added on the declining balance at the statutory rate, pursuant to the *Code of Virginia*, § 32.1-313.1. Repayment and interest will not apply pending the administrative appeal. Repayment schedules must ensure full repayment within 12 months unless the provider demonstrates, to the satisfaction of DMAS, a financial hardship warranting extended repayment terms.

State-Operated Provider

The following procedures will be available to state-operated providers when DMAS takes adverse action which includes termination or suspension of the provider agreement or

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denial of payment for services rendered. State-operated provider means a provider of Medicaid services that is enrolled in the Medicaid program operated by the Commonwealth of Virginia.

A state-operated provider has the right to request a reconsideration of any issue that would be otherwise administratively appealable under the State Plan by a non-state operated provider. This is the sole procedure available to state-operated providers.

The reconsideration process will consist of three phases: an informal review by the Division Director, a further review by the DMAS Agency Director, and a Secretarial review. First, the state-operated provider must submit to the appropriate DMAS Division Director written information specifying the nature of the dispute and the relief sought. This request must be received by DMAS within 30 calendar days after the provider receives a Notice of Program Reimbursement (NPR), notice of proposed action, findings letter, or other DMAS notice giving rise to a dispute. If a reimbursement adjustment is sought, the written information must include the nature of the adjustment sought, the amount of the adjustment sought and the reason(s) for seeking the adjustment. The Division Director or his/her designee will review this information, requesting additional information as necessary. If either party so requests, an informal meeting may be arranged to discuss a resolution.

Any designee must then recommend to the Division Director whether relief is appropriate in accordance with applicable laws and regulations. The Division Director shall consider any recommendation of his/her designee and render a decision.

The second step permits a state-operated provider to request, within 30 days after receipt of the Division Director's decision, that the DMAS Agency Director or his/her designee review the Decision of the Division Director. The DMAS Agency Director has the authority to take whatever measures he/she deems appropriate to resolve the dispute.

The third step, where the preceding steps do not resolve the dispute to the satisfaction of the state-operated provider, permits the provider to request, within 30 days after receipt of the DMAS Agency Director's Decision, that the DMAS Agency Director refer the matter to the Secretary of Health and Human Resources and any other Cabinet Secretary, as appropriate. Any determination by such Secretary or Secretaries must be final.

PROVIDER REQUIREMENTS - PHARMACY

A participating provider is a pharmacy licensed by the Virginia Board of Pharmacy and having a current, signed participation agreement with the Department of Medical Assistance Services (DMAS).

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PARTICIPATION CONDITIONS

All pharmacies enrolled in the Virginia Medicaid Program must adhere to the conditions of participation outlined in their provider agreements. The paragraphs which follow outline special participation conditions which must be agreed to by pharmacies.

Requirements for pharmacy providers for participation include, but are not limited to:

- A license from the Virginia State Board of Pharmacy to operate in accordance with State statutes; drugs are to be dispensed by a pharmacist authorized to practice pharmacy under the laws of the state in which the applicant is licensed and practicing.
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CERTIFICATION OF UNIT-DOSE DISPENSING

To be certified as a unit-dose provider to nursing facilities, the pharmacy should contact the Pharmacy Manager and request that certification information and forms be sent to the pharmacy. The address is:

Pharmacy Manager
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

To be considered for certification, the pharmacy must submit Form DMAS-32 (Unit-Dose Distribution Services) that describes the unit-dose system to be utilized, identifies the facilities and location of each, and identifies the unit-dose dosage forms. A certification statement must be signed by the pharmacy owner or official indicating agreement to meet the requirements and to provide a prompt (within 30 days) written notification to the Pharmacy Manager if there are any changes in the method of dispensing to the facilities.

Requirements for Certification

The requirements for certification are as follows:

- Each dose must be packaged individually;
- Each dose must be labeled identifying the drug and strength;
- Packaging/labeling must meet the requirements established by the State Board of Pharmacy for unit-dose dispensing;
- Up to a seven-day supply can be dispensed to the facility;

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- A multiple-day dose (e.g., greater than seven days and up to 30-day supply) system does not qualify for unit-dose certification;
 - The facility must be identified as a nursing facility;
 - Unit-dose dispensing to a home for the aged, adult day care residence, or assisted living facilities does not qualify for unit-dose certification.

DOCUMENTATION OF RECORDS

Pursuant to federal law [42 CFR § 440.120(a)(2)], Medicaid can only provide payment for drugs dispensed by a licensed pharmacist and licensed authorized practitioners in accordance with the State Medical Practice Act. In Virginia, this means that Medicaid can provide payment only for prescribed drugs dispensed and documented in accordance with the Drug Control Act and the Board of Pharmacy Regulations. Documentation supporting Medicaid claims must be maintained for a minimum of five (5) years. The following elements constitute Medicaid policy regarding documentation.

Original Prescriptions

Original prescriptions must include the information required by the Virginia Board of Pharmacy in its Guidance Document 110-35
(<https://www.dhp.virginia.gov/pharmacy/guidelines/110-35.pdf>)

Prescription Refills

Refills of prescriptions must include the following information on the back of the prescription:

- The refill date and initials of the dispensing licensed pharmacist;
- The quantity dispensed, if different from the face amount; and
- A notation of the refill authorization by the prescriber, if different from that on the face of the prescription.

Automated Records

In lieu of maintaining refill documentation on the back of the prescription, pharmacies with an automated data processing system must have online retrieval (via CRT display or hard-copy print-outs) documenting the following:

- The prescription number, name, strength, and quantity of the drug dispensed;
- The refill date and code or initials of the dispensing licensed pharmacist;
- The total number of refills authorized by the prescriber and the balance number of refills remaining;

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- The name of both the member and the prescriber; and
 - The address of both the member and the prescriber, if not on file elsewhere in the pharmacy.

Records of Dispensing to Nursing Facilities

Physician orders must be on file for each drug dispensed for a member residing in a nursing facility.

Non-Unit-Dose

Non-unit-dose packaged drugs provided to the facilities by either unit-dose certified pharmacies or non-unit-dose pharmacy providers are to be documented in the prescription records as described above or in a patient profile as described below for unit-dose.

Unit-Dose

In lieu of the foregoing described documentation, certified unit-dose pharmacies must maintain records (patient profiles) which include the following information:

- The name and address of the member receiving the service;
- The name of the prescriber and his or her address, if not available elsewhere in the pharmacy;
- The prescription number, name, strength, and quantity of the drug dispensed; The directions for use; and
- Documentation on a daily basis of the delivery of a 24-hour supply of each drug.

Non-Legend Drugs

Documentation requirements described above apply to both legend and covered non-legend (over-the-counter) drugs.

Discontinued Drugs

Pursuant to the Board of Pharmacy regulations, records must show dispensed medications, which have been discontinued and not administered to the patient, as having been returned to the pharmacy. Billing records must reflect an adjustment in payments where appropriate.

Signature Log

Pharmacy providers must maintain a log containing the following information:

- Member's name;
- The signature of the member or that of his representative; and
- The date of receipt of the prescription.

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The log must effectively differentiate between prescriptions received by a member for which counseling was accepted and provided, and those for which counseling was offered and was declined. This log must be retained for review by DMAS or DMAS' agent for five (5) years and is subject to audit.

The signature log serves as verification of the member receiving the prescription billed. The absence of the appropriate signature indicates the member did not receive the prescription, and funds may be subject to recoupment.

Prescription signature records for shipped prescriptions must be retained for a period of five (5) years and must include the delivery confirmation for audit purposes.

TAMPER-RESISTANT PRESCRIPTION PADS

In 2007, Congress enacted Section 7002 (b) of the U.S. Troop Readiness, Veterans' Health Care, Katrina Recovery and Iraq Accountability Appropriations Act (P.L. 110-28), which mandates that federal reimbursement be denied to states for Medicaid patients' outpatient prescriptions that are not written on tamper-resistant prescription pads/paper. To comply with this federal mandate, the Virginia Medicaid and FAMIS Fee-For-Service Program requires the use of tamper-resistant pads/paper on all non-electronic, outpatient prescriptions (excluding e-prescribing, fax, or telephone).

Affected Medicaid/FAMIS Clients

The use of tamper-resistant prescription pads is mandated for the Medicaid, FAMIS fee-for-service, and FAMIS Plus fee-for-service populations. Based on CMS guidance, the tamper-resistant pad requirement applies to all outpatient drugs, including over-the-counter drugs, whether Medicaid is the primary or secondary payor of the prescription. While the law specifies the term "prescription pad", the Centers for Medicare and Medicaid Services (CMS) have stated that these requirements also apply to computer-generated prescriptions that are printed using paper inserted into the printer.

Exemptions to Requirement:

According to CMS, the following are exemptions to the tamper-resistant prescription pad requirements:

Prescriptions paid by a Medicaid/FAMIS managed care entity (this means prescriptions written for patients enrolled in any of Virginia's contracted managed care organizations are not subject to this requirement). Dentists contracted through Doral Dental are NOT exempt from this requirement.

Prescriptions transmitted to the pharmacy via e-prescribing, fax, or telephone (faxing is

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the preferred method). (Please note, however, that Drug Enforcement Administration regulations require Schedule II controlled substances to be written prescriptions). In addition, Guidance Document 110-35 from the Virginia Board of Pharmacy(<https://www.dhp.virginia.gov/pharmacy/guidelines/110-35.pdf>) provides further guidance on faxed and electronically transmitted prescriptions.

Drugs provided in nursing facilities, intermediate care facilities for individuals with intellectually disabilities, and other specified institutional and clinical settings, as long as the patient never has the opportunity to handle the written prescription.

What Qualifies As A Tamper-Resistant Prescription Pad?

Although this is a federal law, there is not a single national regulation. Each State Medicaid Agency must determine which tamper-resistant features will be required. Virginia Medicaid has reviewed the recommendations of the industry and of states that currently use tamper-resistant prescription pads/paper. Virginia Medicaid requires that all prescription pads/paper used for Medicaid and FAMIS fee-for-service members contain at least one of the following three characteristics:

- One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form,
- One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber, or
- One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Prescription pads/paper are required to contain at least one feature in all of the three categories above. Providers who write prescriptions for Medicaid and FAMIS fee-for-service members should contact their vendor to secure an appropriate supply of prescription pads/paper that will meet the above requirements. Table 1 is a summary of features that could be used on a tamper-resistant pad/paper in compliance with the CMS guidelines within the timeframe required. They are categorized according to the three types of tamper-proof features as described by CMS. Features in bold tend to be less costly and easier for physicians to implement than other features.

Table 1

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

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Uniform non-white background color: Background is one color. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase or copy, the consistent background color will look altered.

“Void” or “Illegal” pantograph: The word “Void” appears when the prescription is photocopied. Due to the word “Void” on faxed prescriptions, this feature requires the pharmacy to document if the prescription was faxed.

Reverse “RX” or White Area on prescription: “Rx” symbol or white area disappears when photocopied at light setting. This feature is normally paired with the “Void” pantograph to prohibit copying on a light setting.

Coin-reactive ink: Ink that changes color when rubbed by a coin. This is an expensive option.

Security Back print: Printed on the back of prescription form. The most popular wording for the security back print is “Security Prescription” or the security back print can include the states name.

Watermarking (fourdrinier) Diagonal lines (patented “Void”)

Special paper containing “watermarking”.

Diagonal lines with the word “void” or “copy”. Can be distracting or expensive.

Micro printing: Very small font writing, perhaps acting as a signature line. This is difficult to photocopy and difficult to implement if using computer printer. It is also difficult for a pharmacist to see.

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

Quantity check off boxes: In addition to the written quantity on the prescription, Quantities are indicated in ranges. It is recommended that ranges be multiples of 25 with the highest being “151 and over”. The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid.

Refill Indicator (circle or check number of refills or “NR”): Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.

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Pre-print "Rx is void if more than ____ Rxs on paper" on prescription paper: Reduces the ability to add medications to the prescription. - Line must be completed for this feature to be valid. Reduces the ability to add medications to the prescription. Computer printer paper can accommodate this feature by printing "This space intentionally left blank" in an empty space or quadrant.

Quantity Border and Fill (for computer generated prescriptions on paper only): Quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional)

Refill Border and Fill (for computer generated prescriptions on paper only): Refill quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **5** Value may also be expressed as text, e.g. (FIVE), (optional)

Chemically reactive paper: If exposed to chemical solvents, oxidants, acids, or alkalis to alter, the prescription paper will react and leave a mark visible to the pharmacist.

Paper toner fuser: Special printer toner that establishes strong bond to prescription paper and is difficult to tamper.

Safety or security paper with colored pattern: White (or some other color) mark appears when erased. This is expensive paper.

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

Security features and descriptions listed on prescriptions: Complete list of the security features on the prescription paper for compliance purposes. The pharmacy community, as represented by the American Pharmacist Association (APhA), National Association of Chain Drug Stores (NACDS), and National Community Pharmacist Association (NCPA) strongly believe this feature would be helpful to include to aid the pharmacist in identifying a tamper-resistant prescription.

Form Batch Numbers: Each batch of prescriptions has a unique identifier. This feature is only effective in states with an approved vendor listing.

Serial number: Number issued by printer of prescription, may or may not be sequential. This feature is most effective where serial numbers are reported to

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the state.

Encoding techniques (bar codes): Bar codes on prescription. Serial number or Batch number is encoded in a bar code.

Logos: Sometimes used as part of the background color or pantograph.

Metal stripe security: Metal stripe on paper, difficult to counterfeit.

Heat sensing imprint: By touching the imprint or design, the imprint will disappear.

Invisible fluorescent fibers/ink: Visible only under black light.

Thermo chromic ink: Ink changes color with temperature change. This is expensive paper and problematic for storage in areas not climate controlled.

Holograms that interfere with photocopying. May interfere with photocopying or scanning.