DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule concerning Telemedicine Extension, Section 8.200.3.B and .3.D, 8.520.4.B, 8.700.1, 8.730.3.B, 8.740.1, 8.750.3.B
Rule Number: MSB 20-05-21-A
Division / Contact / Phone: Health Programs Office / Russ Zigler / 303-866-5927

SECRETARY OF STATE

RULES ACTION SUMMARY AND FILING INSTRUCTIONS

SUMMARY OF ACTION ON RULE(S)

1. Department / Agency Name: Health Care Policy and Financing / Medical Services Board

2. Title of Rule: MSB 20-05-21-A, Revision to the Medical Assistance Act Rule concerning Telemedicine Extension, Section 8.200.3.B and .3.D, 8.520.4.B, 8.700.1, 8.730.3.B, 8.740.1, 8.750.3.B

3. This action is an adoption of: an amendment

4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) 8.200.3.B and .3.D, 8.520.4.B, 8.700.1, 8.730.3.B, 8.740.1, 8.750.3.B, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).

5. Does this action involve any temporary or emergency rule(s)? No
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.200.3.B with the proposed text beginning at 8.200.3.B.3 through the end of 8.200.3.B.3. Replace the current text at 8.200.3.D.2 with the proposed text beginning at 8.200.3.D.2.c.i.7 through the end of 8.200.3.D.2.c.i.7. Replace the current text at 8.520.4.B.1.g through the end of 8.520.4.B.1.g. Replace the current text at 8.700.1.C with the proposed text beginning at 8.700.1.C through the end of 8.700.1.C. Replace the current text at 8.730.B.11 with the proposed text beginning at 8.730.B.11 through the end of 8.730.B.11. Replace the current text at 8.740.1.4 with the proposed text beginning at 8.740.1.4 through the end of 8.740.1.4. Replace the

*to be completed by MSB Board Coordinator

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current text at 8.750.3.B with the proposed text beginning at 8.750.3.B through the end of 8.750.3.B. This rule is effective September 30, 2020.

*to be completed by MSB Board Coordinator

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Title of Rule: Revision to the Medical Assistance Act Rule concerning Telemedicine Extension, Section 8.200.3.B and .3.D, 8.520.4.B, 8.700.1, 8.730.3.B, 8.740.1, 8.750.3.B
Rule Number: MSB 20-05-21-A
Division / Contact / Phone: Health Programs Office / Russ Zigler / 303-866-5927

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   This rule revision makes permanent the expanded telemedicine authorized during the Coronavirus Disease 2019 (COVID-19) public health emergency, and as authorized for permanent adoption in Senate Bill 20-212, for select physician services, home health, Federally-Qualified Health Center, Family Planning, Rural Health Clinic, and Community Mental Health Centers/Clinic services. The expanded telemedicine modalities include interactive audio, interactive video, or interactive data communication in lieu of face-to-face visits between clients and health professionals. The purpose of the rule revision is to present the Telemedicine emergency rule for permanent adoption. The Department will work with stakeholders to study the rule's implementation and prepare a report for the SMART Government Act hearing, as required by legislation.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2020);
   Section 25.5-5-320, C.R.S. (2019)

Initial Review **07/10/2020** Final Adoption **08/14/2020**
Proposed Effective Date **10/01/2020** Emergency Adoption

DOCUMENT #01

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Title of Rule: Revision to the Medical Assistance Act Rule concerning Telemedicine Extension, Section 8.200.3.B and .3.D, 8.520.4.B, 8.700.1, 8.730.3.B, 8.740.1, 8.750.3.B
Rule Number: MSB 20-05-21-A
Division / Contact / Phone: Health Programs Office / Russ Zigler / 303-866-5927

REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   Clients receiving services for telemedicine-eligible physician services, home health, Federally-Qualified Health Center, family planning, Rural Health Clinic, and Community Mental Health Center/Clinic services, and the providers that render such services, will be benefit from the proposed rule. Providers of such services will bear the cost of maintaining any technology resources required to provide telemedicine services to clients.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   Affected clients and providers will benefit from continued telemedicine expansion following the authorization of such services during the COVID-19 public health emergency. Clients and providers may maintain the telemedicine services utilized during the COVID-19 public health emergency.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   The Department estimates that the proposed rule will result in additional utilization by Medicaid members at FQHCs and RHCs and for supervisory visits for HCBS and home health services. The Department estimates an impact of $5,068,380 in FY 2020-21 and $10,136,758 in FY 2021-22. The additional funding needed for these policy changes was appropriated through SB 20-212.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The probable cost of the proposed rule to a provider is setting up and maintaining the technology resources necessary to implement telemedicine, if such technology is not already utilized by a provider. The benefits of the proposed rule are maintaining

the telemedicine services utilized during the COVID-19 public health emergency. The costs of inaction are disrupting the telemedicine services utilized during the COVID-19 public health emergency. There are no benefits to inaction.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There are no less costly or less intrusive methods for achieving the purpose of the proposed rule.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   There are no alternative methods for achieving the purpose for the proposed rule.

8.200 PHYSICIAN SERVICES

8.200.3. BENEFITS

8.200.3.B Telemedicine is the delivery of medical services and any diagnosis, consultation, treatment, transfer of medical data or education related to health care services using interactive audio, interactive video or interactive data communication instead of in-person contact.

1. Physician services may be provided as telemedicine.

2. Any health benefits provided through telemedicine shall meet the same standard of care as in-person care.

3. Telemedicine includes interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission). Any health benefits provided through interactive audio, interactive video, or interactive data communication must meet the same standard of care as in-person care.

8.200.3.D.2 Speech – Language and Hearing Services

c. ELIGIBLE PLACES OF SERVICE

i. Eligible Places of Service shall include:

1. Office

2. Home

3. School

A. Therapies provided as part of a member's school requirement are not separately reimbursable. These services are paid for by the school district which is reimbursed by the Department. Providers may not submit claims for therapy services performed as part of a member's school requirement.

4. FQHC

5. Outpatient Hospital

6. Community Based Organization

7. Telemedicine, including interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission). Any health benefits provided through interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) must meet the same standard of care as in-person care.

8.520 HOME HEALTH SERVICES

8.520.4. Covered Services

8.520.4.B. Place of Service

1. Services shall be provided in the client's place of residence or one of the following places of service:

   a. Assisted Living Facilities (ALFs);

   b. Alternative Care Facilities (ACFs);

   c. Group Residential Services and Supports (GRSS) including host homes, apartments or homes where three or fewer clients reside. Services shall not duplicate those that are the contracted responsibility of the GRSS;

   d. Individual Residential Services and Supports (IRSS) including host homes, apartments or homes where three or fewer clients reside Services shall not duplicate those that are the contracted responsibility of the IRSS; or

e. Hotels, or similar temporary accommodations while traveling, will be considered the temporary place of residence for purposes of this rule.

f. Nothing in this section should be read to prohibit a client from receiving Home Health Services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.

g. Services may be provided using interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) instead of in-person contact. Any health benefits provided through interactive audio, interactive video, or interactive data communication must meet the same standard of care as in-person care.

8.700 FEDERALLY QUALIFIED HEALTH CENTERS

8.700.1 DEFINITIONS

A. Federally Qualified Health Center (FQHC) means a hospital-based or freestanding center that meets the FQHC definition found in Title 42 of the Code of Federal Regulations, Part 405, Subpart X (2015). Title 42 of the Code of Federal Regulations, Part 405, Subpart X (2015) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. These regulations are available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. 24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule:

B. Visit means a one-on-one, face-to-face encounter between a center client and physician, dentist, dental hygienist, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, clinical psychologist, podiatrist, clinical social worker, licensed marriage and family therapist, licensed professional counselor, or licensed addiction counselor providing the services set forth in Section 8.700.3.A. Group sessions do not generate a billable encounter for any FQHC services.

1. A visit includes a one-on-one, face-to-face encounter between a center client and a supervised person pursuing mental health therapy licensure as a licensed clinical social worker, licensed professional counselor, licensed marriage and family therapist, or psychologist in the state of Colorado providing services set forth in Section 8.700.3.A. The supervised person must hold a candidate permit as a licensed professional counselor or a candidate permit as a licensed marriage and family therapist, or a candidate permit as a psychologist, or a be a licensed social worker. Group sessions do not generate a billable encounter for any FQHC services.

C. The visit definition includes interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) encounters.

1. Any health benefits provided through interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) must meet the same standard of care as in-person care.

8.730 FAMILY PLANNING SERVICES

8.730.3 Provider Eligibility

8.730.3.A. The following Medicaid enrolled providers may offer family planning services:

1. Physician
2. Osteopath
3. Nurse Practitioner
4. Certified Nurse-Midwife
5. Physician Assistant
6. Clinical Nurse Specialist
7. Certified Registered Nurse Anesthetist
8. Family Planning Clinic
9. Public Health Agency
10. Non-physician Practitioner Group

8.730.3.B. Eligible places of service include:

1. Office
2. Clinic
3. Public Health Agency
4. Home

5. School

6. School-based Health Center

7. Federally Qualified Health Center

8. Rural Health Center

9. Hospital

10. Ambulatory Surgery Center

11. Telemedicine, including interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission). Any health benefits provided through interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) must meet the same standard of care as in-person care.

8.740 RURAL HEALTH CLINICS

8.740.1 DEFINITIONS

Rural Health Clinic means a clinic or center that:

1. Has been certified as a Rural Health Clinic under Medicare.

2. Is located in a rural area, which is an area that is not delineated as an urbanized area by the Bureau of the Census.

3. Has been designated by the Secretary of Health and Human Services as a Health Professional Shortage Area (HPSA) through the Colorado Department of Public Health and Environment.

4. Is not a rehabilitation facility or a facility primarily for the care and treatment of mental diseases.

Visit means a face-to-face encounter, or an interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) encounter between a clinic client and any health professional providing the services set forth in 8.740.4. Any health benefits provided through interactive audio, interactive video, or interactive data communication must meet the same standard of care as in-person care

8.750 COMMUNITY MENTAL HEALTH CENTERS/CLINICS

8.750.3 COVERED SERVICES

8.750.3.A. Services shall include but are not limited to prevention, diagnosis and treatment of emotional or mental disorders. Such services shall be rendered primarily on an outpatient and consultative basis for clients residing in a particular community in or near the facility so situated.

8.750.3.B. Community Mental Health Centers/Clinics shall provide medically necessary rehabilitation services in an outpatient setting. Covered services shall include:

1. Case management services, including but not limited to:

   a. Service planning and program linkage.

   b. Referral recommendations.

   c. Monitoring and follow up.

   d. Client advocacy.

   e. Crisis management.

2. Group psychotherapy services shall be face-to-face, or interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) services that are insight-oriented, behavior modifying, and that involve emotional interactions of the group members. Group psychotherapy services shall assist in providing relief from distress and behavior issues with other clients who have similar problems and who meet regularly with a practitioner. Any health benefits provided through interactive audio, interactive video, or interactive data communication must meet the same standard of care as in-person care

3. Individual psychotherapy services shall be face-to-face, or interactive audio (including but not limited to telephone and relay calls), interactive video (including but not limited to interactive audiovisual modalities), or interactive data communication (including but not limited to live chat and excluding text messaging, electronic mail, and facsimile transmission) services that are tailored to address the individual needs of the client. Services shall be insight-oriented, behavior modifying and/or supportive with the client in an office or outpatient facility setting. Individual psychotherapy services are limited to thirty-five visits per State fiscal year. Any health benefits provided through interactive audio, interactive video, or interactive data communication must meet the same standard of care as in-person care

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule concerning the Pharmaceutical Rate Methodology, Section(s) 8.800.1 and 8.800.13
Rule Number: MSB 20-04-24-A
Division / Contact / Phone: Pharmacy / Kristina Gould / 6715

SECRETARY OF STATE

RULES ACTION SUMMARY AND FILING INSTRUCTIONS

SUMMARY OF ACTION ON RULE(S)

1. Department / Agency Name: Health Care Policy and Financing / Medical Services Board

2. Title of Rule: MSB 20-04-24-A, Revision to the Medical Assistance Act Rule concerning the Pharmaceutical Rate Methodology, Section(s) 8.800.1 and 8.800.13.

3. This action is an adoption of: an amendment

4. Rule sections affected in this action (if existing rule, also give Code of Regulations number and page numbers affected):

   Sections(s) 8.800.1 and 8.800.13, Colorado Department of Health Care Policy and Financing, Staff Manual Volume 8, Medical Assistance (10 CCR 2505-10).

5. Does this action involve any temporary or emergency rule(s)? No
   If yes, state effective date:
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.800.1 with the proposed text beginning at 8.800.1 through the end of 8.800.1. Replace the current at 8.800.13 with the proposed text beginning at 8.800.13 through the end of 8.800.13. This rule is effective October 1, 2020.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule concerning the Pharmaceutical Rate Methodology, Section(s) 8.800.1 and 8.800.13
Rule Number: MSB 20-04-24-A
Division / Contact / Phone: Pharmacy / Kristina Gould / 6715

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   This proposed rule change will update the reimbursement methodology for outpatient pharmacy by incorporating the National Average Drug Acquisition Cost (NADAC) and Maximum Allowable Cost (MAC) rates into the lesser-of calculation. NADAC is a Centers for Medicare and Medicaid Services published rate which represents the national average of the drug acquisition costs submitted by retail community pharmacies. MAC is a rate which will be utilized when a covered drug does not possess Average Acquisition Cost (AAC) nor National Average Drug Acquisition Cost (NADAC) rates. The MAC rate is calculated using an adjustment of the national pricing benchmark Wholesale Acquisition Cost (WAC) whereby generic drug MAC rates will be WAC minus 10 percent and brand name MAC rates will be WAC minus 3 percent.

   The NADAC and MAC rates will help address a gap in the current AAC rate setting for some prescription drugs, resulting in rates better aligned with acquisition costs. In addition, the Joint Budget Committee voted in May 2020 in favor of implementing the MAC rates. The Department anticipates the incorporation of MAC rates into outpatient pharmacy reimbursement will be mandated in the FY2020-21 Long Bill.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

   1927 42 USC 1396r-8(e)

   42 CFR 447.331-334

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2020);

Initial Review	**[date]**	Final Adoption	**[date]**
Proposed Effective Date	**[date]**	Emergency Adoption	**[date]**

DOCUMENT #

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Title of Rule: Revision to the Medical Assistance Act Rule concerning the Pharmaceutical Rate Methodology, Section(s) 8.800.1 and 8.800.13
Rule Number: MSB 20-04-24-A
Division / Contact / Phone: Pharmacy / Kristina Gould / 6715

REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   The class of persons who will be affected by this proposed rule is pharmacy providers as they may receive lower reimbursement, depending on the drug billed, due to the integration of the NADAC and MAC rates into the lesser-of reimbursement methodology. The class of persons who will benefit from the proposed rule is the Department as it will address a gap in the current AAC rate setting for some prescription drugs, resulting in rates better aligned with acquisition costs.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   The probable quantitative and qualitative impact is that providers may receive lower reimbursement, for some billed drugs, due to the integration of NADAC and MAC rates into the lesser-of methodology; whereas the Department will utilize rates better aligned with acquisition costs.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   There are no probable costs to the Department as the new reimbursement methodology can be implemented with existing resources.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The probable cost of action is that providers may receive lower reimbursement, for some billed drugs, due to the incorporation of the NADAC and MAC rates into the lesser-of methodology; whereas the probable benefit of action is that the Department will be able to utilize rates better aligned with acquisition costs and comply with an expected mandate to implement MAC rates in the FY2020-21 Long Bill. The probable benefit of inaction is that providers may not receive lower reimbursement due to the incorporation of the NADAC and MAC rates into the lesser-of methodology; whereas the probable cost of inaction is that the Department

will reimburse well over acquisition costs for some drugs and will not be able to comply with the expected mandate to implement MAC rates in the FY2020-21 Long Bill.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   N/A

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   N/A

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8.800 PHARMACEUTICALS

8.800.1 DEFINITIONS

A. 340B Pharmacy means any pharmacy that participates in the Federal Public Health Service's 340B Drug Pricing Program as described in Title 42 of the United States Code, Section 256b (2014). Title 42 of the United States Code, Section 256b (2014) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

B. Average Acquisition Cost (AAC) means the average acquisition cost for like drugs grouped by Generic Code Number (GCN). For GCNs with both generic and brand drugs, the Department shall determine two separate AAC rates for the GCN. One AAC rate shall be based on the average acquisition cost for all generic drugs while the other shall be based on the average acquisition cost for all brand drugs.

C. Conflict of Interest means having competing professional or personal obligations or personal or financial interests that would make it difficult to fulfill duties in an objective manner.

D. Department means the Colorado Department of Health Care Policy and Financing.

E. Dispensing Fee means the reimbursement amount for costs associated with filling a prescription. Costs include salary costs, pharmacy department costs, facility costs, and other costs.

F. Dispensing Prescriber means a health care professional who, as licensed by Colorado state law, prepares, dispenses and instructs members to self-administer medication.

G. Drug Class means a group composed of drugs that all treat a particular disease, symptom or indication.

H. Emergency Situation means any condition that is life threatening or requires immediate medical intervention as determined in good faith by the pharmacist.

I. E-prescription means the transmission of a prescription through an electronic application.

J. Fiscal agent means a contractor that supports and operates the pharmacy benefit management system on behalf of the Medical Assistance Program.

K. Federal Upper Limit (FUL) means the upper limit for multiple source drugs as set by the Centers for Medicare and Medicaid Services pursuant to Title 42 of the Code of Federal Regulations, Part 447.512-447.516 (2016). Title 42 of the Code of Federal Regulations, Part 447.512-447.516 (2016) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

L. Generic Code Number (GCN) means a standard number to group together drugs that have the same ingredients, route of administration, drug strength, and dosage form.

M. Good Cause means failing to disclose a Conflict of Interest; participating in wrongdoing or misconduct in the case of serving as a member of a committee or other advisory body for the Department; failing to perform required duties; or missing two scheduled meetings per calendar year.

N. Government Pharmacy means any pharmacy whose primary function is to provide drugs and services to members of a facility whose operating funds are appropriated directly from the State of Colorado or the federal government excluding pharmacies funded through Indian Health Services.

O. Institutional Pharmacy means any pharmacy whose primary function is to provide drugs and services to hospitalized patients and others receiving health care provided by the facility with which the pharmacy is associated.

P. Mail Order Pharmacy means any pharmacy that delivers drugs primarily by mail.

Q. Maintenance Medication means any drug, as determined by the Department, which is used to treat a chronic illness or symptoms of a chronic illness.

R. Maximum Allowable Cost (MAC) means the rate for a covered drug which does not possess Average Acquisition Cost (AAC) nor National Average Drug Acquisition Cost (NADAC) rates. This rate is calculated using an adjustment of the national pricing benchmark Wholesale Acquisition Cost (WAC).

SR. Medical Assistance Program shall have the meaning defined in Section 25.5-1-103(5), C.R.S. (2016).

TS. Medical Assistance Program Allowable Charge means the allowed ingredient cost plus a dispensing fee or the provider's Usual and Customary Charge, whichever is less, minus the member's copayment as determined according to 10 C.C.R. 2505-10, Section 8.754.

UT. Medical Director means the physician or physicians who advise the Department.

VU. Medicare Part D means the prescription drug benefit provided to Part D eligible individuals pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

WV. Medicare Part D Drugs means drugs defined at Title 42 of the United States Code, Section 1395w-102(e) (2014) and Title 42 of the Code of Federal Regulations, Section 423.100 (2015). Title 42 of the United States Code, Section 1395w-102(e) (2014) and Title 42 of the Code of Federal Regulations, Section 423.100 (2015) are hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the referenced material. This statute is available for public inspection at the Department of Health Care Policy and Financing, 1570 Grant Street, Denver, CO 80203. Pursuant to C.R.S. §24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall

provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

XW. Non-preferred Drug means a drug that is designated as non-preferred by the Medical Director pursuant to 10 CCR 2505-10, Section 8.800.16, and requires prior-authorization before being payable by the Medical Assistance Program.

Y. National Average Drug Acquisition Cost (NADAC) is a Centers for Medicare and Medicaid Services published rate which represents the national average of the drug acquisition costs submitted by retail community pharmacies.

ZX. Old Age Pension Health Care Program and Old Age Pension Health Care Supplemental Program (OAP State Only) means the program established to provide necessary medical care for clients that qualify for Old Age Pension but do not qualify for the Medical Assistance Program under Title XIX of the Social Security Act and Colorado statutes.

AAY. Over-the-Counter (OTC) means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

BBZ. Part D eligible individual has the same meaning as defined in 10 C.C.R. 2505-10, Section 8.1000.1.

CCAA. Pharmacy and Therapeutics Committee (P&T Committee) means an advisory board that shall perform reviews and make recommendations which facilitate the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.800.17.

DDBB. Preferred Drug means a drug that is designated preferred by the Medical Director pursuant to 10 CCR 2505-10, Section 8.800.16.B, that is payable by the Medical Assistance Program without first obtaining a prior authorization unless otherwise required to protect the health and safety of specific members.

EECC. Preferred Drug List (PDL) means a list, applicable only to fee-for-service and primary care physician Medical Assistance Program members, which identifies the Preferred Drugs and Non-preferred Drugs within a drug class.

FFDD. Prescriber means a healthcare professional who, as licensed by Colorado state law, may prescribe and authorize the use of medicine or treatment to a member. Prescribers must be enrolled in the Medical Assistance Program to receive reimbursement.

GGEE. Provider Bulletin means a document published and distributed by program and policy staff to communicate information to providers related to the Department.

HHFF. Retail Pharmacy means any pharmacy that is not a 340B Pharmacy, Government Pharmacy, Institutional Pharmacy, Mail Order Pharmacy, or Rural Pharmacy.

IIGG. Rural Pharmacy means any pharmacy that is the only pharmacy within a twenty-mile radius.

JJHH. Submitted Ingredient Cost means a pharmacy's calculated ingredient cost. For drugs purchased through the Federal Public Health Service's 340B Drug Pricing Program, the Submitted Ingredient Cost means the 340B purchase price.

KK~~II~~. Total Prescription Volume means all new and refill prescriptions dispensed for all payer types. Payer types include but are not limited to Medicaid, Medicare, commercial, third-party, and uninsured.

LL~~JJ~~. Usual and Customary Charge means the reimbursement amount the provider charges the general public to pay for a drug.

MM~~KK~~. Wholesale Acquisition Cost (WAC) means with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

8.800.13 REIMBURSEMENT CALCULATION

8.800.13.A. Covered drugs for all members except for OAP State Only clients shall be reimbursed the lesser of:

1. The Usual and Customary Charge minus the member's copayment, as determined according to 10 C.C.R. 2505-10, Section 8.754; or

2. The allowed ingredient cost plus a Dispensing Fee minus the member's copayment, as determined according to 10 C.C.R. 2505-10, Section 8.754.

Covered drugs for the OAP State Only Program shall be reimbursed according to 10 C.C.R. 2505-10, Section 8.941.9.

8.800.13.B. The allowed ingredient cost for Retail Pharmacies, Rural Pharmacies, 340B Pharmacies, Institutional Pharmacies, Government Pharmacies and Mail Order Pharmacies shall be the lesser of AAC, NADAC or Submitted Ingredient Cost. If AAC and~~or~~ NADAC are~~is~~ not available, the allowed ingredient cost shall be the lesser of MAC~~WAC~~ , ~~or~~ Submitted Ingredient Cost.

1. The Department shall grant an exception to the allowed ingredient cost for clotting factor which shall be ~~reimbursed~~ the lesser of ~~the provider's usual and customary charge to the general public, or the~~ S~~s~~ubmitted I~~i~~ngredient C~~c~~ost ~~, or the~~ WAC.

8.800.13.C. MAC rates shall be calculated as follows:

1. The generic drug MAC rate shall be WAC minus 10 percent.

2. The brand name drug MAC rate shall be WAC minus 3 percent.

8.800.13.DC. AAC rates shall be rebased monthly using invoices and/or purchase records provided to the Department through a representative group of pharmacies. If the Department cannot establish a process to obtain invoices and/or purchase records on a monthly basis, the Department shall survey one-fourth (1/4) of all Medicaid enrolled pharmacies every quarter to rebase AAC rates.

8.800.13.ED. A pharmacy wanting to inquire about a listed AAC rate shall complete the Average Acquisition Cost Inquiry Worksheet posted on the Department's website. The pharmacy shall email the completed worksheet with a copy of the receipt invoice to the Department or designated vendor as indicated on the Average Acquisition Cost Inquiry Worksheet. The Department shall have five (5) days to provide an inquiry response to the pharmacy. If the AAC rate requires revision, the Department shall then have 5 additional days to update the AAC rate.

~~8.800.13.E MAC rates shall be calculated as follows:~~

~~1. The generic drug MAC rate shall be WAC minus 10 percent.~~

~~2. The brand name drug MAC rate shall be WAC minus 3 percent.~~

8.800.13.FE. To address weekly fluctuations in drug prices, the Department shall apply a percent adjustment to existing AAC rates for drugs experiencing significant changes in price. The percent adjustment shall be determined using weekly changes in price based on national pricing benchmarks. Every week, the Department shall post an updated AAC price list, with the adjusted AAC rates, on the Department's website (www.colorado.gov/hcpf). A percent adjustment shall only be applied to an AAC rate until the Department can rebase the rate through the process discussed in 10 C.C.R. 2505-10, 8.800.13.DC.

8.800.13.GF. Any pharmacy, except a Mail Order Pharmacy, that is the only pharmacy within a twenty-mile radius may submit a letter to the Department requesting the designation as a Rural Pharmacy. ~~If the designation is approved by the Department, the allowed ingredient cost shall be AAC. If AAC is not available, the allowed ingredient cost shall be WAC.~~

8.800.13.HG. Dispensing Fees shall be determined based upon reported dispensing costs provided through a Cost of Dispensing (COD) survey completed every two fiscal years. The Dispensing Fees for Retail Pharmacies, 340B Pharmacies, Institutional Pharmacies and Mail Order Pharmacies shall be tiered based upon annual Total Prescription Volume. The Dispensing Fees shall be tiered at:

1. Less than 60,000 total prescriptions filled per year = $13.40

2. Between 60,000 and 90,000 total prescriptions filled per year = $11.49

3. Between 90,000 and 110,000 total prescriptions filled per year = $10.25

4. Greater than 110,000 total prescriptions filled per year = $9.31

8.800.13.IH. The designation of a pharmacy's Dispensing Fee shall be updated annually. Every October, the Department shall contact a pharmacy requesting the completion of an attestation letter stating the pharmacy's Total Prescription Volume for the period September 1 to August 31. A pharmacy shall have until October 31 to provide the completed attestation letter to the Department. Using the attestation letter, the Department shall update a pharmacy's Dispensing Fee effective January 1. A pharmacy failing to provide the Department an attestation letter on or before October 31, regardless of their previous Dispensing Fee, shall be reimbursed the $9.31 Dispensing Fee.

8.800.13.JI. The Department shall determine the Dispensing Fee for a pharmacy enrolling as a Medicaid provider based on the pharmacy's Total Prescription Volume. During the enrollment

process, a pharmacy shall provide the Department an attestation letter stating their Total Prescription Volume for the previous twelve (12) months. Using the attestation letter, the Department shall determine the pharmacy's Dispensing Fee effective upon approval of enrollment. If a pharmacy has been open for less than 12 months, the Department shall annualize the Total Prescription Volume to determine the pharmacy's Dispensing Fee. A pharmacy failing to provide the Department an attestation letter during the enrollment process shall be reimbursed the $9.31 Dispensing Fee. The Dispensing Fee shall be used until it can be updated the following year in accordance with 10 C.C.R. 2505-10, 8.800.13.I~~H~~.

8.800.13.K~~J~~. In November of each year, the Department shall compare a pharmacy's Total Prescription Volume and Medicaid percent provided with the attestation letter to their Medicaid claims data. If the Department identifies any inconsistencies, the Department shall request a pharmacy to provide documentation that substantiates their Total Prescription Volume for the period September 1 to August 31 within thirty (30) days. If the Department determines that the pharmacy incorrectly reported their Total Prescription Volume, the pharmacy shall be reimbursed at the correct tier based on their actual Total Prescription Volume. If a pharmacy does not provide the documentation to the Department within the 30 days, the pharmacy shall be reimbursed the $9.31 Dispensing Fee.

8.800.13.L~~K~~. The tiered Dispensing Fee shall not apply to Government Pharmacies which shall instead be reimbursed a $0.00 Dispensing Fee.

8.800.13.M~~L~~. The tiered Dispensing Fee shall not apply to Rural Pharmacies which shall instead be reimbursed a $14.14 Dispensing Fee.

8.800.13.N~~M~~. Dispensing Prescribers who dispense medications that are reimbursed as a pharmacy benefit pursuant to 8.800 shall be reimbursed a $1.89 Dispensing Fee.