MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	12/03/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/8/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	18	01	01-.09
10	18	05	01-.09
10	18	06	01, .03-.07 and .09-.12
10	18	07	01-.11
10	18	10	01-.09

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator **Telephone Number**
Michele Phinney 410-767-5623

Mailing Address

201 W. Preston Street

City **State** **Zip Code**
Baltimore MD 21201

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5. Name of Person to Call About this Document **Telephone No.**
Blair Inniss 410-767-1935

Email Address
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6. Check applicable items:
X- New Regulations
X- Amendments to Existing Regulations
Date when existing text was downloaded from COMAR online: May 13, 2015.
X- Repeal of Existing Regulations
X- Recodification
_ Incorporation by Reference of Documents Requiring DSD Approval
_ Reproposal of Substantively Different Text:

: Md. R
(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:
_ Yes **X-** No

8. Incorporation by Reference
_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting
_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.
_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection
_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer
I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Claire Pierson, Assistant Attorney General, (telephone #410-767-6526) on December 1, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer
Van T. Mitchell
Title **Telephone No.**
Secretary 410-767-6500

Date
December 3, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.01 Maryland AIDS Drug Assistance Program: Temporary Assistance Program

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.05 Maryland AIDS Drug Assistance Program: Eligibility

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.06 Maryland AIDS Drug Assistance Program: Pharmacy Services

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.07 Maryland AIDS Drug Assistance Program: Health Insurance (MADAP-PLUS)

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.10 Urgent Maryland AIDS Drug Assistance Program

Authority: See proposal.

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to :
(1) Adopt new Regulations .01—.09 under a new chapter COMAR 10.18.01 Maryland AIDS Drug Assistance Program: Temporary Assistance Program;
(2) Repeal and adopt new Regulations .01—.05, repeal Regulations .06—.11, amend and recodify Regulations .12, .14, and .15 to be Regulations .06, .08, and .09 respectively, and recodify Regulation .13 to be Regulation .07 under COMAR 10.18.05 Maryland AIDS Drug Assistance Program: Eligibility;
(3) Repeal and adopt new Regulations .01 and .04-1, and amend Regulations .03, .04, .04-2, .05—.07, and .09—.12 under COMAR 10.18.06 Maryland AIDS Drug Assistance Program: Pharmacy Services;
(4) Repeal and adopt new Regulations .01—.06, .08, .09, and .11, repeal Regulations .07, .10, .12, .14 and .16, and amend and recodify Regulations .13 and .15 to be Regulations .07 and .10 respectively, under COMAR 10.18.07 Maryland AIDS Drug Assistance Program: Health Insurance (MADAP-PLUS); and

(5) Adopt new Regulations .01—.09 under a new chapter COMAR 10.18.10 Urgent Maryland AIDS Drug Assistance Program.

Statement of Purpose

The purpose of this action is to align COMAR 10.18.05, 10.18.06, and 10.18.07 with current practices and bring these chapters into closer alignment with the Affordable Care Act. This proposal will also establish regulations for two existing programs – the Maryland AIDS Drug Assistance Program (MADAP) Temporary Assistance Program (TAP) and Urgent MADAP – codified as COMAR 10.18.01 and 10.18.10, respectively. Amendments to COMAR 10.18.07 will expand the capacity to help clients through the payment of co-pays, co-insurance, and deductibles associated with health care visits.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

As a result of proposed changes to COMAR 10.18.07 MADAP-Plus, this proposal will have a minimal economic impact on the Department of Health and Mental Hygiene (Department) and a positive impact on health care providers and clients, resulting from coverage of additional outpatient healthcare services. The Department's expenditures in MADAP-Plus will increase by an estimated $910,800 annually for co-pays, co-insurance, and deductibles based on estimated utilization for the following services: primary medical care, HIV subspecialty care, and laboratory services. The Department has sufficient federal funds (Ryan White Part B) and special funds (pharmaceutical rebates) to cover the cost of these additional services. The other proposed changes to COMAR 10.18.01, 10.18.05, 10.18.06, and 10.18.10 either update existing regulations or establish new regulations that reflect current practice.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(E+)	$910,800
B. On other State agencies:	NONE	
C. On local governments:	NONE	

	Benefit (+) Cost (-)	Magnitude

D. On regulated industries or trade groups:	(+)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. Under this proposal, the Department will pay for co-pays, co-insurance, and deductibles for additional covered healthcare services in the MADAP-Plus program. The estimated average number of visits per client is five visits per year. The Department has sufficient federal funds (Ryan White Part B) and special funds (pharmaceutical rebates) to cover the cost of these additional services.

Expenditures are based on estimated client utilization of services and estimated average cost per visit. The estimated number of clients who may be served through this expansion is 1,800 clients. The estimated total number of visits provided through this expansion is 9,000 visits. The estimated average amount paid by MADAP for these visits is $101.20 per visit.

9,000 x $101.20 = $910,800

D. There will be a minimal positive economic impact on health care providers resulting from an increase in client utilization of covered healthcare services.

F. The effects on the public will be positive as the proposed regulatory changes will remove a barrier to care for MADAP-Plus clients.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 8, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
The regulations will only have a minimal economic impact on small businesses resulting from their patients being able to keep medical and laboratory appointments with the assistance of MADAP-Plus covering the visit co-pays, co-insurances, and deductibles for these patients. The other proposed changes will update and establish regulations that reflect current practice, no significant change to operations will occur for any businesses, including small businesses.
G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

10.18.01 Maryland AIDS Drug Assistance Program: Temporary Assistance Program

Authority: *Health-General Article, §§2-104(b), 2-104(j), 2-105(a), and 18-102(a), Annotated Code of Maryland*

.01 Purpose.

The purpose of the Maryland AIDS Drug Assistance Program's Temporary Assistance Program is to provide short term assistance to individuals with Human Immunodeficiency Virus (HIV) who:

A. Need HIV drugs and other products;

B. Have an application for Medical Assistance or Low-Income Subsidy pending; and

C. Are considered likely to have their application approved.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquired Immunodeficiency Syndrome (AIDS)" means the medical condition caused by the Human Immunodeficiency Virus.

(2) "Agent" means a case manager, licensed social worker, registered nurse, or any other related professional that assists an individual in submitting an application to the Temporary Assistance Program.

(3) "Applicant" means an individual on whose behalf an application has been submitted to the Temporary Assistance Program and whose eligibility status for the Temporary Assistance Program has not yet been determined.

(4) "Department" means the Department of Health and Mental Hygiene.

(5) "Drug" means an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease licensed by the U.S. Food and Drug Administration, and covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04.

(6) "Enrollment period" means the period of time a recipient may receive Temporary Assistance Program benefits.

(7) "Formulary" means a list of prescription drugs and other products covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04-1.

(8) "Health care practitioner" means any individual licensed to prescribe U.S. Food and Drug Administration-approved drugs or other products in the state in which they practice.

(9) "Human Immunodeficiency Virus (HIV)" means the virus that causes AIDS.

(10) "Low-Income Subsidy (LIS)" means the federal program available under the Medicare Part D prescription drug program and Medicare advantage plans that assists persons who have limited income to pay for the cost of premiums, deductibles, and copayments.

(11) "Maryland AIDS Drug Assistance Program (MADAP)" means the program administered by the Department that provides services specified in COMAR 10.18.06.04 for enrolled recipients.

(12) "Medical Assistance" has the meaning specified in COMAR 10.09.24.02.

(13) "Recipient" means an individual who is enrolled in the Temporary Assistance Program.

(14) "Resident" means an individual:

(a) Who is living in the State voluntarily with the intention of making it that individual's home and not for a temporary purpose; and

(b) For whom any temporary absence from the State is coupled with an intent to return so as not to interrupt the continuity of residence.

(15) "Temporary Assistance Program (TAP)" means the program administered by the Department that provides short term MADAP services as specified in Regulation .05 of this chapter for low income eligible individuals.

.03 Eligibility.

To be eligible for benefits, an individual shall meet the following criteria:

A. Be a resident of Maryland;

B. Be infected with HIV; and

C. Have a pending application to Medical Assistance or LIS.

.04 Application and Enrollment.

A. Application.

(1) The agent of the applicant shall submit a completed TAP application to the Department on the form designated by the Department that includes:

(a) Responses to all applicable questions; and

(b) A copy of the completed application or other verifiable documentation for Medical Assistance or LIS enrollment.

(2) The agent of the applicant or the applicant may voluntarily withdraw the application at any time without prejudice.

(3) The Department shall:

(a) Review and process a TAP application by the end of the first business day following receipt;

(b) Approve a TAP application if the:

(i) TAP application is complete;

(ii) Applicant is determined to be eligible; and

(iii) Department is able to ascertain that the applicant will likely be found eligible for Medical Assistance or LIS;

(c) Issue a client identification number if the TAP application is approved;

(d) Disapprove a TAP application if the:

(i) TAP application is incomplete; or

(ii) Agent of the applicant fails to provide sufficient information or documentation to determine eligibility; and

(e) Contact the agent of the applicant with the status of the TAP application.

B. Enrollment.

(1) A recipient shall be approved for coverage beginning the first day of the month in which the TAP application was received.

(2) Benefits shall end on the date that a determination of Medical Assistance or LIS coverage occurs.

.05 Covered Services.

A. The recipient shall obtain a prescription for each drug or other product ordered for the recipient.

B. TAP shall pay for each prescription drug or other product within the limits established by the Department on the formulary if the prescription is ordered and signed by a health care practitioner for a recipient.

.06 Recovery of Payments.

If benefits have been incorrectly paid or another payer has been identified, the Department shall seek recovery of the amount of those payments.

.07 Fraud.

The Department shall pursue cases of suspected misrepresentation or fraud pursuant to Criminal Law Article, §8-503, Annotated Code of Maryland, or any other applicable statutory provision.

.08 Confidentiality.

Except when communicating with the parties listed in §B of this regulation and unless otherwise authorized by law, the agent of an applicant, or the agent of a recipient, the Department:

A. Shall keep all applicant and recipient personal information confidential;

B. May not disclose personal information kept on an applicant or recipient without written consent of the:

(1) Applicant;

(2) Recipient;

(3) Applicant's parent or legal guardian; or

(4) Recipient's parent or legal guardian;

C. Shall comply with the laws and regulations concerning the privacy and security of protected health information under:

(1) Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland; and

(2) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. §§1320d et seq., as amended, the HITECH Act, 42 U.S.C. §§17932, et seq., as amended, and 45 CFR Parts 160 and 164, as amended, and their implementing regulations; and

D. Shall ensure that all interactive video technology-assisted communication comply with HIPAA patient privacy and security regulations.

.09 Availability of Funding and Program Termination.

A. If sufficient monies are not available to fund TAP, the Department shall take the action necessary to eliminate a deficit which may include program termination.

B. If TAP is terminated, the Department shall provide benefits for each current recipient in accordance with Regulation .04B of this chapter.

10.18.05 Maryland AIDS Drug Assistance Program: Eligibility

Authority: Health General Article, §§2-104(b) and (i), 2-105(a) and (b), and 18-102(a) Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquired Immunodeficiency Syndrome (AIDS)" means the medical condition caused by the Human Immunodeficiency Virus.

(2) "Applicant" means an individual who has submitted an application to the Maryland AIDS Drug Assistance Program and whose eligibility status for the Maryland AIDS Drug Assistance Program has not yet been determined.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Disenroll" means to end Maryland AIDS Drug Assistance Program benefits.

(5) "Drug" means an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease licensed by the U.S. Food and Drug Administration and covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04.

(6) "Enrollment period" means the period of time a recipient may receive Maryland AIDS Drug Assistance Program benefits.

(7) "Formulary" means a list of prescription drugs and other products covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04-1.

(8) "Gross income" means the income derived from sources provided in Regulation .02.

(9) "Health care practitioner" means any individual licensed to prescribe U.S. Food and Drug Administration-approved drugs or other products in the state in which they practice.

(10) "Human Immunodeficiency Virus (HIV)" means the virus that causes AIDS.

(11) "Maryland AIDS Drug Assistance Program (MADAP)" means the program administered by the Department that provides services specified in COMAR 10.18.06.04 for enrolled recipients.

(12) "Medical Assistance" has the meaning stated in COMAR 10.09.24.02.

(13) "Recipient" means an individual who is enrolled in MADAP.

(14) "Resident" means an individual:

(a) Who is living in the State voluntarily with the intention of making it that individual's home and not for a temporary purpose; and

(b) For whom any temporary absence from the State is coupled with an intent to return so as not to interrupt the continuity of the residence.

.*02* Eligibility.

A. Except when an individual is enrolled in Medical Assistance but does not have prescription coverage assistance, an individual who is eligible for Medical Assistance is not eligible for MADAP.

B. To be eligible for benefits, an individual shall meet the following criteria:

(1) Residency;

(2) Medical; and

(3) Financial.

C. Residency Criteria. To meet the residency criteria the individual shall be a resident of Maryland.

D. Medical Criteria. To meet the medical criteria the individual shall be:

(1) Infected with HIV as verified by the individual's health care practitioner on the medical form provided by the Department; and

(2) Prescribed or will be prescribed, within three months from the date the completed application was received by the Department, one or more of the antiretroviral drugs in the formulary.

E. Financial Criteria.

(1) To meet the financial criteria the individual shall have a projected gross income less than or equal to 500 percent of the Federal Poverty Level Guidelines as updated annually in the Federal Register by the U.S. Department of Health and Human Services under authority of 42 U.S.C. §9902(2).

(2) Projected gross income shall be determined based on what can reasonably be expected to be received during the 12-month period beginning with the month in which the completed application is filed.

(3) Gross income includes income derived from:

(a) Wages and salaries, including tips;

(b) Net income from self-employment or business;

(c) Unemployment compensation;

(d) Social security payments, including disability payments;

(e) Alimony;

(f) Retirement or pension;

(g) Investments, including dividends or interest;

(h) Rental income; and

(i) Other taxable income, such as prizes, awards, and gambling winnings.

(4) Gross income under this chapter does not include income derived from:

(a) Child support;

(b) Gifts;

(c) Supplemental Social Security Income;

(d) Veterans' disability payments;

(e) Workers' compensation; and

(f) Proceeds from loans, such as student loans, home equity loans, or bank loans.

.03 Application and Enrollment.

A. Application.

(1) Applicant.

(a) An applicant shall submit a completed application to the Department on the form designated by the Department that includes:

(i) Responses to all applicable questions; and

(ii) Supporting documentation related to residency, medical, and financial eligibility criteria.

(b) An applicant may voluntarily withdraw the application at any time without prejudice.

(c) An applicant may submit a new application at any time.

(2) The Department shall:

(a) Approve the application if the:

(i) Application is complete; and

(ii) Applicant is determined to be eligible;

(b) Disapprove the application if the:

(i) Application is incomplete;

(ii) Applicant fails to provide sufficient information or documentation to determine eligibility; or

(iii) Applicant provides the appropriate documentation but is determined ineligible; and

(c) Provide the applicant with written notice of the final disposition of the application.

B. Enrollment.

(1) A recipient shall:

(a) Attest to continuing eligibility by completing and submitting the eligibility verification form provided by the Department during the sixth month of the current enrollment period; or

(b) Lose MADAP benefits, effective at the end of the seventh month of the current enrollment period, if the recipient fails to attest to continued eligibility for MADAP benefits during the sixth month of the current enrollment period;

(2) A recipient who seeks to continue enrollment shall reapply by submitting a new completed application at least ten business days prior to the end of the current 12-month enrollment period; and

(3) The Department shall:

(a) Enroll an applicant who has been determined eligible for a 12-month enrollment period with the stipulation that continued eligibility must be verified by the Department during the sixth month of the enrollment period;

(b) Establish the 12-month enrollment period beginning on the first day of the month in which the Department approves the application;

(c) Redetermine eligibility if the Department receives information that may affect continued eligibility; and

(d) Send any relevant application or eligibility verification forms at least 45 calendar days before the end of the:

(i) First six months of the current enrollment period; and

(ii) Current enrollment period.

.04 Changes in Eligibility and Disenrollment.

A. A recipient shall notify the Department within 10 business days of a change in:

(1) Availability of third-party payment for services covered under MADAP;

(2) Gross income; or

(3) Address.

B. If a change reported in §A of this regulation results in a recipient no longer qualifying for MADAP, the Department shall:

(1) Determine the recipient ineligible for MADAP; and

(2) Disenroll the recipient.

C. The notice of intended action, which notifies the recipient of the disenrollment, shall:

(1) Be mailed to the recipient at least 15 business days before the effective date of disenrollment;

(2) Include an explanation of the action;

(3) Cite the regulation supporting the action; and

(4) Explain the right of the recipient to request reconsideration or an appeal of the decision.

D. If the recipient is determined to be ineligible before the end of the current enrollment period because of a change in residency, medical, or financial eligibility criteria, the disenrollment shall be the earlier of:

(1) The date on which the recipient's current enrollment ends; or

(2) The first day of the month that is at least 15 calendar days after the date of the notice of ineligibility for MADAP benefits.

E. If the recipient's Medical Assistance coverage is pending or active, the recipient shall be disenrolled, as determined by the Department.

.05 Reconsideration and Appeal.

A. An applicant or recipient who has been notified by the Department of ineligibility for or disenrollment from MADAP benefits may request reconsideration of the decision by submitting additional supporting documentation or information to the Department within 30 business days of notification.

B. If an applicant or recipient submits a timely request for reconsideration, the Department shall:

(1) Review all additional supporting documentation, within five business days of the Department's receipt of the request for reconsideration; and

(2) Issue a final decision in writing to the applicant or recipient.

C. If an applicant or recipient is dissatisfied with the final decision of the Department, the applicant or recipient may appeal the reconsideration by requesting in writing for a hearing with the Department.

D. The Office of Administrative Hearings shall:

(1) Conduct a hearing according to the procedures set forth in COMAR 28.02.01;

(2) Hold a hearing to review the decision within 45 days of the postmarked date on the letter requesting a hearing; and

(3) Issue a decision in writing to the applicant or recipient.

[.12] *.06* Recovery of [Fees] *Payments*.

If MADAP benefits have been incorrectly paid **[**as a result of a recipient's action or inaction**]** *or another payer has been identified*, the Department shall seek recovery of the amount of those **[**benefits**]** *payments*.

[.13] *.07* (text unchanged)

[.14] *.08* Confidentiality.

Unless otherwise authorized by law, the Department:

A. Shall keep all **[**personal**]** applicant and recipient *personal* information confidential; **[**and**]**

B. May not disclose *personal* information **[**from the applicant's or recipient's record**]** *kept on an applicant or recipient* without written consent of the:

(1) (text unchanged)

(2) **[**Applicant's representative**]** *Recipient*;

(3) **[**Recipient; or**]** *Applicant's parent or legal guardian; or*

(4) Recipient's **[**representative**]** *parent or legal guardian;*

C. Shall comply with the laws and regulations concerning the privacy and security of protected health information under:

(1) Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland; and

(2) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. §§1320d et seq., as amended, the HITECH Act, 42 U.S.C. §§17932, et seq., as amended, and 45 CFR Parts 160 and 164, as amended, and their implementing regulations; and

D. Shall ensure that all interactive video technology-assisted communication comply with HIPAA patient privacy and security regulations.

[.15] .*09 Availability of Funding and* Program Termination.

A. If **[**monies received by the Department under Part B of the federal Ryan White CARE Act**]** *sufficient monies* are not **[**sufficient**]** *available* to fund MADAP, the Department **[**may terminate MADAP.**]** *shall take the action necessary to eliminate a deficit which may include MADAP termination.*

B. **[**In the event of MADAP's termination,**]** *If MADAP is terminated* the Department shall **[**pay**]** *provide* benefits for each current recipient until **[**the end of the recipient's certification period.**]** *the earlier of:*

(1) The end of the recipient's enrollment period; or

(2) Six months from the date MADAP is terminated.

10.18.06 Maryland AIDS Drug Assistance Program: *Pharmacy* Services

Authority: Health General Article, §§2-104(b) and (i), 2-105(a) and (b), and 18-102(a), Annotated Code of Maryland

10.18.06 (May 13, 2015)

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquired Immunodeficiency Syndrome (AIDS)" means the medical condition caused by the Human Immunodeficiency Virus.

(2) "Department" means the Department of Health and Mental Hygiene.

(3) "Drug" means an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease licensed by the U.S. Food and Drug Administration and covered by the Maryland AIDS Drug Assistance Program as specified in Regulation .04 of this chapter.

(4) "Enrollment period" means the period of time a recipient may receive Maryland AIDS Drug Assistance Program benefits.

(5) "Formulary" means a list of prescription drugs and other products covered by the Maryland AIDS Drug Assistance Program as specified in Regulation .04-1 of this chapter.

(6) "Health care practitioner" means any individual licensed to prescribe U.S. Food and Drug Administration-approved drugs or other products in the state in which they practice.

(7) "Human Immunodeficiency Virus (HIV)" means the virus that causes AIDS.

(8) "Maryland AIDS Drug Assistance Program (MADAP)" means the program administered by the Department that provides services specified in Regulation .04 of this chapter for enrolled recipients.

(9) "Medical Assistance" has the meaning stated in COMAR 10.09.24.02.

(10) "Pharmacist" means an individual registered and licensed to practice pharmacy in the state where the prescription is filled.

(11) "Pharmacy" means an establishment or institution registered and licensed to dispense U.S. Food and Drug Administration-approved drugs or other products to the public in the state in which the establishment or institution is located.

(12) "Preauthorization" means an approval required before the dispensing of the prescription.

(13) "Prescription" means a direction, usually written by a health care provider authorized to prescribe drugs and other products and sent to the pharmacist for the preparation, dispensing, and directions for use of a drug or other product included in the MADAP formulary.

(14) "Recipient" means an individual who is enrolled in MADAP.

.03 Conditions for Participation.

A. To participate in MADAP, a **[**provider**]** *pharmacy* shall:

(1) Be **[**approved by the Department for participation in the**]** *enrolled in* Medical Assistance **[**Program**]** *or submit a request for exception to, and receive approval from, the Department*;

(2) Accept payment by MADAP as payment in full for the professional services rendered and make no additional charges to the **[**patient**]** *recipient* or the **[**patient's**]** *recipient's* family;

(3) Maintain records **[**as required by the**]** in accordance with standards established by Medical Assistance **[**Program**]**;

(4) Maintain prescriptions for a minimum of 5 years and make them available for inspection, upon request, to the Department or its designee;

(5) Include **[**on all prescriptions sufficient**]** information **[**to justify the**]** *required by the Department on all* pharmacy **[**invoice charges**]** *invoices*;

(6) Provide services without regard to race, color, *creed*, age, sex, sexual orientation, *gender identity*, national origin, marital status, **[**and physical or mental handicap**]** *or disability*;

(7) Verify **[**the recipient's**]** *an individual's* eligibility; and

(8) Bill the recipient's third-party insurance payer in accordance with the payer's requirements in order to reduce the cost to be **[**borne**]** *paid* by **[**MADAP**]** *the Department.*

B. A **[**MADAP provider**]** *pharmacy* may not:

(1) Knowingly employ a person who has been disqualified from **[**MADAP or the**]** Medical Assistance **[**Program to compound or dispense prescriptions, unless prior written approval has been received from the Department**]**; or

(2) Place a restriction on a recipient's right to select **[**providers**]** *a pharmacy* of the recipient's choice.

.04 Covered Services.

A. **[**A**]** *The* recipient shall obtain a prescription for each **[**medication**]** *drug or other product* ordered for the recipient.

B. **[**MADAP**]** *The Department* shall pay for **[**prescriptions for**]** *a prescription* **[**drugs in**]** *drug or other product on* the formulary *within the limits established by the Department* if the prescription is ordered and signed by **[**prescribers**]** *a health care practitioner* for **[**recipients within the limits established by MADAP**]** *the recipient.*

[C. In accordance with policy guidance issued by the Health Resources and Services Administration, MADAP may pay for:

(1) Core medical services; and

(2) Support services.**]**

.04-1 Formulary.

The Department shall:

A. Maintain an updated formulary that is available electronically;

B. Make available copies of the formulary; and

C. Consider the recommendations of the MADAP Advisory Board in revising the formulary, in accordance with Regulation .04-2G of this chapter.

.04-2 Advisory Board.

A.—F. (text unchanged)

G. The Board shall:

(1) (text unchanged)

(2) Develop recommendations for the formulary **[**for MADAP**]** by considering the:

(a)—(b) (text unchanged)

(c) Needs of **[**MADAP**]** recipients, such as the:

(i) (text unchanged)

(ii) Availability of other drugs on the **[**MADAP**]** formulary to treat the same condition; and

(3) Recommend:

(a) **[**The addition to or deletion from**]** *Revisions to* the formulary **[**of existing drugs**]** as necessary; and

(b) (text unchanged)

H. (text unchanged)

.05 Limitations on Covered Services.

A. A **[**provider**]** *pharmacist* may not dispense more than a 100-day supply of **[**the**]** *a* prescribed drug **[**on one prescription at one time**]** *or other product*.

B. **[**MADAP**]** *The Department* may not pay for:

(1) A drug *or other product* prescribed as part of a recipient's care in **[**an**]** *a correctional institution*, inpatient hospital, nursing home, or long-term care setting; or

(2) **[**The drug peginterferon alfa-2b, peginterferon alfa-2a, ribavirin, epoetin alpha, filgrastim, or oxandrolone, unless the recipient has submitted to MADAP a written statement as specified in COMAR 10.18.05.05.**]** *Drugs or other products indicated as restricted on the formulary, unless the:*

(a) Recipient has submitted the completed preauthorization request form to the Department; and

(b) The Department has approved the request.

.06 Preauthorization Requirement.

[A.**]** A **[**provider**]** *pharmacist* shall obtain preauthorization **[**from MADAP**]** for each prescription or refill before dispensing **[**the**]** *a* drug *or other product marked as restricted*.

[B. If MADAP knows about third-party insurance coverage that could pay some or all of the cost of the services provided to the recipient, MADAP shall notify the provider when the provider contacts MADAP for preauthorization.

C. If a recipient's third-party insurance carrier requires preauthorization before a prescription is filled, the provider shall obtain preauthorizations from both the third-party insurance carrier and MADAP before filling the prescription.**]**

.07 Payment Procedures.

A. Except as provided in §§B and C of this regulation, **[**MADAP**]** *the Department* shall pay a **[**provider**]** *pharmacy* in accordance with the procedures of the Medical Assistance Pharmacy Services Program set forth at COMAR 10.09.03.07.

B. If **[**MADAP**]** *the Department* or the recipient tells the **[**provider**]** *pharmacy* that the recipient has or may have third-party insurance coverage **[**that will pay**]** *to offset* some or all of the cost for services provided under MADAP, the **[**provider**]** *pharmacy* shall:

(1) Bill the third-party payer the **[**provider's**]** *pharmacy's* usual and customary charge for the services provided; *and*

[(2) Determine the amount to be paid by the third-party payer; and**]**

[(3)**]** *(2)* Bill **[**MADAP**]** *the Department* for the difference between the **[**provider's**]** *pharmacy's* usual and customary charge and the anticipated third-party receipts**[**, as determined in accordance with §B(2) of this regulation**]**.

C. If the recipient has third-party insurance coverage, **[**MADAP**]** *the Department* shall pay the **[**provider**]** *pharmacy* the difference between the **[**provider's**]** *pharmacy's* usual and customary charge and the anticipated third-party insurance receipts, not to exceed the amount permitted under COMAR 10.09.03.07F and G.

D. The Department shall make *payments related to* MADAP **[**payments**]** in accordance with any applicable policies and procedures for the administration of federal funds issued pursuant to the **[**Ryan White CARE Act Amendments of 1996, P.L. 104—106**]** *Ryan White HIV/AIDS Treatment Extension Act of 2009*, and any subsequent modifications to the Act.

.09 Cause for Suspension or Removal and Imposition of Sanctions.

A. If the Department determines that a **[**provider or the provider's**]** *pharmacy or the pharmacy's* employee, or both, has failed to comply with federal or State laws and regulations, the Department may:

(1) Suspend the **[**provider**]** *pharmacy* from MADAP;

(2) Withhold payment to the **[**provider**]** *pharmacy* by MADAP; or

(3) (text unchanged)

B. **[**If a provider or the provider's employee is removed from Medical Assistance, MADAP shall remove the provider or provider's employee from MADAP.**]** *Removal of a pharmacy or a pharmacy's employee from Medical Assistance shall result in removal from MADAP*.

C. The Department:

(1) May consult with the **[**State Pharmaceutical Association and the**]** State Board of Pharmacy regarding the actions of a **[**provider**]** *pharmacy*, such as:

(a)—(c) (text unchanged)

(2) Shall consider the findings and recommendations of the **[**State Pharmaceutical Association and the**]** State Board of Pharmacy when deciding on the imposition of a sanction as stated in §A of this regulation.

D. The Department shall give the **[**provider**]** *pharmacy* written notice of the Department's intention to impose sanctions referred to in §A of this regulation, including:

(1)—(2) (text unchanged)

(3) **[**That the provider has a**]** *The pharmacy's* right to appeal the proposed action.

E. **[**Before rendering services to a recipient, a provider**]** *A pharmacy* voluntarily withdrawing from MADAP or removed or suspended from MADAP according to this regulation shall notify a recipient that the **[**provider**]** *pharmacy is* no longer **[**:

(1) Is**]** a MADAP **[**provider; and

(2) Honors MADAP cards**]** *pharmacy*.

.10 Appeal Procedures.

A **[**provider**]** *pharmacy* filing an appeal **[**under MADAP] shall do so in accordance with the Medical Assistance Pharmacy Services Program *as* set forth at COMAR 10.09.03.10.

.11 Confidentiality.

Unless otherwise authorized by law, the Department:

A. Shall keep all **[**personal**]** applicant and recipient *personal* information confidential; **[**and**]**

B. May not disclose *personal* information **[**from the applicant's or recipient's record**]** *kept on an applicant or recipient* without written consent of the:

(1) (text unchanged)

(2) **[**Applicant's representative**]** *Recipient*;

(3) **[**Recipient; or**]** *Applicant's parent or legal guardian; or*

(4) Recipient's **[**representative**]** *parent or legal guardian;*

C. Shall comply with the laws and regulations concerning the privacy and security of protected health information under:

(1) Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland; and

(2) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. §§1320d et seq., as amended, the HITECH Act, 42 U.S.C. §§17932, et seq., as amended, and 45 CFR Parts 160 and 164, as amended, and their implementing regulations; and

D. Shall ensure that all interactive video technology-assisted communication comply with HIPAA patient privacy and security regulations.

.12 *Availability of Funding and* Program Termination.

A. If **[**monies received by the Department under Part B of the federal Ryan White CARE Act**]** *sufficient monies* are not **[**sufficient**]** *available* to fund MADAP, the Department **[**may terminate MADAP**]** *shall take the action necessary to eliminate a deficit which may include MADAP termination*.

B. **[**In the event of the termination of MADAP,**]** *If MADAP is terminated,* the Department shall **[**pay**]** *provide* benefits for each current recipient **[**until the end of the recipient's certification period**]** *in accordance with COMAR 10.18.05.09B*.

10.18.07 Maryland AIDS Drug Assistance Program: Health Insurance (MADAP-PLUS)

Authority: Health-General Article, §§2-104(b) and (i), 2-105(a) and (b), and 18-102(a) Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquired Immunodeficiency Syndrome (AIDS)" means the medical condition caused by the Human Immunodeficiency Virus.

(2) "Applicant" means an individual who has submitted an application to the Maryland AIDS Drug Assistance Program—Plus and whose eligibility status for the Maryland AIDS Drug Assistance Program—Plus has not yet determined.

(3) "Core medical services" means a set of direct health care services as specified by the Ryan White Care Act Part B Program administered by the U.S. Health Resource and Services Administration.

(4) "Department" means the Department of Health and Mental Hygiene.

(5) "Enrollment period" means the period of time a recipient may receive Maryland AIDS Drug Assistance Program—Plus coverage.

(6) "Formulary" means a list of prescription drugs and other products covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04-1.

(7) "Health care provider" means an individual licensed to provide core medical services in the state where services are rendered.

(8) "Human immunodeficiency virus (HIV)" means the virus that causes AIDS.

(9) "Maryland AIDS Drug Assistance Program (MADAP)" means the program administered by the Department that provides services specified in COMAR 10.18.06.04 for enrolled recipients.

(10) "Maryland AIDS Drug Assistance Program—Plus (MADAP-Plus)" means the program administered by the Department to pay insurance premiums, copays, coinsurance, and deductibles for formulary drugs and core medical services.

(11) "Medical Assistance" has the meaning stated in COMAR 10.09.24.02.

(12) "Recipient" means an individual who is enrolled in MADAP-Plus.

.02 Eligibility.

To be eligible for MADAP-Plus coverage, an individual shall be:

A. Enrolled in MADAP; and

B. Receiving or eligible to receive health insurance and prescription drug coverage.

.03 Application and Enrollment.

A. An applicant shall apply in the manner set forth in COMAR 10.18.05.03A.

B. A recipient and the Department shall meet the enrollment responsibilities set forth in COMAR 10.18.05.03B.

C. The recipient's enrollment period for MADAP-Plus shall be the same as the MADAP enrollment period in 10.18.05.03B.

.04 Covered Services.

A. The Department shall pay for health and prescription plan premiums with a prescription drug formulary comparable to the MADAP formulary.

B. Within the limits established by the Department and in accordance with policy guidance issued by the Health Resources and Services Administration, the Department:

(1) Shall pay for copays, coinsurance, and deductibles for formulary drugs; and

(2) May pay for visits associated with core medical services.

C. An individual who is eligible for employer sponsored health insurance with a prescription drug formulary comparable to the MADAP formulary may not receive premium assistance unless the individual is:

(1) Enrolled in the employer sponsored health plan; and

(2) Paying 50 percent or more of the total monthly health insurance premiums.

.05 Changes in Eligibility and Disenrollment.

A. A recipient shall inform the Department of a change in eligibility as set forth in COMAR 10.18.05.04A.

B. If a change reported in §A of this regulation results in a recipient no longer qualifying for MADAP-Plus, the Department shall:

(1) Determine the recipient ineligible for MADAP-Plus; and

(2) Disenroll the recipient.

C. If a MADAP-Plus recipient is disenrolled from MADAP, the recipient is automatically disenrolled from MADAP-Plus.

.06 Reconsideration and Appeal.

A. An applicant or recipient who has been notified by the Department of disenrollment or ineligibility for MADAP-Plus benefits may request reconsideration of the decision by submitting additional supporting documentation or information to the Department within 30 business days of notification.

B. If an applicant or recipient submits a timely request for reconsideration, the Department shall:

(1) Review all additional supporting documentation, within five business days of the Department's receipt of the request for reconsideration; and

(2) Issue a final decision in writing to the applicant or recipient.

C. If an applicant or recipient is dissatisfied with the final decision of the Department, the applicant or recipient may appeal the reconsideration by requesting in writing for a hearing with the Department.

D. The Office of Administrative Hearings shall:

(1) Conduct a hearing according to the procedures set forth in COMAR 28.02.01;

(2) Hold a hearing to review the decision within 45 days of the postmarked date on the letter requesting a hearing; and

(3) Issue a decision in writing to the applicant or recipient.

E. The Department shall pay any health insurance plan or prescription drug plan costs due pending a decision by the Office of Administrative Hearings.

F. If the final decision finds in favor of the Department, the Department shall, upon the date of the decision, cease paying the health insurance costs allowed under this chapter and seek recovery in accordance with regulation .08 of this chapter.

[.13] *.07* Payment Procedures.

A. **[**An**]** *A recipient, recipient's representative, health care provider,* insurer, employer, *or* health plan administrator, **[**recipient, or recipient's representative**]** *as applicable*:

(1) May request payment **[**for health insurance benefits**]** *costs allowed under this chapter on behalf of the recipient* according to procedures established by the Department **[**in this chapter**]**;

(2) Shall submit a payment request that is:

(a) An invoice for the recipient's health *or prescription drug plan* insurance premium, *copays, coinsurance, and deductibles for core medical services* issued **[**by:

(i) An insurer;

(ii) An employer; or

(iii) A health plan administrator;**]** *by an insurer, an employer, a health plan administrator, prescription drug plan administrator, or a health care provider;* and

(b) Submitted timely to allow for payment in accordance with §§A(3) and B(4) of this regulation; and

(3) Shall make the initial request for the payment of costs within the time frames established **[**under:

(a) COBRA;

(b) FEHBAA; or

(c) The**]** *by the health or prescription drug* insurance policy.

B. The Department:

(1) May not process a payment request that is not submitted as required by this chapter;

(2) Shall **[**return unpaid an invoice that is not submitted as required by this chapter**]** *inform a recipient or the recipient's representative if an invoice is not paid*;

(3) Shall make **[**health insurance premium**]** payments in accordance with any applicable policies and procedures for the administration of federal funds issued pursuant to the Ryan White CARE Act Amendments of 1996, P. L. 104-146, and any subsequent modifications to the Act; *and*

(4) Shall make subsequent payments:

(a) On the designated due date or on a later date as permitted under **[**the**]** *a* health *or prescription drug* plan; or

(b) Upon agreement between the Department and the:

(i) (text unchanged)

(ii) Employer; **[**or**]**

(iii) Health plan administrator; **[**and**]**

(iv) Prescription drug plan administrator; or

(iv) Health care provider.

[(5) May seek from the insurer repayment of any remaining prepaid premiums in the event of the death of a recipient**]**.

.08 Recovery of Payments.

If MADAP-Plus payments have been incorrectly paid or another payer has been identified, the Department shall seek recovery of the amount of those payments.

.09 Fraud.

The Department shall pursue cases of suspected misrepresentation or fraud pursuant to Criminal Law Article, §8-503, Annotated Code of Maryland, or any other applicable statutory provision.

[.15] *.10* Confidentiality.

Unless otherwise authorized by law, the Department:

A. Shall keep all **[**personal**]** applicant and recipient *personal* information confidential; **[**and**]**

B. May not disclose *personal* information **[**from the applicant's or recipient's record**]** *kept on an applicant or recipient* without the written consent of the **[**applicant or recipient.**]***:*

(1) Applicant;

(2) Recipient;

(3) Applicant's parent or legal guardian; or

(4) Recipient's parent or legal guardian;

C. Shall comply with the laws and regulations concerning the privacy and security of protected health information under:

(1) Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland; and

(2) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C; §§1320d et seq., as amended, the HITECH Act, 42 U.S.C. §§17932, et seq., as amended, and 45 CFR Parts 160 and 164, as amended, and their implementing regulations; and

D. Shall ensure that all interactive video technology-assisted communication comply with HIPAA patient privacy and security regulations.

.11 Availability of Funding and Program Termination.

A. If sufficient monies are not available to fund MADAP-Plus, the Department shall take the action necessary to eliminate a deficit which may include MADAP-Plus termination.

B. If MADAP-Plus is terminated, the Department shall provide coverage for each current recipient until the earlier of:

(1) The end of the recipient's enrollment period; or

(2) Six months from the date MADAP-Plus is terminated.

10.18.10 Urgent Maryland AIDS Drug Assistance Program

Authority: Health-General Article, §§2-104(b), 2-104(j), 2-105(a), and 18-102(a), Annotated Code of Maryland

.01 Purpose.

The purpose of the Urgent Maryland AIDS Drug Assistance Program is to provide expedited assistance to individuals with Human Immunodeficiency Virus (HIV) who have an immediate need for HIV drugs and other products.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquired Immunodeficiency Syndrome (AIDS)" means the medical condition caused by the Human Immunodeficiency Virus.

(2) "Agent" means a case manager, licensed social worker, registered nurse, or any other related professional that assists an individual in submitting an application to the Urgent Maryland AIDS Drug Assistance Program.

(3) "Applicant" means an individual on whose behalf an application has been submitted to the Urgent Maryland AIDS Drug Assistance Program and whose eligibility status for the Urgent Maryland AIDS Drug Assistance Program has not yet been determined.

(4) "Department" means the Department of Health and Mental Hygiene.

(5) "Drug" means an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease licensed by the U.S. Food and Drug Administration, and covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04.

(6) "Enrollment period" means the period of time a recipient may receive Urgent Maryland AIDS Drug Assistance Program benefits.

(7) "Formulary" means a list of prescription drugs and other products covered by the Maryland AIDS Drug Assistance Program as specified in COMAR 10.18.06.04-1.

(8) "Health care practitioner" means any individual licensed to prescribe U.S. Food and Drug Administration-approved drugs or other products in the state in which they practice.

(9) "Human Immunodeficiency Virus (HIV)" means the virus that causes AIDS.

(10) "Maryland AIDS Drug Assistance Program (MADAP)" means the program administered by the Department that provides services specified in COMAR 10.18.06.04 for enrolled recipients.

(11) "Recipient" means an individual who is enrolled in Urgent MADAP.

(12) "Urgent MADAP" means the program administered by the Department that provides expedited access to MADAP services as specified in Regulation .05 of this chapter for eligible individuals.

.03 Eligibility.

To be eligible for coverage, an individual shall be eligible for MADAP as specified in COMAR 10.18.05.02 and:

A. Be taking antiretroviral medication and have less than 2 week supply;

B. Have an acute medical condition needing immediate access to formulary medication as attested by the agent; or

C. Be a pregnant woman needing medications to prevent perinatal transmission of HIV.

.04 Application and Enrollment.

A. Application.

(1) The agent of the applicant shall:

(a) Submit a complete Urgent MADAP application to the Department on the form designated by the Department;

(b) Submit a copy of the complete or incomplete MADAP application; and

(c) Attest to submitting supporting documentation to complete the MADAP application within 30 calendar days after submission of the Urgent MADAP application.

(2) The agent of the applicant or applicant may voluntarily withdraw the Urgent MADAP application at any time without prejudice.

(3) The Department shall:

(a) Review and process an Urgent MADAP application by the end of the first business day following receipt;

(b) Approve an Urgent MADAP application if the:

(i) Urgent MADAP application is complete; and

(ii) Applicant is determined to be eligible;

(c) Issue a client identification number if the Urgent MADAP application is approved;

(d) Disapprove an Urgent MADAP application if the:

(i) Urgent MADAP application is incomplete;

(ii) Applicant is determined to be ineligible; or

(iii) Agent of the applicant fails to provide sufficient information or documentation to determine eligibility; and

(e) Contact the agent of the applicant with the status of the Urgent MADAP application.

B. Enrollment.

(1) A recipient shall be approved for coverage beginning the first day of the month in which the Urgent MADAP application was received.

(2) Benefits shall end on the date that a determination of MADAP coverage occurs and not later than 60 calendar days from the date the Urgent MADAP application was approved.

.05 Covered Services.

A. The recipient shall obtain a prescription for each drug or other product ordered for the recipient.

B. Urgent MADAP shall pay for each prescription drug or other product within the limits established by the Department on the formulary if the prescription is ordered and signed by a health care practitioner for a recipient.

.06 Recovery of Payments.

If benefits have been incorrectly paid or another payer has been identified, the Department shall seek recovery of the amount of those payments.

.07 Fraud.

The Department shall pursue cases of suspected misrepresentation or fraud pursuant to:

A. Criminal Law Article, §8-503, Annotated Code of Maryland; or

B. Any other applicable statutory provision.

.08 Confidentiality.

Except when communicating with the parties listed in §B of this regulation and unless otherwise authorized by law, the agent of an applicant, or the agent of a recipient, the Department:

A. Shall keep all applicant and recipient personal information confidential;

B. May not disclose personal information kept on an applicant or recipient without written consent of the:

(1) Applicant;

(2) Recipient;

(3) Applicant's parent or legal guardian; or

(4) Recipient's parent or legal guardian;

C. Shall comply with the laws and regulations concerning the privacy and security of protected health information under:

(1) Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland; and

(2) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. §§1320d et seq., as amended, the HITECH Act, 42 U.S.C. §§17932, et seq., as amended, and 45 CFR Parts 160 and 164, as amended, and their implementing regulations; and

(D) Shall ensure that all interactive video technology-assisted communication comply with HIPAA patient privacy and security regulations.

.09 Availability of Funding and Program Termination.

A. If sufficient monies are not available to fund Urgent MADAP, the Department shall take the action necessary to eliminate a deficit which may include program termination.

B. If Urgent MADAP is terminated, the Department shall provide benefits for each current recipient in accordance with Regulation .04B of this chapter.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene