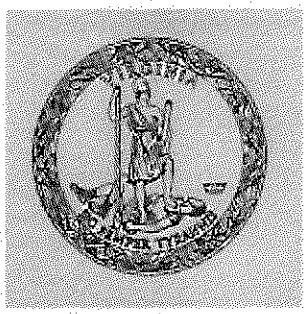

COMMONWEALTH of VIRGINIA

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TO: **BRIAN MCCORMICK**
Regulatory Supervisor
Virginia Department of Medical Assistance Services

FROM: **USHA KODURU**
Assistant Attorney General

DATE: **August 14, 2014**

SUBJECT: **Emergency Regulations and Notice of Intended Regulatory Action to Promulgate Commonwealth Coordinated Care (4016/6652)**

I am in receipt of the attached regulations to implement Commonwealth Coordinated Care that will allow the DMAS to combine certain aspects of Medicaid managed care and long-term care, and Medicare into one program for those individuals eligible for Medicare and Medicaid. You have asked the Office of the Attorney General to review and determine if DMAS has the legal authority to promulgate the regulations and if the regulations comport with state and federal law.

Based on that review, it is my view that the Director, acting on behalf of the Board of Medical Assistance Services pursuant to Virginia Code §§ 32.1-324 and 325, has the authority to promulgate these regulations, subject to compliance with the provisions of Article 2 of the Administrative Process Act and has not exceeded that authority.

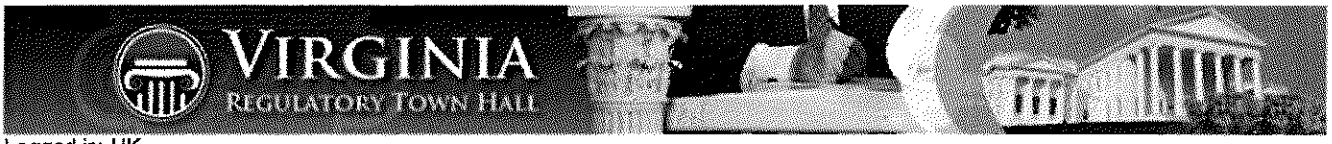
The authority for this emergency action is found in Va. Code § 2.2-4011(ii). Chapter 806, Item 307 RR of the Virginia Appropriations Act grants DMAS the authority to promulgate these regulations. Accordingly, these regulations qualify for the "emergency" exemption from

Article 2 requirements. A Notice of Intended Regulatory Action relating to the proposed replacement regulations must be filed with the Registrar within sixty days of the effective date of the emergency regulations, and appears to already have been so filed at the same time as the emergency regulations. The proposed replacement regulations must be filed with the Registrar within 180 days after the effective date of the emergency regulations.

If you have any questions or need additional information about this regulation, please contact me at 786-4074.

cc: Kim F. Piner, Esquire

Attachment



Emergency Text

Action: Commonwealth Coordinated Care

Stage: Emergency 8/12/14 2:56 PM [latest]

12VAC30-50-600
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-50-600. Section 1932 Dual eligible Medicare-Medicaid individuals.

A. Consistent with the Social Security Act § 1932(a)(1)(A) (the Act), the Commonwealth enrolls Medicaid enrollees on a voluntary basis into Medicare-Medicaid plans (MMPs) in the absence of § 1115 or § 1915(b) waiver authority.

B. Consistent with § 1932(a)(1)(B) of the Act, the Commonwealth shall contract with MMPs. The payment method to the contracting entity shall be a capitation method.

C. The public process used by DMAS for both the design of the program and its initial implementation entailed:

1. DMAS convened public stake holder meetings, in March and July of 2012. Participants were informed and given the opportunity to provide recommendations.

2. DMAS considered these recommendations and incorporated many into its program proposal.

3. DMAS has established an advisory committee which meets quarterly throughout the duration of the program on topics such as program design, educational and outreach materials, provider and beneficiary issues.

D. Enrollment will be voluntary in the counties and cities designated by the following regions: (i) Central Virginia, (ii) Northern Virginia, (iii) Tidewater, (iv) Western/Charlottesville, and (v) Roanoke.

E. The Commonwealth assures that all of the applicable requirements of § 1903 (m) of the Act for MMPs and MMP contracts are met.

F. The Commonwealth assures that all the applicable requirements of § 1932 of the Act for the state's option to limit freedom of choice by requiring enrollees to receive their benefits through managed care entities will be met. MMPs shall be required to pass readiness reviews prior to enrolling individuals.

G. The Commonwealth assures that all the applicable requirements of 42 CFR 431.51 regarding freedom of choice for family planning services and supplies as defined in § 1905(a)(4)(C) of the Act will be met.

H. The Commonwealth assures that all applicable managed care requirements of 42 CFR Part 438 for MMPs will be met. Enrollees shall be permitted to opt out at any time with or without cause from the program pursuant to 42 CFR 438.56(c).

I. The Commonwealth assures that all applicable requirements of 42 CFR 438.6(c) for payments under any risk contracts will be met.

J. The Commonwealth assures that all applicable requirements of 45 CFR 92.36

for procurement of contracts will be met.

K. Eligible groups.

1. No groups shall be enrolled on a mandatory basis. Enrollment shall be voluntary.

2. Enrollees shall also be eligible for Medicare. Full-benefit dual eligible (eligible for both Medicare and Medicaid) individuals ages 21 and older who are eligible for the program shall be passively enrolled. Individuals shall have 60 days after notification of program enrollment to opt out before they are passively enrolled into an MMP. Individuals shall be permitted to change MMPs or opt out of the program and return to fee-for-service services at any time. With the exception of the following two reasons in this subsection, individuals shall be allowed to re-enroll in the program at any time. The exceptions shall be:

a. Individuals who are in hospice shall be excluded from enrolling in the program. If an enrollee is in the program and then enters hospice care, he shall be dis-enrolled from the program. If such an individual elects to leave hospice, he will be permitted to re-enroll in the program.

b. Individuals who receive the Medicare end stage renal disease (ESRD) benefit after enrolling in the program shall be permitted to remain in the program. If such individuals opt out of the program, they shall not be permitted to re-enroll.

L. Pursuant to § 1932(a)(2) of the Act, the Commonwealth provides that the following individuals will be exempt from mandatory enrollment into this program's managed care: full-benefit dual eligible individuals based on their eligibility for Medicare Parts A, B, and D and for full Medicaid benefits, also known as Qualified Medicare Beneficiaries (QMB) Plus individuals.

M. Enrollment process.

1. DMAS shall use a pre-assignment algorithm, through its Medicaid Management Information System (MMIS), and an enrollment broker to facilitate the continuity of care of Medicaid individuals by providers that have traditionally served this population.

2. DMAS shall not use a lock in for managed care pursuant to 42 CFR 438.50.

3. Individuals shall have 60 days to choose a health plan before being automatically assigned.

4. Eligible individuals will receive a notice that indicates to which Medicare-Medicaid Plan (MMP) they have been assigned. The notice will have instructions for the individual to contact DMAS' contracted enrollment broker to either:

(a) Accept the pre-assigned MMP;

(b) Select a different MMP that is operating in their region; or,

(c) To opt out of the program altogether and stay in the fee-for-service environment. If an individual does not select an MMP, he shall be passively enrolled into the pre-assigned MMP.

5. Enrollees shall be assigned to an MMP based on six months of claims prior to pre-assignment using the rules below in order of priority:

a. Individuals in a nursing facility shall be pre-assigned to an MMP that includes the individual's nursing facility in its provider network;

b. Individuals in the EDCD Waiver shall be assigned to an MMP that includes the individual's current adult day health care provider in its provider network;

c. If more than one MMP network includes the nursing facility or adult day healthcare provider used by an individual, the individual will be assigned to the MMP with which he has previously been assigned in the past six months. If he has no history of previous MMP assignment, he shall be randomly assigned to an MMP in which his provider participates.

d. Individuals shall be pre-assigned to an MMP with whom they have previously been assigned within the past six months.

N. The Commonwealth assures that it has an enrollment system that allows individuals who are already enrolled to be given priority to continue that enrollment if the MMPs does not have capacity to accept all who are seeking enrollment under the program.

O. The Commonwealth assures that, pursuant to the choice requirements in 42 CFR 438.52, Medicaid individuals who are enrolled in an MMP will have a choice of at least two entities unless the area is considered rural as defined in 42 CFR 438.52(b)(3).

P. The Commonwealth shall apply the automatic reenrollment provision in accordance with 42 CFR 438.56(g) if the individual is dis-enrolled solely because he loses Medicaid eligibility for a period of two months or less.

Q. The following services shall be excluded from coverage by the MMP in this program:

1. Induced abortions.

2. Targeted case management.

3. Dental services. (refer to 12VAC30-121-70 for specific coverage)

R. The Commonwealth shall intentionally limit the number of entities it contracts with under the option permitted by § 1932 of the Act. The Commonwealth assures that such limits on the number of contracting entities shall not substantially impair enrollee access to services.

12VAC30-121
CHAPTER 121
MEDICARE-MEDICAID DEMONSTRATION WAIVER

12VAC30-121-10
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-10. Demonstration program authority.

A. Medicare Authority: The Medicare elements of the program shall operate according to existing Medicare Parts C and D laws and regulations, as amended or modified, except to the extent these requirements are waived or modified as provided for in the Memorandum of Understanding (MOU) between the Centers for Medicare and Medicaid (CMS) and the Department. As a term and condition of the program, participating plans will be required to comply with Medicare Advantage and Medicare Prescription Drug Program requirements in Part C and Part D of Title XVIII of the Social Security Act (the Act), and 42 CFR Parts 422 and 423, as amended from-time to time, except to the extent specified in the MOU for waivers, and the three-way contract.

B. Medicaid Authority: The Medicaid elements of the program shall operate according to existing Medicaid laws and regulations, including but not limited to all requirements of the § 1915(c) of the Act waivers for individuals enrolled in the

Elderly or Disabled with Consumer Direction (EDCD), as amended or modified, except to the extent waived as provided for in the MOU. As a term and condition of the program, the State and participating plans shall comply with Medicaid managed care requirements under Title XIX of the Act and 42 CFR Part 438, other applicable regulations, as amended or modified, except to the extent specified in the MOU, and the three-way contract. The Commonwealth will add concurrent authority to the relevant § 1915(c) programs via amendments in the next update or scheduled renewal, whichever occurs sooner.

C. CMS reserves the right to withdraw programs or expenditure authorities at any time it determines that continuing the programs or expenditure authorities would no longer be in the public interest or promote the objectives of Title XVIII of the Social Security Act. CMS will promptly notify DMAS in writing of the determination, the reasons for the withdrawal, the effective date, and, subject to Section 1115A(d)(2) of the Social Security Act, afford DMAS a reasonable opportunity to request a reconsideration of CMS' determination prior to the effective date.

D. Termination and phase out would proceed as described in Section III.L of the MOU between CMS and DMAS. If a program or expenditure authority is withdrawn, federal financial participation (FFP) is limited to normal closeout costs associated with terminating the program or expenditure authority, including covered services and administrative costs of dis-enrolling enrollees.

12VAC30-121-20
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Action" means, consistent with 42 CFR 438.400, an action by the participating plan, subcontractor, service provider or Virginia Department of Medical Assistance Services, that constitutes a denial or limited authorization of a service authorization request, including (i) type or level of service; (ii) reduction, suspension, or termination of a previously authorized service; (iii) failure to act on a service request; (iv) denial in whole or in part of a payment for a covered service; (v) failure by the participating plan to render a decision within the required timeframes; or (vi) denial of an enrollee's request to exercise his right under 42 CFR 438.52(b)(2)(ii) to obtain services outside of the network.

"Appellant" means an applicant for or recipient of Medicaid benefits who seeks to challenge an action taken by the participating plan regarding eligibility for services and payment determinations.

"CPT" means Current Procedural Terminology, Revised 2014, as published by the American Medical Association.

"Capitation payment" means a payment the department makes periodically to a participating plan on behalf of each enrollee enrolled under a contract for the provision of services under the State Plan and waivers, regardless of whether the enrollee receives services during the period covered by the payment.

"Capitation rate" means the monthly amount, payable to the plan, per enrollee, for the provision of contract services. The plans shall accept the established capitation rates paid each month by the department and CMS as payment in full for all Medicaid and Medicare services to be provided pursuant to the three-way contract and all associated administrative costs , pending final recoupment, reconciliation, sanctions or payment of quality withhold amounts.

"Care management" means the collaborative, person-centered process that

assists enrollees in gaining access to needed health care services and includes (i) assessing for and planning of health care services; (ii) linking the enrollee to services and supports identified in the Plan of Care; (iii) working with the enrollee directly for the purpose of locating, developing, or obtaining needed health care services and resources; (iv) coordinating health care services and service planning with other agencies, providers and family members involved with the enrollee; (v) making collateral contacts to promote the implementation of the Plan of Care and community integration; (vi) monitoring to assess ongoing progress and ensuring services are delivered; and (vii) education and counseling that guides the enrollee and develops a supportive relationship that promotes the Plan of Care.

"Carved-out services" means the subset of Medicaid and Medicare covered services for which the plan shall not be fiscally responsible under the demonstration.

"Centers for Medicare and Medicaid Services" or "CMS" means the federal agency of the United States Department of Health and Human Services that is responsible for the administration of Titles XVIII, XIX, and XXI of the Social Security Act.

"Commonwealth Coordinated Care" or "CCC" means the program name for the Virginia Financial Alignment Model.

"Cost sharing" means copayments, coinsurance, or deductibles paid by an enrollee when receiving medical services.

"Covered enrollee" means an enrollee enrolled in the demonstration, including the duration of any month in which his eligibility for the demonstration ends.

"Covered services" means the set of required services offered by the participating plan as set forth in the three-way contract.

"Cultural competency" means understanding those values, beliefs, and needs that are associated with the enrollees' age, gender identity, sexual orientation, or racial, ethnic, or religious backgrounds. Cultural competency (i) includes a set of competencies that are required to ensure appropriate, culturally sensitive health care to persons with congenital or acquired disabilities and (ii) is based on the premise of respect for enrollee and cultural differences, and an implementation of a trust-promoting method of inquiry and assistance.

"Department of Medical Assistance Services" or "the department" or "DMAS" means the Virginia Department of Medical Assistance Services, the single state agency for the Medicaid program in Virginia and that is responsible for implementation and oversight of the demonstration.

"Demonstration" means the capitated model under the Medicare-Medicaid Financial Alignment Demonstration as authorized by the Center for Medicare and Medicaid Services and as set out in the Patient Protection and Affordable Care Act of 2010 and authorized under Section 1115A of the Social Security Act. The demonstration requires compliance with Title XIX of the Social Security Act and Medicaid regulations set forth in 42 CFR Chapter IV, Part C of Title XVIII and Medicare Advantage regulations set forth in 42 CFR Part 4224, and Part D of Title XVIII and Medicare Part D regulations set forth in 42 CFR part 4236, except to the extent that waivers and variances are documented in the Memorandum of Understanding (MOU) between CMS and DMAS. Under the demonstration, states, CMS, and participating plans will enter into three-way contracts through which the plans will receive a capitated rate to cover the full continuum of Medicare and Medicaid benefits provided to dual eligible enrollees. Demonstrations will be for the period as outlined in the MOU, unless terminated earlier as provided for in section 1115A of the Social Security Act, the MOU, and the three-way contract.

"Disenrollment" means the process of changing enrollment from one participating

plan to another participating plan or returning from the participating plan to the fee-for-service system but shall not include ending eligibility in the Medicare or Medicaid programs.

"Division" means the Appeals Division of DMAS.

"Dual eligible enrollees" means a Medicare enrollee who receives (i) Medicare Parts A, B, and D benefits and also receives full Medicaid benefits and (ii) does not meet any exclusionary reasons as outlined in the MOU. This term will be used to reference enrollees who are eligible for the demonstration.

"Effective date of enrollment" means the date on which a participating plan's coverage begins for an enrollee.

"Elderly or Disabled with Consumer Direction Waiver" or "EDCD Waiver" means, as provided in 12VAC30-120-900 et seq., the CMS-approved waiver that covers a limited range of community support services offered to enrollees who are elderly or who have a disability and meet Virginia nursing facility level of care criteria as set out in 12VAC30-60-300 et seq.

"Enrollee" means a person eligible for full Medicaid benefits and Medicare Parts A, B and D who is also enrolled in a participating plan to receive services under the demonstration.

"Enrollee appeal" means an enrollee's request for review of a participating plan's coverage or payment determination. In accordance with 42 CFR 438.400, a Medicaid-based appeal is defined as a request for review of an action, as defined herein. An appeal is an enrollee's challenge to the actions regarding services, benefits, and reimbursement provided by the participating plan, its service providers or the Department of Medical Assistance Services.

"Enrollment" means the completion of approved enrollment forms by or on behalf of an eligible person and assignment of an enrollee to a participating plan by DMAS in accordance with federal law.

"Enrollee communications" means the materials designed to communicate to enrollees plan benefits, policies, processes and enrollee rights, including pre-enrollment, post-enrollment, and operational materials.

"Enrollment facilitator" means an independent entity contracted with DMAS that (i) enrolls beneficiaries in the plan, (ii) is responsible for the operation and documentation of a toll-free helpline, (iii) educates enrollees about the plan, (iv) assists with and tracking of enrollees' grievance resolutions, and (v) may market and perform outreach to potential enrollees.

"Enrollment period" means the time that an enrollee is actually enrolled in a participating plan.

"Evidence of coverage" or "EOC" means a document, prepared by the MMP and provided to the enrollee, that is consistent with the requirements of 42 CFR 438.10, 422.11, and 423.128 and includes information about all the services covered by that plan.

"Expedited appeal" means the process by which the department must respond to an appeal by an enrollee if a denial of care decision and the subsequent internal appeal by a participating plan may jeopardize life, health, or ability to attain, maintain or regain maximum function.

"External appeal" means an appeal, subsequent to the participating plan appeal decision, to the state fair hearing process for Medicaid-based adverse decisions or to the Medicare process for Medicare-based adverse decisions. The Department's external appeal decision shall be binding upon the participating plan or plans and not subject to further appeal by the participating plan or plans.

"Fee-for-service" or "FFS" means the traditional health care payment system in which physicians and other providers receive a payment for each service they provide.

"Fiscal/employer agent (F/EA)" means an organization operating under Section 3504 of the IRS Code and IRS Revenue Procedure 70-6 and Notice 2003-70 which has a separate Federal Employer Identification Number used for the sole purpose of filing federal employment tax forms and payments on behalf of program enrollees who are receiving consumer-directed services.

"Final decision" means a written determination by a hearing officer that is binding on the department, unless modified during or after the judicial process and that may be appealed to the local circuit court.

"Full benefit dual eligible" means an enrollee defined as QMB-Plus pursuant to 12VAC30-10-320(A).

"Good cause" means to provide sufficient cause or reason for failing to file a timely appeal or for missing a scheduled appeal hearing.

"Health risk assessment " or "HRA" means a comprehensive assessment of an enrollee's medical, psychosocial, cognitive, and functional status in order to determine his medical, behavioral health, long-term care support and social needs.

"Hearing" means an informal evidentiary proceeding conducted by a department hearing officer during which an enrollee has the opportunity to present his concerns with, or objections to, the participating plan's internal appeal decision.

"Hearing officer" means an impartial decision maker who conducts evidentiary hearings for enrollee appeals on behalf of the department.

"Home and community-based waiver services" or "waiver services" means a variety of home and community-based services eligible for payment by DMAS as authorized under a § 1915(c) waiver designed to offer enrollees an alternative to institutionalization.

"ICF/IID" means an Intermediate Care Facility for Individuals with Intellectual Disabilities.

"Integrated appeals process" means the process that incorporates relevant Medicare and Medicaid requirements and allows enrollees to appeal actions for either Medicare-based services or Medicaid-based services to the MMP with one request.

"Interdisciplinary care team" or "ICT" means a team of professionals that collaborate, either in person or through other means, with the enrollee to develop and implement, employing both medical and social models of care, a plan of care that meets his medical, behavioral health, long term care supports, and social needs. ICTs may include physicians, physician assistants, long-term care providers, nurses, specialists, pharmacists, behavior health specialists, and social workers, as may be appropriate for the enrollee's medical diagnoses and health condition, co-morbidities, and community support needs.

"Intermediate sanctions" means sanctions that may be imposed on the Medicare-Medicaid Plans (MMP) such as civil money penalties, appointment of temporary management, permission for individuals to terminate enrollment in the Medicare-Medicaid Plan without cause, suspension or default of all enrollment of individuals, and suspension of payment to the Medicare-Medicaid Plan for individuals enrolled pursuant to 42 USC § 1396u-2(e)(2).

"Internal appeal" means an enrollee's initial request for review of a participating plan's coverage or payment determination by his MMP.

"Long-stay hospitals" mean specialty Medicaid facilities that serve enrollees who require a higher intensity of nursing care than that which is normally provided in a nursing facility and who do not require the degree of care and treatment that an acute care hospital is designed to provide.

"Long term services and supports" or "LTSS" means a variety of services and supports that (i) help elderly enrollees and enrollees with disabilities who need assistance to perform activities of daily living and instrumental activities of daily living to improve the quality of their lives and (ii) are provided over an extended period, predominantly in homes and communities, but also in facility-based settings such as nursing facilities. Examples of these activities include assistance with bathing, dressing and other basic activities of daily life and self-care, as well as support for everyday tasks such as laundry, shopping, and transportation.

"MMP" means Medicare-Medicaid Plans.

"Medicaid" means the program of medical assistance benefits under Title XIX of the Social Security Act and various demonstrations and waivers thereof.

"Medically necessary" or "medical necessity" means, per Medicare, services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, or otherwise medically necessary under 42 USC § 1395y. Per Virginia Medicaid, an item or service provided for the diagnosis or treatment of a patient's condition consistent with community standards of medical practice and in accordance with Medicaid policy (12VAC30-130-600). Furthermore, as defined in 42 CFR 440.230, services must be sufficient in amount, duration and scope to reasonably achieve their purpose. Services must be provided in a way that provides all protections to covered enrollees provided by Medicare and Virginia Medicaid.

"Medicare" means Title XVIII of the Social Security Act, the federal health insurance program for people age 65 or older, people younger than 65 years of age who have certain disabilities, and people with end stage renal disease (ESRD) or amyotrophic lateral sclerosis (ALS).

"Medicare independent review entity" means an independent organization contracted by CMS to review appeals for Medicare-covered services which have been denied by the enrollee's MMP

"Medicare Part A" means hospital insurance that helps cover inpatient care in hospitals, skilled nursing facilities, hospice, and home health care.

"Medicare Part B" means insurance that helps cover medically necessary services such as doctors' services, outpatient care, durable medical equipment (DME), home health services, other medical services and some preventive services.

"Medicare Part C" or "Medicare Advantage" means plans that (i) provide all of an enrollees Medicare Part A and Medicare Part B coverage; (ii) may offer extra coverage, such as vision, hearing, dental, or health and wellness programs; and (iii) may include Medicare prescription drug coverage (Part D).

"Medicare Part D" means Medicare prescription drug coverage.

"Medicare-Medicaid enrollees" means, for the purposes of this demonstration, enrollees who are (i) entitled to Medicare Part A and enrolled in Medicare Parts B and D (ii) receive full benefits under the Virginia State Plan for Medical Assistance, and (iii) otherwise meet eligibility criteria for the demonstration.

"Memorandum of Understanding" or "MOU" means the document setting out the mutually agreed to understanding of this program between DMAS and CMS.

"Minimum Data Set" or "MDS" means part of the federally-mandated process for assessing enrollees receiving care in certified skilled nursing facilities in order to

record their overall health status, regardless of payer source.

"Model of care" means a comprehensive plan that (i) describes the plan's population, (ii) identifies measurable goals for providing high quality care and improving the health of the enrolled population, (iii) describes the plan's staff structure and care management roles, (iv) describes the interdisciplinary care team, the system for disseminating the model of care to plan staff and network providers and (vi) contains other information designed to ensure that the plans provide services that meet the needs of enrollees.

"Money Follows the Person" or "MFP" means a demonstration project administered by DMAS that is designed to create a system of long-term services and supports that better enable enrollees to transition from certain LTC institutions into the community.

"Network" means doctors, hospitals, or other health care providers who participate or contract with a participating plan and, as a result, agree to accept a mutually-agreed upon payment amount or fee schedule as payment in full for covered services that are rendered to eligible enrollees.

"Nursing facility" means any skilled nursing facility, skilled care facility, intermediate care facility, nursing care facility, or nursing facility, whether freestanding or a portion of a freestanding medical care facility, that is certified for participation as a Medicare or Medicaid provider, or both, pursuant to Title XVIII and Title XIX of the United States Social Security Act, as amended, and, § 32.1-137 of the Code of Virginia.

"Opt-out option" means the process by which an enrollee can choose to not participate in the demonstration.

"Participating plan", or "MMP" means a health plan selected to participate in Virginia's Medicare-Medicaid Alignment Demonstration and that is a party to the three-way contract with CMS and DMAS.

"Passive enrollment" means an enrollment process through which an eligible enrollee is enrolled by DMAS (or its vendor) into a participating plan, when not otherwise affirmatively electing one, following a minimum 60-day advance notification that includes the opportunity to make another enrollment decision or opt out of the demonstration prior to the enrollment effective date.

"Plan of care" or "POC" means a plan, primarily directed by the enrollee, and family members of the enrollee as appropriate, with the assistance of the enrollee's interdisciplinary care team to meet the enrollee's medical, behavioral health, long-term care service and supports needs, and social needs.

"Preadmission screening" means the process to: (i) evaluate the functional, nursing, and social supports of enrollees referred for preadmission screening; (ii) assist enrollees in determining what specific services the enrollees need; (iii) evaluate whether a service or a combination of existing community services are available to meet the enrollees' needs; and (iv) refer enrollees to the appropriate entity for either Medicaid-funded nursing facility services or home and community-based care for those enrollees who meet the criteria for nursing facility level of care.

"Preadmission screening committee/team" means the entity contracted with DMAS that is responsible for performing preadmission screening pursuant to § 32.1-330 of the Code of Virginia.

"Previously authorized" means, in relation to continuation of benefits, as described in 42 CFR 438.420, a prior approved course of treatment, and is best clarified by the following example: If the plan authorizes 20 visits and then later reduces this authorization to 10 visits, this exemplifies a "previously authorized service" that is

being reduced. Conversely, "previously authorized" does not include the example whereby (i) the plan authorizes 10 visits; (ii) the 10 visits are rendered; and (iii) another 10 visits are requested but are denied by the plan. In this case, the fact that the plan had authorized 10 visits on a prior request for authorization is not germane to continuation of benefits requirements for previously authorized services that are terminated, suspended or reduced.

"Primary care provider" or "PCP" means a practitioner who provides preventive and primary medical care and certifies service authorizations and referrals for medically necessary specialty services. PCPs may include pediatricians, family and general practitioners, internists, obstetrician/gynecologists, geriatricians, and specialists who perform primary care functions (such as surgeons) and clinics including, but not limited to, local health departments, federally qualified health centers (FQHCs), rural health clinics (RHCs).

"Privacy" means the requirements established in the Health Insurance Portability and Accountability Act of 1996, and implementing regulations, Medicaid regulations, including 42 CFR 431.300 through 431.307, as well as relevant Virginia privacy laws.

"Program of All-Inclusive Care for the Elderly" or "PACE" means the program in which the PACE provider provides the entire spectrum of health and long-term care services (preventive, primary, acute and long-term care services) to its enrollees without limit as to duration or cost of services pursuant to 12VAC30-50-320 et seq.

"Provider appeal" means an appeal filed by a Medicare, Medicaid or other service provider that has already provided a service and has received an action regarding payment or audit result.

"Quality withhold amounts" means percentages of the respective components, with the exception of Part D amounts, of the capitation rate due to the participating plans, to be retained by CMS and DMAS until such time as the plan's performance is consistent with established quality thresholds.

"Remand" means the return of a case by the hearing officer to the participating plan for further review, evaluation, and action.

"Remote patient monitoring" means monitoring a patient remotely and is often used for patients with one or more chronic conditions, such as congestive heart failure, cardiac arrhythmias, diabetes, pulmonary diseases or the need for anticoagulation treatment and must be agreed to by the enrollee. Examples of remote patient monitoring activities include, but are not limited to, transferring vital signs such as weight, blood pressure, blood sugar, and heart rate from the enrollee to the physician's office.

"Representative" means an attorney or other individual who has been authorized to represent an enrollee pursuant to these regulations.

"Reverse" means to overturn the participating plan's action and internal appeal decision, and direct that the participating plan fully approve the amount, duration, and scope of requested services.

"Secretary" means the Secretary of the U.S. Department of Health and Human Services.

"Social Security Act" means the federal act, codified through Chapter 7 of Title 42 of the United States Code, which established social insurance programs including Medicare and Medicaid.

"Spend down" means when a Medicaid applicant meets all Medicaid eligibility requirements other than income, Medicaid eligibility staff conduct a "medically

needy" calculation which compares the enrollee's income to a medically needy income limit for a specific period of time referred to as the "budget period" (not to exceed 6 months). When a Medicaid applicant's incurred medical expenses equal the spend down amount, the applicant is eligible for full benefit Medicaid for the remainder of the spend down budget period.

"State fair hearing" means DMAS' evidentiary hearing process as administered by the DMAS' Appeals Division.

"State Plan for Medical Assistance" or "State Plan" means the comprehensive written statement submitted to CMS by the department describing the nature and scope of the Virginia Medicaid program and giving assurance that it will be administered in conformity with the requirements, standards, procedures, and conditions for obtaining federal financial participation. DMAS has the authority to administer such State Plan for the Commonwealth pursuant to the authority of the § 32.1-325 of the Code of Virginia, as amended.

"Store and forward" means when pre-recorded images, such as x-rays, video clips, and photographs are captured and then forwarded to and retrieved, viewed, and assessed by a provider at a later time.Some common applications include: (i) tele-dermatology where digital pictures of a skin problem are transmitted and assessed by a dermatologist; (ii) teleradiology where x-ray images are sent to and read by a radiologist; and, (iii) tele-retinal imaging where images are sent to and evaluated by an ophthalmologist to assess for diabetic retinopathy.

"Sustain" means to uphold the participating plan's appeal decision.

"Targeted case management" or "TCM" means the Medicaid-funded State Plan case management service provided by private providers for enrollees with substance use disorders or developmental disabilities and by community services boards/behavioral health authorities for enrollees with behavioral health disorders or intellectual disabilities and encompasses both referral/transition management and clinical services such as monitoring, self-management support, and medication review and adjustment. TCM is separate from "care management" as defined in the MOU.

"Tele-health" or "tele-medicine" means the real time or near real time two-way transfer of data and information using an interactive audio/video connection for the purposes of medical diagnosis and treatment.

"Three-way contract" means the three-way agreement between CMS, DMAS, and a participating plan specifying the terms and conditions pursuant to which a participating plan shall participate in CCC.

"Uniform Assessment Instrument" or "UAI" means the standardized multidimensional questionnaire that is completed by a preadmission screening team or a hospital discharge planner for applicants residing in a hospital setting that assesses an enrollee's psychosocial health, physical health, mental health, and functional abilities to determine if an applicant meets level of care criteria for long-term services and supports that are funded through Medicaid.

"Vulnerable subpopulation" means individuals, at a minimum, from the following groups: (i) individuals who are enrolled in the Elderly or Disabled with Consumer Direction (EDCD) Waiver (12VAC30-120-900 et seq.) ; (ii) individuals who have either intellectual or developmental disabilities, or both; (iii) individuals who have cognitive or memory problems, or both, (e.g., dementia and traumatic brain injury); (iv) individuals with physical or sensory disabilities; (v) individuals who are residing in nursing facilities; (vi) individuals who have serious and persistent mental illness or illnesses; (vii) individuals who have end stage renal disease; and (viii) individuals who have complex or multiple chronic health conditions, or both.

"Withdrawal" means a written request from the enrollee or the enrollee's representative for the department to terminate the appeal process without a final decision on the merits.

12VAC30-121-30
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-30. Selected localities.

A. The demonstration shall operate in specific regions within the Commonwealth.

B. The department and CMS will implement the demonstration in Central Virginia, Northern Virginia, Roanoke, Tidewater and Western/Charlottesville regions.

C. Under the demonstration, DMAS will conduct a regional phase-in. Phase I will impact Central Virginia and Tidewater. Phase II will impact Western/Charlottesville, Northern Virginia, and Roanoke.

D. Participating plans must cover all eligible enrollees in all localities within the region or regions in which such plans participate.

12VAC30-121-40
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-40. Eligible enrollees.

A. Medicaid-eligible enrollees who qualify as follows may be eligible to be enrolled in the demonstration:

1. Individuals who are 21 years of age and older at the time of enrollment;

2. Individuals who are entitled to benefits under Medicare Part A, enrolled under Medicare Parts B and D, and who are receiving full Medicaid benefits. This includes enrollees participating in the Elderly or Disabled with Consumer Direction (EDCD) Waiver and those residing in nursing facilities (NF);

3. Individuals who reside in a program region; and,

4. Individuals who do not meet any of the exclusions identified in 12VAC30-121-45, Excluded individuals.

B. Individuals who have been excluded from CCC, for any reason, shall be permitted to opt in to the program once the reason for their exclusion no longer exists.

12VAC30-121-45
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12VAC30-121-45. Individuals who meet at least one of the criteria listed below shall be excluded from the program.

1. Individuals who are younger than 21 years of age.

2. Individuals who are required to "spend down" income in order to meet Medicaid eligibility requirements.

3. Individuals for whom DMAS only pays a limited amount each month toward their

cost of care (e.g., deductibles), including non full benefit Medicaid beneficiaries. These Individuals may receive Medicaid coverage for the following: Medicare monthly premiums for Part A, Part B, or both (carved-out payment); coinsurance, copayment, and deductible for Medicare-allowed services; Medicaid-covered services, including those that are not covered by Medicare. These individuals may include:

a. Qualified Medicare Beneficiaries (QMBs);

b. Special Low Income Medicare Beneficiaries (SLMBs);

c. Qualified Disabled Working Individuals (QDWIs); or,

d. Qualifying Individuals (QIs).

4. Individuals who are inpatients in state mental hospitals, including but not limited to: Catawba Hospital, Central State Hospital, Eastern State Hospital, HW Davis Medical Center, Northern Virginia Mental Health Institution, Piedmont Geriatric Hospital, Southern Virginia Mental Health Institution, Southwestern State HM&S, Southwestern VA Mental Health Institution, Western State HM&S, and Western State Hospital.

5. Individuals who are residents of state hospitals, ICF/IID facilities, residential treatment facilities, or long stay hospitals.

6. Individuals who are participating in federal waiver programs for home and-community-based Medicaid coverage other than the EDCD Waiver (e.g., Individual and Family Developmental Disabilities Support, Intellectual Disability, Day Support, Technology Assisted Waiver, and Alzheimer's Assisted Living Waivers).

7. Individuals receiving hospice services at the time of enrollment will be excluded from the program. If an enrollee enters a hospice program while enrolled in the waiver, he will be disenrolled from the program. If such enrollees opt-out of this program, they shall not be permitted to reenter it. If enrollees do not opt-out but leave this program due to program action, they shall be permitted to return to the program upon their leaving the hospice program. However, participating plans shall refer these individuals to the pre-admission screening team for additional LTSS if not already in place.

8. Individuals receiving the end stage renal disease (ESRD) Medicare benefit at the time of enrollment into the program. However, an enrollee who develops ESRD while enrolled in the waiver will remain in the program unless he opts out. If he opts out, the enrollee shall not be permitted to opt back into the program.

9. Individuals with other comprehensive group or enrollee health insurance coverage, other than full benefit Medicare; insurance provided to military dependents; and any other insurance purchased through the Health Insurance Premium Payment Program (HIPP).

10. Individuals who have a Medicaid eligibility period that is less than three months.

11. Individuals who have a Medicaid eligibility period that is only retroactive.

12. Individuals enrolled in the Virginia Birth-Related Neurological Injury Compensation Program established pursuant to Chapter 50 (§ 38.2-5000 et seq.) of Title 38.2 of the Code of Virginia.

13. Individuals enrolled in the Money Follows the Person (MFP) Program.

14. Individuals residing outside of the program coverage regions.

15. Individuals enrolled in a Program of All-Inclusive Care for the Elderly (PACE). However, PACE participants may enroll in the waiver if they choose to disenroll

from their PACE provider.

16. Individuals participating in the CMS Independence at Home (IAH) demonstration or any other demonstration that bases some or all payment on achievement of Medicare savings.

12VAC30-121-50
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-50. Enrollment process.

Individuals who qualify as indicated in 12VAC30-121-40 and are not excluded as provided in 12VAC30-121-45 shall be enrolled as follows, except if they choose to opt-out:

1. Enrollees shall be assigned to a participating plan based on their previous six months of Medicaid claims history prior to pre-assignment using the rules in this order of priority:

a. Enrollees in a nursing facility shall be pre-assigned to a participating plan that includes the enrollee's nursing facility in its provider network;

b. Enrollees in the EDCD Waiver shall be assigned to a participating plan that includes the enrollee's current adult day health care provider in the MMP's existing provider network;

c. If more than one participating plan network includes the nursing facility or adult day health care provider used by an enrollee, he shall be assigned to the participating plan with which he has previously been assigned in the past six months. If he has no history of previous participating plan assignment, he shall be randomly assigned to a participating plan in which his provider participates.

d. Enrollees shall be pre-assigned to a participating plan, first the Medicare plan and secondly the Medicaid participating plan, with whom they have previously been assigned within the past six months.

2. Utilizing passive enrollment, eligible enrollees will be notified of their right to select among contracted participating plans no fewer than 60 days prior to the effective date of enrollment.

3. Eligible enrollees shall receive a notice that indicates the participating plan to which they have been pre-assigned. The notice shall have instructions for the enrollee to contact the Department's contracted enrollment broker to (1) accept the pre-assigned participating plan; (2) select a different participating plan that is operating in their region; or, (3) to opt out of the Program and remain in the fee-for-service environment. If an enrollee does not select a participating plan, he shall be passively enrolled into the pre-assigned participating plan.

4. Prior to the effective date of their plan enrollment, enrollees who would be passively enrolled will have the opportunity to opt out and will receive sufficient notice and information with which to do so.

5. All enrollment effective dates shall be prospective. Enrollee-elected enrollment is effective the first day of the month following an enrollee's request to enroll, so long as the request is received on or before five days before the end of the month. Enrollment requests, including requests to change among participating plans, received later than five days before the end of the month, will become effective the first of the second month following the request. Passive enrollment is effective not sooner than 60 days after enrollee notification.

6. Dis-enrollment from participating plans and transfers between participating plans shall be allowed on a month-to-month basis any time during the year; however, coverage for these enrollees will continue through the end of the month. All dis-enrollment requests will be effective the first day of the month following an enrollee's request to disenroll from the CCC Program.

7. CMS and DMAS will monitor enrollments and disenrollments for both evaluation purposes and for compliance with applicable marketing and enrollment laws, regulations and CMS policies, for the purposes of identifying any inappropriate or illegal marketing practices. As part of this analysis, CMS and DMAS will monitor any unusual shifts in enrollment by enrollees identified for passive enrollment into a particular participating plan to a Medicare Advantage plan operated by the same parent organization. If those shifts appear to be due to inappropriate or illegal marketing practices, CMS or DMAS, or both, may require corrective action. Any illegal marketing practices will be referred to appropriate agencies for investigation.

8. As mutually agreed upon in the three-way contract, CMS and DMAS shall utilize an independent third party entity to facilitate all enrollments into the participating plans.

9. Participating plan enrollments, transfers, and opt-outs shall become effective on the same day for both Medicare and Medicaid. For enrollees who lose Medicaid eligibility during a month, coverage and Federal Financial Participation will continue through the end of the month in which Medicaid eligibility is ended.

12VAC30-121-70
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-70. Covered services.

A. CMS and DMAS shall contract with participating plans that demonstrate the capacity to provide directly, or by subcontracting with other qualified entities, the full continuum of medically necessary Medicare and Medicaid covered services to enrollees, in accordance with the MOU, CMS guidance, the three-way contract, 42 CFR Part 422 and 42 CFR Part 423, 42 CFR Part 438, the requirements in the Medicaid State Plan, including any applicable State Plan amendments and §1915 (c), of the Act, EDCD Waiver (12VAC30-120-900 et seq.), 42 USC § 1395y; 12VAC30-130-600; the ADA, and the *Olmstead* decision. Furthermore, as defined in 42 CFR 440.230, services shall be sufficient in amount, duration and scope to reasonably achieve their purpose. Participating plans shall be required to provide services in a way that preserves all protections to enrollees and provides enrollees with coverage to at least the same extent provided by Medicare and Medicaid. Where there is overlap between Medicare and Medicaid benefits, coverage and rules shall be delineated in the three-way contract. Participating plans will be required to abide by the more generous of the applicable Medicare, Medicaid, or the combined Medicare-Medicaid standard.

B. With the exception of those services that are specifically carved out of this program as set out in subdivision C of this section, the required covered services shall include, but not be limited to:

1. Medicare Parts A, B, and D services.

2. Participating plans will be responsible for medically necessary procedures, including but not limited to, the following:

a. CPT codes billed for dental services performed as a result of a dental accident (i. e., an accident that damages the mouth);

b. Medically necessary procedures, including but not limited to: preparation of the mouth for radiation therapy, maxillary or mandibular frenectomy when not related to a dental procedure, orthognathic surgery to attain functional capacity, and surgical services on the hard or soft tissue in the mouth where the main purpose is not to treat or help the teeth and their supporting structures.

c. Participating plans shall cover anesthesia and hospitalization for medically necessary dental services.

d. At their option, participating plans may cover additional flexible dental services for program enrollees.

e. Case management services for participants of Auxiliary Grants (although not widely used (this service is included as part of the annual reassessment screening process for assisted living recipients), this service will be provided under fee-for-service).

3. Acute care services provided under the State Plan for Medical Assistance as found in 12 VAC 30 Chapter 50, and further defined by written DMAS regulations, policies and instructions, except as otherwise modified or excluded in the three-way contract;

4. Covered LTSS provided under the EDCD Waiver (adult day health care; personal care (agency and consumer-directed options); personal emergency response services (PERS) with or without medication monitoring; respite care (agency and consumer-directed options); transition coordination; and, transition service).

5. The integrated formulary for prescription drugs shall include Medicaid-covered drugs that are excluded by Medicare Part D. Participating plans must also cover drugs covered by Medicare Parts A or B. In all respects, unless stated otherwise in the MOU or the three-way contract, Part D requirements will continue to apply.

6. Nursing facility services as defined in 42 CFR 440.40.

7. Health Risk Assessments.

a. Each Enrollee shall receive, and be an active participant in, a timely, comprehensive, assessment of medical, behavioral health, LTSS, and social needs completed by the participating plan's care management team. All health risk assessment tools are subject to approval by DMAS. Assessment domains will include, but not be limited to, the following: medical, psychosocial, functional, cognitive, and behavioral health. Relevant and comprehensive data sources, including the enrollee, providers, family/caregivers, additional significant others as may be designated by the enrollee, shall be used by the participating plans.

b. During the first year of the program, all enrollees meeting any of the following criteria shall receive a health risk assessment to be completed no later than 60 days from the onset of these enrollees' enrollment:

(1) Individuals enrolled in the EDCD Waiver;

(2) Individuals with intellectual/developmental disabilities;

(3) Individuals with cognitive or memory problems (e.g., dementia or traumatic brain injury);

(4) Individuals with physical or sensory disabilities;

(5) Individuals residing in nursing facilities;

(6) Individuals with serious and persistent mental illnesses;

(7) Individuals with end stage renal disease; and,

(8) Individuals with complex or multiple chronic conditions.

c. During the first year of the program and for all other enrollees, health risk assessments must be conducted within 90 days of enrollment.

d. Health risk assessments for individuals enrolled in the EDCD Program and for individuals residing in nursing facilities must be conducted face-to-face. The health risk assessments for individuals residing in nursing facilities must also incorporate the MDS.

e. During subsequent years of the program, individuals enrolled in the EDCD waiver program must receive a health risk assessment within 30 days of enrollment and all other enrollees must receive a health risk assessment within 60 days of enrollment.

8. Level of Care (LOC) determinations.

a. Initial level of care determinations shall be conducted by hospitals and local pre-admission screening teams as defined in § 32.1-330 of the Code of Virginia.

b. Participating plans must ensure that LOC annual reassessments are conducted timely for EDCD Waiver participants (minimum within 365 days of the last annual reassessment or as the participants' needs change). Participating plans shall conduct annual face-to-face assessments for continued NF level of care eligibility requirements for the EDCD waiver.

c. The plans shall establish criteria which includes health status change (the triggering events that precipitate a need for reassessment, including a change in the ability to perform ADLs and IADLs) for reassessments to be performed prior to the reassessment.

d. The LOC annual reassessment shall include all the elements required by the three-way contract for enrollees who are in the EDCD Waiver who have a change in status.

e. LOC annual reassessments for EDCD Waiver enrollees shall be performed by providers with the following qualifications: (i) a Registered Nurse licensed in Virginia with at least one year of experience as an RN; (ii) a social worker licensed in Virginia; or (iii) an individual who holds at least a bachelor's degree in a health or human services field and has at least two years of experience working with individuals who are elderly or have disabilities, or both.

f. Participating plans shall ensure that quarterly and annual assessments are conducted timely for nursing facility residents based on the Minimum Data Set (MDS) process and shall work cooperatively with nursing facilities to provide information regarding the completion of the assessments for continued nursing facility placement.

g. Participating plans shall communicate annual LOC reassessment data for EDCD Waiver enrollees and nursing facility residents to DMAS according to requirements in the three-way contract.

9. Plans of care (POC).

a. Participating plans shall develop a person-centered POC for each enrollee. The POC shall be tailored to the individual enrollee's needs and be agreed to and signed by the enrollee or the enrollee's Employer of Record.

b. Participating plans shall implement a person-centered and culturally competent plan of care development process. Participating plans shall also develop a process that will incorporate but not duplicate Targeted Case Management for applicable enrollees.

c. During the first year of the CCC Program, participating plans shall ensure that plans of care for all enrollees are completed within 90 days of the enrollees' enrollment. Participating plans shall honor all existing plans of care and service authorizations until the authorization ends or 180 days from enrollees' enrollment, whichever is sooner. For EDCD Waiver individuals, the plan of care shall be developed and implemented by the participating plan no later than the end date of any existing service authorization.

d. During subsequent years of the program, participating plans shall ensure that plans of care are developed within the following timeframes:

(1) Within 30 days of enrollment for EDCD Waiver participants;

(2) Within 60 days of enrollment for vulnerable subpopulations (excluding EDCD Waiver participants); and,

(3) Within 90 days of enrollment for all other enrollees.

e. Participating plans shall incorporate information from the Uniform Assessment Instrument (UAI) and the LOC determinations into the POCs for individuals in the EDCD Waiver.

f. Participating plans shall develop a process for obtaining nursing facility MDS data and incorporating that information into the POC. Participating plans shall ensure that nursing facilities' residents who wish to move to the community will be referred to the preadmission screening teams or the Money Follows the Person (MFP) program. If the individual enrolls in the MFP program, he will be dis-enrolled from this program.

g. Participating plans shall develop a process for addressing health, safety (including minimizing risk), and welfare of the enrollee in the POC.

h. The POC shall contain the following:

(1) Prioritized list of enrollee's concerns, needs, and strengths;

(2) Attainable goals, outcome measures, and target dates selected by the enrollee or caregiver, or both;

(3) Strategies and actions, including interventions and services to be implemented, and the providers responsible for specific interventions and services and the frequency of the interventions and strategies;

(4) Progress noting success, barriers or obstacles;

(5) Enrollee's informal support network and services;

(6) Back up plans as appropriate (for EDCD Waiver enrollees using personal care and respite services) in the event that the scheduled provider or providers are unable to provide services;

(7) Determined need and plan to access community resources and non-covered services;

(8) Enrollee choice of services (including consumer-direction) and service providers; and,

(9) Elements included in the DMAS-97AB form, (which can be downloaded from **https://www.virginiamedicaid.dmas.virginia.gov/wps/portal**) for individuals enrolled in the EDCD Waiver.

i. Participating plans shall ensure that reassessments and plan of care reviews are conducted:

(1) By the plan of care anniversary for vulnerable subpopulations (excluding EDCD

Waiver participants and nursing facility residents) and all other enrollees;

(2) By plan of care anniversary, not to exceed 365 days for EDCD Waiver enrollees (must be face-to-face); and,

(3) Participating plans must follow MDS guidelines/timeframes for quarterly and annual plan of care development for nursing facility residents.

j. Participating plans must ensure that plans of care are revised based on triggering events, such as hospitalizations or significant changes in health or functional status.

10. Interdisciplinary Care Team (ICT).

a. For each enrollee, participating plans shall support an ICT to ensure the integration of the enrollee's medical, behavioral health, substance use, LTSS and social needs. The team will be person-centered, built on the enrollee's specific preferences and needs, and deliver services with transparency, individualization, respect, linguistic and cultural competence, and dignity.

b. Participating plans ICTs shall employ both medical and social models of care, as appropriate for their enrollees' documented needs.

c. Participating plan members of the team shall agree to participate in approved training on the person-centered planning processes, cultural competence, accessibility and accommodations, independent living and recovery, ADA/*Olmstead* requirements, and wellness principles, along with other required training, as specified by the Commonwealth. Participating plans will offer training to additional members of the team: primary care providers, specialists, as appropriate.

d. If an enrollee is receiving Medicaid State Plan targeted case management services, the participating plans shall develop a mechanism to include the targeted case manager as a member of the ICT.

e. If an enrollee is identified to be eligible to transition into the community through the DOJ Settlement Agreement (Case: 3:12-CV-00059-JAG) (http://www.dbhds.virginia.gov/settlement/FullAgreement.pdf), then the participating plan's ICT shall collaborate with the locality's Community Services Board (CSBs) or Behavioral Health Authority, as appropriate, and the Department of Behavioral Health and Developmental Services to successfully transition the enrollee into the community. The enrollee's CSB case manager shall participate as a part of the participating plan's ICT to monitor his service needs. If the enrollee transitions into the either the IID or DD Waivers, the enrollee shall be disenrolled from this program. If the enrollee transitions to the EDCD Waiver, the enrollee may remain in the program.

11. State requirements for care coordination.

a. The participating plan shall provide person-centered care management functions for all enrollees.

b. All enrollees shall have access to the following supports depending on their needs and preferences; however, care management for vulnerable subpopulations shall include the items described below in items (vi) - (xii):

(1) A single, toll-free point of contact for all questions;

(2) Ability to develop, maintain and monitor the POC;

(3) Assurance that referrals result in timely appointments;

(4) Communication and education regarding available services and community resources;

(5) Assistance developing self-management skills to effectively access and use services.

(6) Assistance in receiving needed medical and behavioral health services, preventive services, medications, LTSS, social services and enhanced benefits; including setting up appointments, in-person contacts as appropriate, strong working relationships between care managers and physicians; evidence-based enrollee education programs, and arranging transportation as needed;

(7) Monitoring of functional and health status;

(8) Seamless transitions of care across specialties and care settings;

(9) Assurance that enrollees with disabilities have effective communication with health care providers and participate in making decisions with respect to treatment options;

(10) Connecting enrollees to services that promote community living and help avoid premature or unnecessary nursing facility placements;

(11) Coordination with social service agencies (e.g. local departments of health, social services, and Community Services Boards) and referrals for enrollees to state, local, and other community resources; and,

(12) Collaboration with nursing facilities to promote adoption of evidence-based interventions to reduce avoidable hospitalizations, and include management of chronic conditions, medication optimization, prevention of falls and pressure ulcers, and coordination of services beyond the scope of the NF benefit.

c. Participating plans shall develop innovative arrangements to provide care management such as:

(1) Partnering or contracting with entities, or both, (such as Community Services Boards (CSBs), adult day care centers, and nursing facilities) that currently perform care management and offer support services to individuals eligible for the Program.

(2) Medical homes,

(3) Sub-capitation, such as payment arrangement whereby the MMP pays its contracted providers on a capitated basis rather than a fee for service basis;

(4) Shared savings, and

(5) Performance incentives.

d. Participating plans and DMAS shall collaborate to avoid duplication of care management services provided under the program.

e. Participating plans shall be required to use one state-wide Fiscal/Employer Agent (F/EA) to manage the F/EA services for individuals using consumer-direction.

12. Participating plans shall be permitted to use and reimburse telehealth for Medicare and Medicaid services as an innovative, cost effective means to decrease hospital admissions, reduce emergency department visits, address disparities in care, increase access, and increase timely interventions. Participating plans shall also encourage the use of telehealth to promote community living and improve access to behavioral health services. Participating plans shall be permitted to use telehealth in rural and urban settings and reimburse for store and forward applications. Participating plans shall also have the ability to cover remote patient monitoring. All telehealth and remote patient monitoring activities shall be compliant with HIPAA requirements and will be further outlined in the three-way contract.

13. Skilled nursing level care may be provided in a long term care facility without a preceding acute care inpatient stay for enrollees enrolled in the program when the provision of this level of care can avert the need for an inpatient hospital stay.

C. The following services shall be carved out of the program and provided under the fee-for-service system:

1. Abortions, induced (this service shall be provided under limited circumstances, e.g., when the life of the mother is endangered, through fee-for-service);

2. Targeted case management services (these services will be provided under fee-for-service) and;

3. Dental services (in limited cases, these services will be provided under fee-for-service).

12VAC30-121-75
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-75. Flexible benefits.

A. Flexible benefits are those which MMPs may elect to offer to their enrollees.

B. Examples of such benefits are: (i) annual physical examinations; (ii) meal benefits; (iii) preventive and comprehensive dental services for adults; (iv) eye examinations; (v) prescription eyeglasses; (vi) hearing examinations, and; (vii) hearing aids.

12VAC30-121-90
THE TEXT OF THIS REGULATIONS IS IN DRAFT FORM AND SHOULD NOT BE RLEIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-90. Capitation payment rates.

A. Capitation rates and payment rules shall be established in the MOU and three-way contract, and may be adjusted by state or federal regulatory changes.

B. If other state or federal statutory changes enacted after the annual baseline determination and rate development process are jointly determined by CMS and DMAS to have a material change in baseline estimates for any given payment year, baseline estimates and corresponding standardized payment rates shall be updated outside of the annual rate development process.

C. Any and all costs incurred by the participating plan in excess of the capitation payment shall be borne in full by the plan.

D. Additional costs shall not be balance billed to the plan's enrollees.

12VAC30-121-110
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-110. Cost sharing requirements.

A. Participating plans shall not charge Medicare Parts C or D premiums, nor assess any cost sharing for Medicare Parts A and B services.

B. For drugs and pharmacy products (including those covered by both Medicare Part D and Medicaid), participating plans shall be permitted to charge co-pays to

enrollees currently eligible to make such payments consistent with co-pays applicable for Medicare and Medicaid drugs, respectively. Co-pays charged by participating plans for Part D drugs shall not exceed the applicable amounts for brand and generic drugs established yearly by CMS under the Part D Low Income Subsidy. Plans may elect to reduce this cost sharing for all enrollees, as a way of testing whether reducing enrollee cost sharing for pharmacy products improves health outcomes and reduces overall health care expenditures through improved medication adherence under the waiver.

C. Patient pay requirements, which are applicable to long term care services, shall be detailed in the contract between CMS, DMAS and the participating plans.

C. Participating plans shall not assess any cost sharing for DMAS services, beyond the pharmacy cost sharing amounts allowed under Medicaid coverage rules.

D. No enrollee may be balance billed by any provider for any reason for covered services or flexible benefits (see 12VAC30-121-75).

12VAC30-121-130
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-130. Access standards.

A. Participating plans shall have the capacity to provide, directly or by subcontracting with other qualified entities, the full continuum of Medicare and Medicaid covered services to enrollees, in accordance with the MOU, CMS guidance, and the three-way contract.

B. Network adequacy. State Medicaid standards shall be utilized for long-term supports and services or for other services for which Medicaid is exclusively responsible for payment, and Medicare standards shall be utilized for pharmacy benefits and for other services for which Medicare is primary, unless applicable Medicaid standards for such services are more stringent. Home health and durable medical equipment requirements, as well as any other services for which Medicaid and Medicare may overlap, shall be subject to the more stringent of the applicable Medicare and Medicaid standards.

C. Participating plans shall ensure that they maintain a network of providers that is sufficient in number, mix of primary care and specialty providers and geographic distribution to meet the complex and diverse needs of the anticipated number of enrollees in the service area as defined by CMS for Medicare and defined by DMAS for Medicaid.

D. For services for which Medicaid is the traditional primary payer (including, but not limited to, LTSS and community mental health and substance abuse services), each enrollee shall have a choice of at least two providers of each covered service type located within no more than 30 minutes travel time from any enrollee in urban areas unless the participating plan has a DMAS-approved alternative time standard. Travel time shall be determined based on driving during normal traffic conditions (i.e., not during commuting hours).

E. The participating plan shall ensure that each enrollee shall have a choice of at least two providers of each covered service type located within no more than 60 minutes travel time from any enrollee in rural areas unless the participating plan has a Department approved alternative time standard.

F. DMAS shall require contractual agreements between nursing facilities and participating plans. Payment for services shall be made to nursing facilities directly

by the participating plans. Participating plans will be required to contract with any nursing facility that is eligible to participate in Medicare and Medicaid and is willing to accept the participating plan payment rates and contract requirements for the time duration of the Demonstration period.

G. For any covered services for which Medicare requires a more rigorous network adequacy standard than Medicaid (including time, distance, or minimum number of providers or facilities), the participating plan shall meet the Medicare requirements.

12VAC30-121-140
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-140. MMPs having low performance.

A. Provided that the MMP is determined by DMAS to meet all plan selection requirements in the three way contract, an interested organization that is either (i) an outlier in CMS' past performance analysis for the upcoming contract year or (ii) has a Low Performance Indicator (LPI) on the Medicare Plan Finder website for the upcoming year, or both, may qualify to offer CCC services.

B. Such MMPs shall not be eligible to receive passive enrollment until the MMP is either (i) no longer considered by CMS to be a past performance outlier or (ii) no longer has an LPI on the Medicare Plan Finder.

C. Either CMS or DMAS, or both, shall determine whether or not an MMP is eligible to accept passive enrollment prior to the scheduled date of execution of the three-way contract. To accept passive enrollment, such MMPs shall be determined by CMS to either (i) no longer be a past performance outlier or (ii) no longer has an LPI on the Medicare Plan Finder, or both.

D. An MMP that is ineligible to receive passive enrollment shall only be able to enroll: (i) individuals who are currently enrolled in another Medicare or Medicaid managed care plan sponsored by the same organization, and (ii) individuals who opt in to the organization's MMP.

12VAC30-121-145
12VAC30-121-145. Sanctions for noncompliance.

A. DMAS may impose intermediate sanctions, which may include any of the types described in paragraph C or terminate the MMP if the MMP:

1. Fails substantially to provide medically necessary items and services that are required under law or under the MMP's contract with DMAS to be provided to an enrollee covered under the contract;

2. Imposes premiums or charges on enrollees in excess of the premiums or charges permitted under this chapter;

3. Acts to discriminate among enrollees on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, except as permitted by this chapter, or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment with the organization by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services;

4. Misrepresents or falsifies information that is furnished to either:

a. The Secretary or DMAS under this chapter; or

b. To an enrollee, potential enrollee, or a health care provider under such chapter; or

5. Fails to comply with the applicable requirements of Title 42 § **1396b(m)(2)(A)(x)**.

B. DMAS may also impose such intermediate sanction against an MMP if DMAS determines that the MMP distributed directly or through any agent or independent contractor marketing materials in violation of section 250 of this chapter.

C. The sanctions described in this paragraph shall be follows:

1. Civil money penalties as follows:

a. Except as provided in clause b, c, or d, not more than $25,000 for each determination under paragraph (A).

b. With respect to a determination under clause (3) or (4)(a) of paragraph (A), not more than $100,000 for each such determination.

c. With respect to a determination under paragraph (A)(2), double the excess amount charged in violation of such subsection (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned).

d. Subject to clause (b), with respect to a determination under paragraph (A)(3), $15,000 for each individual not enrolled as a result of a practice described in such subsection.

2. The appointment of temporary management

a. To oversee the operation of the MMP upon a finding by DMAS that there is continued egregious behavior by the organization or there is a substantial risk to the health of enrollees; or

b. To assure the health of the organizations enrollees if there is a need for temporary management while there is an orderly termination or reorganization of the organization; or

c. Improvements are made to remedy the violations found under paragraph (A) except that temporary management under this subparagraph may not be terminated until DMAS has determined that the MMP has the capability to ensure that the violations shall not recur.

3. Permitting individuals enrolled with the MMP to terminate enrollment without cause and notifying such individuals of such right to terminate enrollment.

4. Suspension or default of all enrollment of individuals under this subchapter after the date the Secretary or DMAS notifies the MMP of a determination of a violation of any requirement of Title 42 § **1396b(m)** or this section.

5. Suspension of payment to the entity under this subchapter for individuals enrolled after the date the Secretary or DMAS notifies the MMP of such a determination and until the Secretary or DMAS is satisfied that the basis for such determination has been corrected and is not likely to recur.

12VAC30-121-150
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-150. Continuity of care.

A. As provided by the MOU and the three-way contract, participating plans shall be required to provide or arrange for all medically necessary services, whether by sub-contract or by single-case agreement, in order to meet the health care and support needs of their enrollees.

B. Participating plans shall allow enrollees to maintain their current Medicaid providers (including out-of-network providers) for 180 days from enrollment. Participating plans shall also allow enrollees to maintain their preauthorized Medicaid services, including frequency and payment rate, for the duration of the prior authorization or for 180 days from enrollment, whichever is less. This shall not apply to enrollees residing in a nursing facility on the date of each region's program implementation.

C. Enrollees in nursing facilities at the time of program implementation may remain in the facility, or move to another nursing facility, as long as they continue to meet DMAS criteria for nursing facility care. In order to move to another nursing facility, the enrollee or his family, or both as may be appropriate, has to agree to the move.

D. During the 180-day period specified in B above, change from an existing Medicaid provider can only occur in the following circumstances:

1. The enrollee requests a change;

2. The provider chooses to discontinue providing services to an enrollee as currently allowed by Medicare or Medicaid;

3. The participating plan, CMS, or DMAS identify provider performance issues that affect enrollees' health and welfare; or

4. The provider shall be excluded from participation in Medicare and Medicaid under state or federal exclusion requirements pursuant to the U.S. Department of Health and Human Services Office of Inspector General List of Excluded Individuals or Entities (LEIE) website). Immediately report in writing to DMAS any exclusion information discovered to: DMAS, ATTN: Program Integrity/Exclusions, 600 E. Broad St., Suite 1300, Richmond, VA 23219 or emailed to providerexclusion@dmas.virginia.gov;

E. Out-of-network reimbursement rules.

1. In an urgent or emergency situation, participating plans shall reimburse an out-of-network provider of emergency or urgent care at the Medicare or Medicaid FFS rate applicable for that service, or as otherwise required under Medicare Advantage rules for Medicare services. For example, where this service would traditionally be covered under Medicare FFS, the participating plan will pay out-of-network providers the lesser of providers' charges or the Medicare FFS.

2. During the 180-day transition period as outlined in the MOU, the participating plan shall honor existing service authorization timeframes and continue to provide access to the same services and providers at the same levels and rates of Medicare or Medicaid FFS payment (not to exceed 180 days) as enrollees were receiving prior to entering the participating plan.

3. Beyond this six month period, under certain defined circumstances, participating plans will be required to offer single-case out-of-network agreements to providers who are currently serving enrollees and are willing to continue serving them at the participating plan's in-network payment rate, but who are not willing to accept new patients or enroll in the participating plan's network.

12VAC30-121-170
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-170. Model of care.

A. All participating plans (in partnership with contracted providers) shall implement

an evidence-based model of care (MOC). Participating plans must meet all CMS MOC standards for Special Needs Plans as well as additional requirements established by the Commonwealth. The Virginia-specific MOC elements are in addition to CMS' elements; likewise, the CMS and DMAS reviews and approvals are separate processes. Participating plans shall obtain approvals from both CMS and DMAS before a MOC is considered final and approved.

B. Participating plans shall be permitted to cure problems with their MOC submissions after their initial submissions. Participating plans with MOCs scoring below 85 percent will have the opportunity to improve their scores based on CMS and DMAS feedback on the elements and factors that require improvement. At the end of the review process, MOCs that do not meet CMS' standards for approval will not be eligible for selection as participating plans. CMS' standards for approval are issued to the states and made available on the Commonwealth's website.

12VAC30-121-190
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-190. State fair hearing process.

A. Notwithstanding the provisions of 12VAC30-110-10 through 12VAC30-110-370, the following regulations govern state fair hearings for dual eligible individuals enrolled in the demonstration.

B. The department's Appeals Division maintains an appeals and fair hearings system for enrollees (also referred to as appellants) to challenge appeal decisions rendered by participating plans in response to enrollee appeals of actions related to Medicaid services. Exhaustion of the participating plan's appeals process is a prerequisite to filing for a state fair hearing with the Department. Appellants who meet criteria for a state fair hearing shall be entitled to a hearing before a department hearing officer.

C. The participating plan shall conduct the initial appeal hearing, pursuant to 42 CFR Part 431 Subpart E, 42 CFR Part 438 and 12VAC30-110-10 through 12VAC30-110-370, and issue a written decision that includes its findings and information regarding the appellant's right to file an appeal with DMAS for a state fair hearing for Medicaid appeals.

D. Enrollees must be notified in writing of the participating plan's integrated appeals process:

1. At the time of the request for services;

2. With the Evidence of Coverage; and

3. Upon receipt of a notice of action from the participating plan.

E. Enrollees must be notified in writing of their right to an external appeal upon receipt of the participating plan's internal appeal decision.

F. An appellant shall have the right to representation by an attorney or other individual of his choice at all stages of an appeal.

1. For those appellants who wish to have a representative, a representative shall be designated in a written statement which is signed by the appellant whose Medicaid benefits were adversely affected. If the appellant is physically unable to sign a written statement, the division shall allow a family member or other person acting on the appellant's behalf to be the representative. If the appellant is mentally unable to sign a written statement, the division shall require written documentation that a family member or other person has been appointed or

designated as his legal representative.

2. If the representative is an attorney or a paralegal working under the supervision of an attorney, a signed statement by such attorney or paralegal that he is authorized to represent the appellant prepared on the attorney's letterhead, shall be accepted as a designation of representation.

3. A member of the same law firm as a designated representative shall have the same rights as the designated representative.

4. An appellant may revoke representation by another person at any time. The revocation is effective when the Department receives written notice from the appellant.

G. Any written communication from an enrollee or his representative which clearly expresses that he wants to present his case to a reviewing authority shall constitute an appeal request.

1.This communication should explain the basis for the appeal of the participating plan's internal appeal decision.

2. The enrollee, or his representative, may examine witnesses or documents, or both, provide testimony, submit evidence, and advance relevant arguments during the hearing.

H. Appeals to the state fair hearing process shall be made to the DMAS Appeals Division in writing, with the exception of expedited appeals, and may be made via US mail, fax transmission, hand-delivery or electronic transmission.

I. Expedited appeals referenced in 12VAC30-121-190 L below may be filed by telephone, or any of the methods set forth in subsection H in this subdivision.

J. Participating plans shall continue benefits while the participating plan's appeal or the state fair hearing is pending when all of the following criteria are met:

1. The enrollee or representative files the appeal within 10 calendar days of the mail date of the participating plan's internal appeal decision;

2. The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

3. The services were ordered by an authorized provider;

4. The original period covered by the initial authorization has not expired; and

5. The enrollee requests continuation of benefits.

K. After the final resolution and if the final resolution of the appeal is adverse to the enrollee (e.g., participating plan's internal appeal is upheld), the participating plan may recover the costs of services furnished to the enrollee while the appeal was pending, to the extent they were furnished solely because of the pending appeal.

L. The department shall maintain an expedited process for appeals when an appellant's treating provider certifies that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. Expedited appeal decisions shall be issued as expeditiously as the enrollee's health condition requires, but no later than three business days after the agency receives a fair hearing request on an appeal decision to uphold denial of a service that it determines meets the criteria for expedited resolution.

12VAC30-121-195

THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-195. Appeal timeframes.

A. Appeals to the Medicaid state fair hearing process must be filed with the DMAS Appeals Division within 60 days of the date of the participating plan's internal appeal decision, unless the time period is extended by DMAS upon a finding of good cause in accordance with state fair hearing regulations.

B. It is presumed that appellants will receive the participating plan's internal appeal decision five days after the participating plan mails it.

C. A request for appeal on the grounds that the participating plan has not acted with reasonable promptness in response to an internal appeal request may be filed at any time until the participating plan has acted.

D. The date of filing shall be the date the request is postmarked, if mailed, or the date the request is received by the department, if delivered other than by mail.

E. Documents postmarked on or before a time limit's expiration shall be accepted as timely.

F. In computing any time period under these regulations, the day of the act or event from which the designated period of time begins to run shall be excluded and the last day included. If a time limit would expire on a Saturday, Sunday, or state or federal holiday, it shall be extended until the next regular business day.

G. An extension of the 60-day period for filing a request for appeal may be granted for good cause shown. Examples of good cause include, but are not limited to, the following situations:

1. Appellant was seriously ill and was prevented by illness from contacting DMAS;

2. The participating plan's decision was not sent to the appellant. The plan may rebut this claim by evidence that the decision was mailed to the appellant's last known address or that the decision was received by the appellant.

3. Appellant sent the request for appeal to another government agency or another division within DMAS that is not the Appeals Division in good faith within the time limit; or

4. Unusual or unavoidable circumstances prevented a timely filing.

H. During the first year of the program, appeals shall be heard and decisions issued within 90 days of the postmark date (if delivered by US mail) or receipt date (if delivered by any method other than US mail).

I. The timeframes for issuing decisions will change to 75 days (during the second year of the program), and 30 days (during the third year of the program and thereafter).

J. Exceptions to standard appeal resolution timeframes. Decisions may be issued beyond the standard appeal resolution timeframes when the appellant/representative requests or causes a delay. Decisions may also be issued beyond the standard appeal resolution timeframe when any of the following circumstances exist:

1. The appellant or representative requests to reschedule/continue the hearing;

2. The appellant or representative provides good cause for failing to keep a scheduled hearing appointment, and the Appeals Division reschedules the hearing;

3. Inclement weather, unanticipated system outage, or the department's closure that prevents the hearing officer's ability to work;

4. Following a hearing, the hearing officer orders an independent medical assessment as described in **12VAC30-121-210**;

5. The hearing officer leaves the hearing record open after the hearing in order to receive additional evidence or argument from the appellant;

6. The hearing officer receives additional evidence from a person other than the appellant or his representative and the appellant requests to comment on such evidence in writing or to have the hearing reconvened to respond to such evidence or;

7. The Appeals Division determines that there is a need for additional information, and documents how the delay is in the appellant's best interest.

K. For delays requested or caused by an appellant or his representative, the delay date for the decision will be calculated as follows:

1. If an appellant or representative requests or causes a delay within 30 days of the request for a hearing, the 90-day time limit will be extended by the number of days from the date when the first hearing was scheduled until the date to which the hearing is rescheduled.

2. If an appellant or representative requests or causes a delay within 31 to 60 days of the request for a hearing, the 90-day time limit will be extended by 1.5 times the number of days from the date when the first hearing was scheduled until the date to which the hearing is rescheduled.

3. If an appellant or representative requests or causes a delay within 61 to 90 days of the request for a hearing, the 90-day time limit will be extended by 2 times the number of days from the date when the first hearing was scheduled until the date to which the hearing is rescheduled.

L. Post hearing delays requested or caused by an appellant or representative (e.g. requests for the record to be left open) will result in a day for day delay for the decision date. The department shall provide the appellant and representative with written notice of the reason for the decision delay and the delayed decision date, if applicable.

12VAC30-121-200
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-200. Prehearing decisions.

A. If the Appeals Division determines that any of the conditions as described below exist, a hearing will not be held and the appeal process shall be terminated.

1. The appeal request was not filed within the time limit imposed by 12VAC30-121-195 or extended pursuant to 12VAC30-121-195 J, and

a. The appellant did not reply to the hearing officer's request for an explanation that met good cause criteria, or

b. The appellant did reply and the hearing officer had sufficient facts to determine that the reply did not meet good cause criteria pursuant to 12VAC30-121-195.

2. The individual who filed the appeal is not the appellant and has not submitted any authorization to represent the appellant under the provisions of 12VAC30-121-190 G.

3. The participating plan's internal appeals process was not exhausted prior to the enrollee's request for a state fair hearing.

4. The services denied or terminated were Medicare covered services. In that instance, the appeal request shall be handled by the Medicare external review entity.

5. The action being appealed was not taken by DMAS, its agent or contractor, or the issue of the appeal is not related to the MMPs internal appeal decision.

6. Subsequent to the appeal request, the appellant's request for services was approved for the full amount, duration and scope of the services requested.

7. The appellant or his representative failed to appear at the scheduled hearing, and

a. Did not reply to the hearing officer's request for an explanation that met good cause criteria, or

b. Did reply and the hearing officer had sufficient facts to determine that the reply did not meet good cause criteria pursuant to 12VAC30-121-195.

8. After a written notice of the telephonic hearing has been agreed to by the appellant and sent to the appellant and the appellant or his representative failed to respond to the hearing officer's request for a telephone number at which he could be reached for the telephonic hearing.

9. The appellant or his representative withdrew the appeal request.

10. The sole issue is a federal or state law requiring an automatic change adversely affecting some or all beneficiaries.

11. The hearing officer determined from the record, without conducting a hearing, that the participating plan's decision was clearly in error and that the case should be resolved in the appellant's favor. The hearing officer may issue a decision pursuant to **12VAC30-121-210 I.**

B. If the hearing officer determined from the record, without conducting a hearing, that the case might be resolved in the appellant's favor if the participating plan obtains and develops additional information, documentation, or verification, the hearing officer may remand the case to the participating plan for action consistent with the hearing officer's written instructions pursuant to 12VAC30-121-210 I.

C. A letter shall be sent to the appellant or his representative that explains the determination made on his appeal.

D. The appellant shall have no opportunity to seek judicial review except in cases where the hearing officer receives and analyses a submission or response from the appellant or representative, or the hearing officer analyzes the merits of the agency's action.

12VAC30-121-210
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-210. Evidentiary hearings and final decisions.

A. All hearings must be scheduled at a reasonable time, date, and place and the appellant and his representative shall be notified in writing at least 15 days before the hearing.

1. The hearing location will be determined by the Appeals Division.

2. A hearing shall be rescheduled at the appellant's request no more than twice unless compelling reasons exist.

3. Rescheduling the hearing at the appellant's request will result in automatic waiver of the 90-day (or 75-day or 30-day) deadline for resolution of the appeal. The delay date for the decision will be calculated as set forth in 12VAC30-121-195 K.

B. The hearing shall be conducted by one or more hearing officers or other impartial individuals who have not been directly involved in the initial determination of the action in question or in the participating plan's appeal decision process. The hearing officer shall review the complete record for all participating plan decisions which are properly appealed, conduct informal, fact-gathering hearings, evaluate evidence presented, research the issues, and render a written final decision.

C. Subject to the requirements of all applicable federal and state laws regarding privacy, confidentiality, disclosure, and personally identifiable information, the appeal record shall be made accessible to the appellant and representative at a convenient place and time before the date of the hearing, as well as during the hearing. The appellant and his representative may examine the content of the appellant's case file and all documents and records the department will rely on at the hearing except those records excluded by law.

D. Appellants who require the attendance of witnesses or the production of records, memoranda, papers, and other documents at the hearing may request in writing the issuance of a subpoena. The request must be received by the Department at least 10 working days before the scheduled hearing. Such request shall include the witness' or respondent's name, home and work addresses, county or city of work and residence, and identify the sheriff's office which will serve the subpoena.

E. The hearing officer shall conduct the hearing, decide on questions of evidence, procedure and law, question witnesses, and assure that the hearing remains relevant to the issue or issues being appealed. The hearing officer shall control the conduct of the hearing and decide who may participate in or observe the hearing.

F. Hearings shall be conducted in an informal, non-adversarial manner. The appellant or his representative shall have the right to bring witnesses, establish all pertinent facts and circumstances; present an argument without undue interference, and question or refute the testimony or evidence, including the opportunity to confront and cross-examine agency representatives.

G. The rules of evidence shall not strictly apply. All relevant, non-repetitive evidence may be admitted, but the probative weight of the evidence will be evaluated by the hearing officer.

H. The hearing officer may leave the hearing record open for a specified period of time after the hearing in order to receive additional evidence or argument from the appellant or his representative.

1. The hearing officer may order an independent medical assessment when the appeal involves medical issues such as a diagnosis, an examining physician's report, or a medical review team's decision; and the hearing officer determines that it is necessary to have an assessment by someone other than the person or team who made the original decision (e.g., to obtain more detailed medical findings about the impairments, to obtain technical or specialized medical information, or to resolve conflicts or differences in medical findings or assessments in the existing evidence). A medical assessment ordered pursuant to this regulation shall be at the department's expense and shall become part of the record.

2. The hearing officer may receive evidence that was not presented by either party if the record indicates that such evidence exists, and the appellant, or his representative, requests to submit it or requests that the hearing officer secure it.

3. If the hearing officer receives additional evidence from an entity other than the appellant or his representative, the hearing officer shall send a copy of such evidence to the appellant and his representative, and give the appellant or his representative the opportunity to comment on such evidence in writing or to have the hearing reconvened to respond to such evidence.

4. Any additional evidence received will become a part of the hearing record, but the hearing officer must determine whether or not it will be used in making the decision.

I. After conducting the hearing, reviewing the record, and deciding questions of law, the hearing officer shall issue a written final decision which either sustains or reverses the participating plan's action or remands the case to the participating plan for further evaluation consistent with his written instructions. Some decisions may be a combination of these dispositions. The hearing officer's final decision shall be considered as the department's final administrative action pursuant to 42 CFR 431.244(f). The final decision shall include:

1. Identification of the issue or issues;

2. Relevant facts, to include a description of the procedural development of the case;

3. Conclusions of law, regulations and policy that relate to the issue or issues;

4. Discussions, analysis of the accuracy of the participating plan's decision, conclusions and hearing officer's decision;

5. Further action, if any, to be taken by the participating plan to implement the decision;

6. The deadline date by which further action must be taken; and

7. A cover letter informing the appellant and representative of the hearing officer's decision. The letter must indicate that the hearing officer's decision is final, and that the final decision may be appealed directly to the Circuit Court.

J. A copy of the hearing record shall be forwarded to the appellant and his representative with the final decision.

K. An appellant who disagrees with the hearing officer's final decision as defined herein may seek judicial review pursuant to the Administrative Process Act (§ **2.2-4026** of the *Code of Virginia*) and Rules of the Supreme Court of Virginia, Part Two A. Written instructions for requesting judicial review must be provided to the appellant or representative with the hearing officer's decision, and upon request by the appellant or representative.

12VAC30-121-220
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12VAC30-121-220. Division appeal records.

A. No person shall take from the division's custody any original record, paper, document, or exhibit which has been certified to the division except as the Appeals Division director or his designee authorizes, or as may be necessary to furnish or transmit copies for other official purposes.

B. Information in the appellant's record can be released only to the appellant, his authorized representative, the participating plan, other entities for official purposes, and other persons named in a release of information authorization signed by an appellant or his representative.

C. The fees to be charged and collected for any copies of division records will be in accordance with Virginia's Freedom of Information Act (§ 2.2-3700 et seq. of the *Code of Virginia*) or other controlling law.

D. When copies are requested from records in the division's custody, the required fee shall be waived if the copies are requested in connection with an enrollee's own appeal.

12VAC30-121-230
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-230. Provider appeals.

A. The departments Appeals Division maintains an appeal process for enrolled providers of Medicaid services who have rendered services and are requesting to challenge a participating plan's internal appeal of an adverse decision regarding payment. The participating plan's internal appeal process is a prerequisite to filing for an external appeal to the department's appeal process. The appeal process is available to (i) enrolled Medicaid service providers that have rendered services and have been denied payment in whole or part for Medicaid covered services, and (ii) enrolled Medicaid service providers who have received a Notice of Program Reimbursement or overpayment demand from the department or its contractors.

B. Department provider appeals shall be conducted in accordance with the department's provider appeal regulations at 12VAC30-20-500 *et. seq.* the *Code of Virginia* at § 32.1-325 *et. seq.* and the Virginia Administrative Process Act § 2.2-4000 *et. seq.*

C. The department's external appeal decision shall be binding upon the participating plan or plans and not subject to further appeal by the participating plan or plans.

D. If the provider is successful in its appeal, then the MMP shall reimburse it for the appealed issue.

12VAC30-121-250
THE TEXT OF THIS REGULATION IS IN DRAFT FORM AND SHOULD NOT BE RELIED UPON FOR LEGAL INTERPRETATION.

12VAC30-121-250. Marketing and enrollee communication standards for participating plans.

A. Participating plans shall be subject to rules governing their marketing and enrollee communications as specified under sections 1851(h) and 1932(d)(2) of the Social Security Act; 42 CFR 422.111, 422.2260 et. seq., 423.120(b) and (c), 423.128, and 423.2260 et. seq., and the Medicare Marketing Guidelines (Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Prescription Drug Benefit Manual).

1. Participating plans shall not be allowed to market directly to potential enrollees. Instead, plans may participate in group marketing events, provide general audience materials (such as general circulation brochures, and media and

billboard advertisements), and provide responses to individual-initiated requests for enrollment.

2. Participating plans shall receive prior approval of all marketing and enrollee communications materials except those that are exempt pursuant to 42 CFR 422.2262(b) and 423.2262(b).

3. Plans shall not begin marketing activity earlier than 90 days prior to the effective date of enrollment for the contract year.

B. At a minimum, participating plans will provide current and prospective enrollees the following materials, subject to the rules regarding content and timing of enrollee receipt as applicable under Section 1851(h) of the Social Security Act; 42 CFR 422.111, 422.2260 et. seq., 423.120(b) and (c), 423.128, and 423.2260 et. seq.; 438.10; 438.104; the three way contract; and the Medicare Marketing Guidelines.

C. Notification of Formulary Changes. The requirement at 42 CFR 423.120(b)(5) that participating plans provide at least 60 days advance notice regarding Medicare Part D formulary changes also applies to participating plans for outpatient prescription or over-the-counter drugs or products covered under Medicaid or as additional benefits.