DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule Concerning HB21-1275 Pharmacy Implementation, Section 8.800.5
Rule Number: MSB 21-09-09-A
Division / Contact / Phone:Pharmacy Office / Kristina Gould / 303-866-6715

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 21-09-09-A, Revision to the Medical Assistance Act Rule Concerning HB21-1275 Pharmacy Implementation, Section 8.800.5

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) 8.800.5, 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)? Yes
   If yes, state effective date: 01/14/22
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.800.5 with the proposed text beginning at 8.800.5.A through the end of 8.800.5.A. this rule is effective January 14, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule Concerning HB21-1275 Pharmacy Implementation, Section 8.800.5
Rule Number: MSB 21-09-09-A
Division / Contact / Phone:Pharmacy Office / Kristina Gould / 303-866-6715

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).

   The pharmacy office is implementing HB21-1275 which requires the Department to A) reimburse pharmacists for all services that are allowed in Part 6 of Article 280 of Title 12 and B) to allow pharmacists to dispense, administer and be reimbursed for long acting injectables for both mental illness and substance use disorders through the pharmacy or medical benefit.

   In order to implement part B of HB21-1275, the Department must modify Section 8.800.5 to allow pharmacists and pharmacies to bill for long acting injectables for both mental illness and substance use disorders for reimbursement through the pharmacy or medical benefit even if the product is administered in a physician's office or clinic.

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 25.5-5-511, C.R.S. (2020)
   Section 25.5-5-512, C.R.S. (2020)

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

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule Concerning HB21-1275 Pharmacy Implementation, Section 8.800.5
Rule Number: MSB 21-09-09-A
Division / Contact / Phone:Pharmacy Office / Kristina Gould / 303-866-6715

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.

   Pharmacists and pharmacies will benefit from the proposed rule because they will have greater flexibility to bill for long acting injectables for both mental illness and substance use disorders. The Department will bear the costs from the proposed rule because the medical claims system and pharmacy claims systems are not configured to inhibit duplicate billing, therefore creating more administrative work to continuously analyze claims for duplicate billing.

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

   Qualitatively, this rule will create greater ease for pharmacists and pharmacies when billing for long acting injectables for both mental illness and substance use disorders because they can bill through either the pharmacy or medical benefit. Qualitatively, this rule will create more work for the Department as it relates to duplicate billing claims analysis.

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 probable cost to the Department is that the medical and pharmacy claims systems are not configured to inhibit duplicate billing as it relates to long acting injectables for both mental illness and substance use disorders.

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 is that the medical and pharmacy claims systems are not configured to inhibit duplicate billing as it relates to long acting injectables for both mental illness and substance use disorders; whereas the benefit of action is compliance with the passage of HB21-1275.

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

   Not applicable.

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.

   Not applicable.

8.800 PHARMACEUTICALS

8.800.5 DRUGS ADMINISTERED OR PROVIDED IN PHYSICIAN OFFICES OR CLINICS

8.800.5.A. Extended-release injectable drugs which treat mental health or substance use disorders, and are administered in a pharmacy, physician's office, or clinic, may be considered part of the physician services benefit and billed on the physician claim form; such drugs may also be considered a pharmacy benefit and billed by a pharmacy. Any other drugs administered in a physician's office or clinic are considered part of the physician's services benefit only and are not a pharmacy benefit. ~~Such drugs shall be billed on the physician claim form with the exception of drugs previously billed under 8.800.5.B. Pharmacies shall not bill for any products that are administered in a physician's office or clinic.~~

8.800.5.B. Dispensing Prescribers whose offices or sites of practice are located within 25 miles from the nearest participating pharmacy shall not be reimbursed for drugs or services that are dispensed from their offices.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacy Reimbursement, Section 8.200.2.B and C
Rule Number: MSB 21-10-01-A
Division / Contact / Phone: Health Programs / 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 21-10-01-A, Revision to the Medical Assistance Rule concerning Pharmacy Reimbursement, Section 8.200.2.B and C

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) Sections 8.200.2.B-C, 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)? Yes
   If yes, state effective date: 1/14/2022
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.200.2 with the proposed text beginning at 8.200.2.B through the end of 8.200.2.C. This rule is effective January 14, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacy Reimbursement, Section 8.200.2.B and C
Rule Number: MSB 21-10-01-A
Division / Contact / Phone: Health Programs / 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).

   The proposed rule implements requirements of Colorado House Bill 21-1275, under which pharmacists may provide covered Health First Colorado (Colorado Medicaid) services, in accordance with the scope of practice for pharmacists as described by the Colorado Department of Regulatory Agencies rules, without a physician order.

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:

   This rule is imperatively necessary to comply with state law at CRS § 25.5-5-511(2)(a), which makes pharmacists eligible to receive Health First Colorado reimbursement for medically necessary services authorized in CRS § 12-6-280 that are not duplicative of other pharmacist services or programs reimbursed under Health First Colorado.

3. Federal authority for the Rule, if any:

   42 CFR 440.120(a) (2021)

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2021);
   CRS § 25.5-5-511(2)(a) (2021)

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Pharmacy Reimbursement, Section 8.200.2.B and C
Rule Number: MSB 21-10-01-A
Division / Contact / Phone: Health Programs / 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.

   Pharmacists and members receiving pharmaceutical services will be affected by the proposed rule, both of which benefit from the increased access to pharmaceutical services and corresponding reimbursement.

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 ability of pharmacists to generate revenue for the same services provided by other health-care providers is equitable, helps fund staff and services in medical homes, and alleviates barriers to access of care in community settings.

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 Colorado House Bill 21-1275 fiscal note estimates additional expenditures of $1,762,820 ($372,554 state share) in state fiscal year 2021-22 and $4,193,853 ($1,363,884 state share) in state fiscal year 2022-23 ongoing. This includes system costs, benefit costs and operating costs.

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 is the additional Health First Colorado expenditures outlined in question #3. The probable benefit of the proposed rule is complying with state statute. The cost of inaction is misalignment between state statute and Department rule. 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 methods or less intrusive methods to align Department rule with state statute.

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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 aligning Department rule with state statute.

8.200 PHYSICIAN SERVICES

8.200.2 Providers

8.200.2.B. Physician services that may be provided by non-physician providers without a physician order.

1. Advanced Practice Nurses may provide and order covered goods and services in accordance with the scope of practice as described in the Colorado Department of Regulatory Agencies rules without a physician order.

2. Licensed Psychologists may provide and order covered mental health goods and services in accordance with the scope of practice as described in the Colorado Department of Regulatory Agencies rules without a physician order.

    a. Services ordered by a Licensed Psychologist but rendered by a non-licensed mental health provider must be signed and dated by the Licensed Psychologist contemporaneously with the rendering of the service by a non-licensed mental health provider.

3. Optometrists may provide covered optometric goods and services within their scope of practice as described by the Colorado Department of Regulatory Agencies rules without a physician order.

4. Podiatrists may provide covered foot care services within their scope of practice as described by the Colorado Department of Regulatory Agencies rules without a physician order.

5. Licensed dental hygienists may provide unsupervised covered dental hygiene services in accordance with the scope of practice for dental hygienists as described in the Colorado Department of Regulatory Agencies rules without a physician order.

6. Licensed pharmacists may provide covered services, in accordance with the scope of practice for pharmacists as described by the Colorado Department of Regulatory Agencies rules, without a physician order.

8.200.2.C. Physician services that may be provided by a non-physician provider when ordered by a provider acting under the authority described in Sections 8.200.2.A. and 8.200.2.B.

1. Registered occupational therapists, licensed physical therapists, licensed audiologists, certified speech-language pathologists, and licensed physician assistants may provide services ordered by a physician.

a. Services must be rendered and supervised in accordance with the scope of practice for the non-physician provider described in the Colorado Department of Regulatory Agencies rules.

~~2. Licensed pharmacists, in accordance with the scope of practice for pharmacists as described in the Colorado Department of Regulatory Agencies rules 3 CCR 719-1 and C.R.S. 12-42.5-101 et. seq., may provide covered services.~~

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the FQHC Rule Concerning Reimbursement for Antiviral Medication for COVID-19, Section 8.700.6.B
Rule Number: MSB 21-01-07-A
Division / Contact / Phone: Health Programs Office / Morgan Anderson / 2362

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 21-01-07-A, Revision to the FQHC Rule Concerning Reimbursement for Antiviral Medication for COVID-19, Section 8.700.6.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) 8.700.6.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)? Yes
   If yes, state effective date: 1/14/2022
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.700.6.B with the proposed text beginning at 8.700.6.B.11 through the end of 8.700.6.B.11. This rule is effective January 14, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the FQHC Rule Concerning Reimbursement for Antiviral Medication for COVID-19, Section 8.700.6.B
Rule Number: MSB 21-01-07-A
Division / Contact / Phone: Health Programs Office / Morgan Anderson / 2362

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).

   The purpose of this rule is to change Federally Qualified Health Center (FQHC) reimbursement for the antiviral medication, remdesivir, when administered in an outpatient setting. Remdesivir is an antiviral medication for COVID-19 that stops the virus from spreading in the body and reduces time to recovery. Remdesivir treatments are expensive, and the current FQHC encounter rate does not cover the cost of providing the drug. This rule will revise reimbursement to reimburse FQHCs at the fee schedule amount for the cost of the remdesivir antiviral medication.

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:

   This rule will remove barriers to access related to COVID-19 antiviral medications that exist due to current FQHC reimbursement structures.

3. Federal authority for the Rule, if any:

   1902(bb) SSA

4. State Authority for the Rule:

   State Plan: Attachment 3.1-A 2.c. and Attachment 4.19-B
   Colorado Statute: CRS 25.5-5-102(1)(m)

Initial Review — Final Adoption
Proposed Effective Date **1/14/2022** Emergency Adoption **1/14/2022**

DOCUMENT #11

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the FQHC Rule Concerning Reimbursement for Antiviral Medication for COVID-19, Section 8.700.6.B
Rule Number: MSB 21-01-07-A
Division / Contact / Phone: Health Programs Office / Morgan Anderson / 2362

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.

   Federally Qualified Health Centers will be impacted by this rule. This rule revision will increase FQHC reimbursement for the COVID-19 antiviral medication, remdesivir, when administered in an outpatient setting. Therefore, FQHCs will not incur budgetary concerns to provide these services. This rule will also improve access to Medicaid members that receive services at FQHCs.

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

   FQHCs will be directly reimbursed at the fee schedule rate for the COVID-19 antiviral medication, remdesivir. This rule will reimburse FQHCs for this service directly instead of an indirect reimbursement through their encounter rates in the future.

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.

   This rule revision will impact the Department and state revenues. The Department will directly reimburse FQHCs for administering the COVID-19 antiviral medication, remdesivir, in the outpatient setting. Without this rule, the costs of these services would be included in future rates. Therefore, there should be no significant budgetary impact as FQHC rates will not increase in the future due to their direct reimbursement due to this rule revision.

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

   If the Department does not adopt this rule change FQHCs will likely suffer budgetary concerns due to not having direct reimbursement for administering COVID-19 antiviral medications. FQHCs will also be less incentivized to provide this service due to lack of direct reimbursement.

DO NOT PUBLISH THIS PAGE

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

   There are no other methods that are less costly or less intrusive to achieve 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.

   The Department considered not reimbursing FQHCs the fee schedule amount for the COVID-19 antiviral medication, remdesivir, but decided it was better to reimburse at the fee schedule amount to improve access.

8.700 FEDERALLY QUALIFIED HEALTH CENTERS

8.700.6 REIMBURSEMENT

8.700.6.A FQHCs shall be reimbursed separate per visit encounter rates based on 100% of reasonable cost for physical health services, dental services, and specialty behavioral health services. An FQHC may be reimbursed for up to three separate encounters with the same client occurring in one day and at the same location, so long as the encounters submitted for reimbursement are any combination of the following: physical health encounter, dental encounter, or specialty behavioral health encounter. Distinct dental encounters are allowable only when rendered services are covered and paid by the Department's dental Administrative Service Organization (ASO). Distinct specialty behavioral health encounters are allowable only when rendered services are covered and paid by either the Regional Accountable Entity (RAE) or through the short-term behavioral health services in the primary care setting policy.

8.700.6.B The following services are reimbursed separately from the FQHC encounter rate. These services shall be reimbursed in accordance with the following:

1. Long-Acting Reversible Contraception (LARC) devices shall be reimbursed separately from the FQHC encounter rate. In addition to payment of the encounter rate for the insertion of the device(s), the LARC device(s) must be billed in accordance with Section 8.730 and shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

2. Services provided in an inpatient hospital setting shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

3. The provision of complete dentures and partial dentures must be billed in accordance with Section 8.201. and Section 8.202. and shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

4. Dental services provided in an outpatient hospital setting shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

5. The Prenatal Plus Program shall be billed and reimbursed in accordance with Section 8.748.

6. The Nurse Home Visitor Program shall be billed and reimbursed in accordance with Section 8.749.

7. An FQHC that operates its own pharmacy that serves Medicaid clients must obtain a separate Medicaid billing number for pharmacy and bill all prescriptions utilizing this number in accordance with Section 8.800.

8. Antagonist injections for substance use disorders provided at the FQHC shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

9. COVID-19 vaccine administration provided at the FQHC shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department

10. Monoclonal Antibody COVID-19 infusion administration provided at the FQHC shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

11. COVID-19 antiviral medication, remdesivir, provided at the FQHC shall be reimbursed the lower of:

    a. Submitted charges; or

    b. Fee schedule as determined by the Department.

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the DMEPOS Rule Concerning Pharmacists Prescribing COVID-19 at-home over-the-counter tests, Section 8.590
Rule Number: MSB 22-01-12-C
Division / Contact / Phone: Health Programs Office / Haylee Rodgers / 9467

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 22-01-12-C, Revision to the DMEPOS Rule Concerning Pharmacists Prescribing COVID-19 at-home over-the-counter tests, Section 8.590

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) 8.590.2.A, 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)? Yes
   If yes, state effective date: 1/14/2022
   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.590.2.A with the proposed text beginning at 8.590.2.A through the end of 8.590.2.A. This rule is effective January 14, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the DMEPOS Rule Concerning Pharmacists Prescribing COVID-19 at-home over-the-counter tests, Section 8.590
Rule Number: MSB 22-01-12-C
Division / Contact / Phone: Health Programs Office / Haylee Rodgers / 9467

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).

   The purpose of this rule is to allows pharmacists to prescribe at-home over-the-counter COVID-19 tests for reimbursement under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit. The basis of this rule is that CMS has mandated coverage of these tests which are available at pharmacies. Pharmacies are enrolled as DMEPOS providers and can bill for the tests, however a prescription is required.

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:

   This rule is necessary to comply with a federal mandate to cover at-home over-the-counter COVID-19 tests.

3. Federal authority for the Rule, if any:

   1905(7) SSA

4. State Authority for the Rule:

   State Plan: Attachment 3.1-A 7.g. and Attachment 4.19-B
   Colorado Statute: CRS 25.5-4-416

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2021)

Initial Review Final Adoption
Proposed Effective Date **1/14/2022** Emergency Adoption **1/14/2022**

DOCUMENT #12

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the DMEPOS Rule Concerning Pharmacists Prescribing COVID-19 at-home over-the-counter tests, Section 8.590
Rule Number: MSB 22-01-12-C
Division / Contact / Phone: Health Programs Office / Haylee Rodgers / 9467

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.

   All members will be affected by, and benefit from, this rule as it will allow them to receive these tests from pharmacies without a prescription from their physician. Pharmacies enrolled as DMEPOS providers will benefit from this rule as it will allow them to be reimbursed for these tests.

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

   DMEPOS Pharmacy providers will receive reimbursement when they submit claims for at-home over-the-counter COVID-19 tests. Members will not have to pay out of pocket for these tests as they will be covered benefits. This rule serves the larger public health objective of ensuring testing is available to everyone.

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.

   This rule revision will incur new costs associated with the mandated coverage of these tests.

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

   There are no other methods that are less costly or less intrusive to achieve the purpose of the proposed rule.

5. 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 is no alternative method for achieving the goal of having these tests covered at a pharmacy which does not involve allowing pharmacists to prescribe the test.

8.590 DURABLE MEDICAL EQUIPMENT AND DISPOSABLE MEDICAL SUPPLIES

8.590.2 BENEFITS

8.590.2.A. All covered DME and Supplies shall, at a minimum, be:

1. A Medical Necessity; and

2. Prescribed by a physician and, when applicable, recommended by an appropriately licensed practitioner.

3. At-home over-the-counter COVID-19 tests may be prescribed by a licensed pharmacist.

8.590.2.B. DME and Supplies for Members Residing in Facilities

1. DME and Supplies for members residing in a hospital, nursing facility or other facility, are provided by those facilities and reimbursed as part of the per diem rate. DME and Supplies shall not be separately billed, except under the following circumstances:

   a. The member is within fourteen days of discharge, and

   b. Prior authorization or training are needed to assist the member with equipment usage, and

   c. The equipment is needed immediately upon discharge from the facility.

2. Repairs and modifications to member owned DME, not required as part of the per diem reimbursement, shall be provided to members residing in a hospital, nursing facility or other facility receiving per diem Medicaid reimbursement.

3. Prosthetic or Orthotic Devices may be provided to members residing in a hospital, nursing facility or other facility receiving per diem Medicaid reimbursement if Prosthetic or Orthotic benefits are not included in the facility's per diem rate.

8.590.2.C. DME and Supplies shall not be duplicative or serve the same purpose as items already utilized by the member unless it is medically required for emergency or backup support. Backup equipment shall be limited to one.

8.590.2.D. All DME and Supplies reimbursed for by the Department shall become the property of the member unless the member and provider are notified otherwise by the Department at the time of purchase.

8.590.2.E. Rental equipment shall be provided if the Department determines it to be cost effective and Medically Necessary.

8.590.2.F. Supplies shall be for a specific purpose, not incidental or general purpose usage.

8.590.2.G. The following DME and Supplies categories are benefits for members regardless of age, and include but are not limited to:

1. Ambulation devices and accessories including but not limited to canes, crutches or walkers.

2. Bath and bedroom safety equipment.

3. Bath and bedroom equipment and accessories including, but not limited to, specialized beds and mattress overlays.

4. Manual or power Wheelchairs and accessories.

5. Diabetic monitoring equipment and related disposable supplies.

6. Elastic supports/stockings.

7. Blood pressure, apnea, blood oxygen, pacemaker and uterine monitoring equipment and supplies.

8. Oxygen and oxygen equipment in the member's home, a nursing facility or other institution. The institutional oxygen benefit is fully described in 10 C.C.R. 2505-10, Sections 8.580, and 8.585.

9. Transcutaneous and/or neuromuscular electrical nerve stimulators (TENS/NMES) and related supplies.

10. Trapeze, traction and fracture frames.

11. Lymphedema pumps and compressors.

12. Specialized use rehabilitation equipment.

13. Oral and enteral formulas and supplies.

14. Parenteral equipment and supplies.

15. Environmental controls for a member living unattended if the controls are needed to assure medical safety.

16. Facilitative Devices.

    a. Telephone communication devices for the hearing impaired and other facilitative listening devices, except hearing aids, and Cochlear Implants.

    b. Computer equipment and reading devices with voice input or output, optical scanners, talking software, Braille printers and other devices that provide access to text.

    c. Computer equipment with voice output, artificial larynges, voice amplification devices and other alternative and augmentative communication devices.

    d. Voice recognition computer equipment software and hardware and other forms of computers for persons with disabilities.

    e. Any other device that enables a person with a disability to communicate, see, hear or maneuver including artificial limbs and orthopedic footwear.

17. Complex Rehabilitation Technology.

8.590.2.H. The following DME are benefits to members under the age of 21:

1. Hearing aids and accessories.

2. Phonic ear.

3. Therapy balls for use in physical or occupational therapy treatment.

4. Selective therapeutic toys.

5. Computers and computer software when utilization is intended to meet medical rather than educational needs.

6. Vision correction unrelated to eye surgery.

8.590.2.I. The following Prosthetic or Orthotic Devices are benefits for members regardless of age:

1. Artificial limbs.

2. Facial Prosthetics.

3. Ankle-foot/knee-ankle-foot orthotics.

4. Recumbent ankle positioning splints.

5. Thoracic-lumbar-sacral orthoses.

6. Lumbar-sacral orthoses.

7. Rigid and semi-rigid braces.

8. Therapeutic shoes.

9. Orthopedic footwear, including shoes, related modifications, inserts and heel/sole replacements.

10. Specialized eating utensils and other medically necessary activities of daily living aids.

11. Augmentative communication devices and communication boards.

8.590.2.J. Repairs and replacement parts are covered under the following conditions:

1. The item was purchased by Medicaid; or

2. The item is owned by the member, member’s family or guardian; and

3. The item is used exclusively by the member; and

4. The item’s need for repair was not caused by member Misuse or Abuse; and

5. The item is no longer under the manufacturer warranty.

8.590.2.K. The minimum replacement timeline for a Speech Generating Device is five years.

1. Stolen devices may be replaced within the five-year timeline; however, the client is limited to one-time replacement due to theft, and a police report must be provided for verification of the incident.

2. Replacement will not be granted within the five-year timeline for devices that are damaged, lost, misused, abused or neglected.

8.590.2.L. Repairs, replacement, and maintenance shall be:

1. Based on the manufacturer's recommendations, and

2. Performed by a qualified rehabilitation professional, and

3. Allowed on the member's primary equipment or one piece of backup equipment.

4. Multiple backup equipment will not be repaired, replaced or maintained.

8.590.2.M. If repairs are frequent and repair costs approach the purchase price of new equipment, the provider shall make a request for the purchase of new equipment. The prior authorization request shall include supporting documentation explaining the need for the replacement equipment and the cost estimates for repairs on both the old equipment and the new equipment purchase.

8.590.2.N. Supplies are a covered benefit when related to the following:

1. Surgical, wound or burn care.

2. Syringes or needles.

3. Bowel or bladder care.

4. Incontinence.

5. Antiseptics or solutions.

6. Gastric feeding sets and supplies.

7. Tracheostomy and endotracheal care supplies.

8. Diabetic monitoring.

8.590.2.O. Quantities of Supplies shall not exceed one month's supply unless they are only available in larger quantities as packaged by the manufacturer.

8.590.2.P. Medicaid members for whom Wheelchairs, Wheelchair component parts and other specialized equipment were authorized and ordered prior to enrollment in a Managed Care Organization, but delivered after the Managed Care Organization enrollment shall be the responsibility of the Department. All other DME and Supplies for members enrolled in a Managed Care Organization shall be the responsibility of the Managed Care Organization.

8.590.2.Q. Items, for the purposes of Rule 8.590, that are used for the following are not a benefit to a member of any age:

1. Routine personal hygiene.

2. Education.

3. Exercise.

4. Participation in sports.

5. Cosmetic purposes.

8.590.2.R. For members age 21 and over, the following items are not a benefit:

1. Hearing aids and accessories.

2. Phonic ears.

3. Therapeutic toys.

4. Vision correction unrelated to eye surgery.

8.590.2.S. Rental Policy.

1. The Department may set a financial cap on certain rental items. The monetary price for those items shall be determined by the Department and noted in the fee schedule. The provider is responsible for all maintenance and repairs as described at 8.590.4.N-P, until the cap is reached.

2. Upon reaching the capped amount, the equipment shall be considered purchased and shall become the property of the member. The provider shall give the member or caregiver all applicable information regarding the equipment. The equipment shall not be under warranty after the rental period ends.

3. The rental period may be interrupted, for a maximum of sixty consecutive days.

    a. If the rental period is interrupted for a period greater than sixty consecutive days, the rental period must begin again. The interruption must be justified, documented by a physician, and maintained by the provider as described at 10 CCR 2505-10, Section 8.590.4.E.

4. If the member changes providers, the current rental cap remains in force.