Title of Rule: Revision to the Medical Assistance Act Rule concerning Definitive Drug Testing, Section 8.660
Rule Number: MSB 25-08-26-A
Division / Contact / Phone: Health Policy Office / Jessica Farmen / jessica.farmen@state.co.us

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 revision affects Section 8.660 Laboratory and X-Ray. Specifically, this revision will add a limit of 16 units of services per state fiscal year for definitive drug testing for adult Health First Colorado members. Definitive drug tests use highly specific, quantitative laboratory methods, including but not limited to liquid chromatography–tandem mass spectrometry (LC-MS/MS) and gas chromatography–mass spectrometry (GC-MS), to identify and measure the concentration of individual drugs and drug metabolites in a patient specimen. Definitive testing is distinguished from presumptive drug testing in that definitive testing confirms the presence or absence of a substance, provides specific analyte identification, and reports exact concentrations, whereas presumptive testing only confirms the presence of absence of a substance.

   This proposed limit is a result of uncontrolled, inappropriate utilization of this specific service.

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:

   The Department has seen a significant and continued expenditure increase for definitive drug tests over the past several years. These tests are being used more often than medically necessary, sometimes with large panels being ordered routinely for members. This drives up Medicaid costs and risks waste or abuse. Health First Colorado and the Department are being harmed financially by this inappropriate billing for definitive drug testing services. By limiting these tests to no more than 16 units per state fiscal year for adult members, the Department aims to ensure drug testing is appropriate, evidence-based, and cost-effective. This will protect program integrity and sustainability. Given the current budget crisis and to preserve the integrity of Health First Colorado, it is critical that funds only be used for medically necessary services. Therefore, to preserve public health, safety and welfare for Health First Colorado members by protecting the Department's budget, it is imperatively necessary to bring this proposed rule revision as an emergency to stop the inappropriate spending within the laboratory benefit.

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3. Federal authority for the Rule, if any:

   42 C.F.R. § 440.30

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2024);

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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.

   Adult Health First Colorado members will be affected by this proposed rule revision. They will be limited to 16 definitive drug tests per state fiscal year, whereas before there was no limit. Members will benefit when receiving the most appropriate, medically necessary lab 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.

   Qualitatively, this rule revision will result in members receiving the most appropriate, medically necessary drug testing and related labs. Definitive drug tests are highly specific labs that produce detailed reports including the exact drugs and their quantities that are present in a sample. These tests are only appropriate for purposes of medical treatment—not for purposes of confirming the presence of a drug.

   Quantitatively, adult members will be limited to 16 definitive drug tests per state fiscal year. The Department has seen a significant and continued expenditure increase for these tests over the past several years. These tests are important in some cases, but they are being used more often than medically necessary, sometimes with large panels ordered routinely. This drives up Medicaid costs and risks waste or abuse. By limiting these tests to no more than 16 per state fiscal year for adult members, the Department aims to ensure drug testing is appropriate, evidence-based, and cost-effective. This will protect program integrity and sustainability.

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 costs to the Department or any other agency to implement or enforce this proposed rule revision. There are savings associated with this policy change. The estimated savings are $12.9m Total Funds in FY 2025-26.

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

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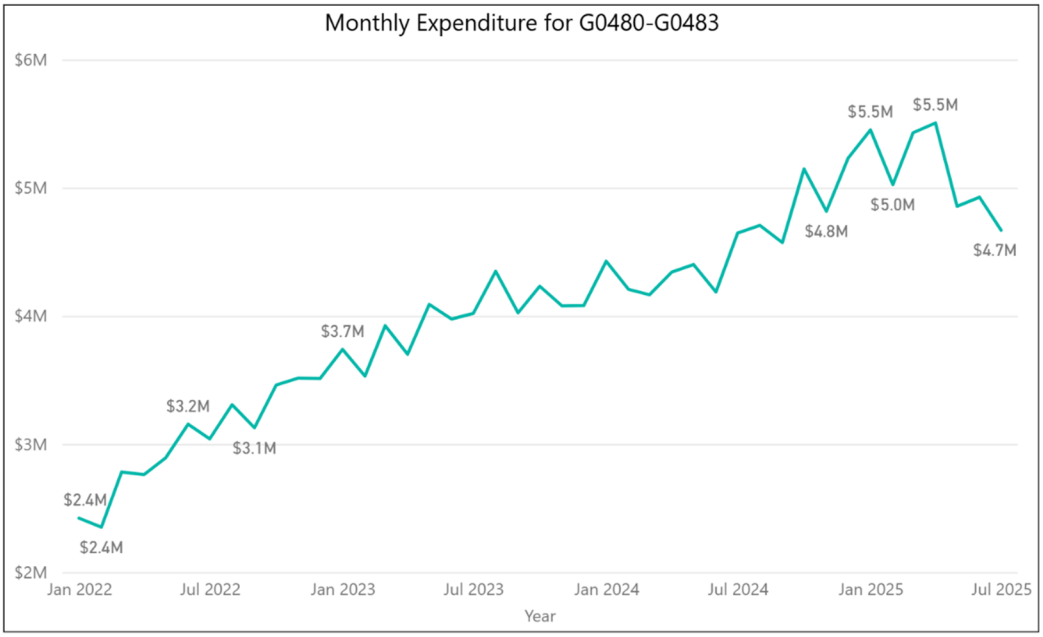
Based on the expenditure trend for G0480–G0483, continuing without intervention will result in costs remaining above $5M per month, or approximately $62M annually, nearly double 2022 levels. By implementing a utilization limit on definitive drug testing, expenditures could be stabilized closer to $3.5–$4.0M per month, generating estimated annual savings of $14M–$20M, with the potential for even greater reductions if spending is brought back toward 2022 levels.



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 for achieving the purpose of this proposed rule revision.

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 setting a soft limit of 16 definitive drug test per adult member per state fiscal year. After which, if an adult member needed more tests, a prior authorization request (PAR) would be required. However, after working with our utilization management vendor, the Department learned that we are unable to implement a PAR for this service due to current budget constraints.

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The Department reviewed other states' limits on definitive drug testing and found wide variation, ranging from limits of six tests per year in New York to 24 per year in North Carolina. Minnesota, Washington, and Oregon also have restrictions in place. Based on this research, the Department proposed a unit limit of 16 tests per fiscal year as a balanced approach that controls costs, ensures medical necessity, and maintains appropriate access.

8.660 LABORATORY AND X-RAY

8.660.1 DEFINITIONS

~~Independent Certified Laboratory means a certified laboratory that performs diagnostic tests and is independent both of the attending or consulting physician's office and of a hospital except where a hospital laboratory has obtained Medicare certification as an independent laboratory and is billing for recipients who are not admitted as patients in the hospital.~~

~~Clinical Laboratory Services mean microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological or other examinations of fluids derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or the assessment of a medical condition.~~

8.660.1.A. Anatomical Laboratory Services mean examinations of tissues derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or the assessment of a medical condition.

8.660.1.B. Certified Clinical Laboratory means a provider who possesses a certificate of waiver or a certificate of registration from the Centers for Medicare and Medicaid Services or its designated agency as meeting Centers for Medicare and Medicaid Services guidelines and whose personnel and director are qualified to perform laboratory services.

8.660.1.C. Clinical Laboratory Services mean microbiological, serological, chemical, hematological, radiobioassay, cytological, immunohematological, pathological or other examinations of fluids derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or the assessment of a medical condition.

8.660.1.D. Definitive Drug Testing means the use of highly specific, quantitative laboratory methods, including but not limited to liquid chromatography–tandem mass spectrometry (LC-MS/MS) and gas chromatography–mass spectrometry (GC-MS), to identify and measure the concentration of individual drugs and drug metabolites in a patient specimen. Definitive Drug Testing confirms the presence or absence of a substance, provides specific analyte identification, and reports exact concentrations of the substances.

8.660.1.E. Independent Certified Laboratory means a certified laboratory that performs diagnostic tests and is independent both of the attending or consulting physician's office and of a hospital except where a hospital laboratory has obtained Medicare certification as an independent laboratory and is billing for recipients who are not admitted as patients in the hospital.

8.660.1.F. X-Ray Services mean services performed by a provider whose x-ray equipment has been certified by the Colorado Department of Public Health and Environment as meeting Medicare guidelines and whose personnel and director are qualified to operate said equipment.

8.660.2 CONDITIONS OF PARTICIPATION

8.660.2. A Certified Clinical Laboratories and providers of X-Ray Services shall enroll as providers in the Medical Assistance Program.

8.660.2.B. All participating laboratories, including out-of-state independent clinical laboratories, must~~shall~~ be certified by the state agency to participate under Health First Colorado~~Medicaid~~. All

laboratories mustshall provide proof of certification status through the provision of the CLIA (Clinical Laboratory Improvement Amendments of 1988) number to the Department.

8.660.2.C. Providers of X-Ray Services shall be certified by the Colorado Department of Public Health and Environment and mustshall provide proof of Medicare certification on the Health First ColoradoMedicaid provider enrollment forms.

8.660.3 LIMITATIONS AND BENEFITS

8.660.3.A. Laboratory and X-Ray Services are a benefit under all of the following conditions:

1. The services have been authorized by a licensed physician.

2. The services are performed to diagnose conditions and illnesses with specific symptoms.

3. The services are performed to prevent or treat conditions that are benefits under the Medical Assistance Program.

4. The services are not routine diagnostic tests performed without apparent relationship to treatment or diagnosis for a specific illness, symptom, complaint or injury.

5. The laboratory services are performed by a certified laboratory in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

6. The X-Ray Services are performed by a provider certified by the Colorado Department of Public Health and Environment and enrolled as a Health First ColoradoMedicaid provider.

8.660.3.B. Collection, handling and/or conveyance of specimens for transfer from physicians' offices to a Certified Clinical Laboratory is reimbursable to the physician.

8.660.3.C. Transfer of a specimen from one Certified Clinical Laboratory to another is a benefit and is reimbursable to the first certified laboratory if the laboratory's equipment is not functioning or the laboratory is not certified to perform the tests ordered by the physician.

8.660.3.D Adult members aged 21 and over are limited to 16 units of service per state fiscal year for Definitive Drug Testing.

8.660.4 BILLING PROCEDURES

8.660.4.A. Certified providers of clinical laboratory and X-Ray Services mustshall bill the Department directly using the designated billing method, the correct Current Procedural Terminology and Healthcare Common Procedure Coding System procedure codes and modifiers as required. Providers mustshall bill the amount of their usual and customary charges to the general public.

8.660.4.B. Laboratory tests and x-rays performed under the personal supervision of the authorizing physician must be billed directly on the physician's services claim form.

8.660.4.C. Laboratory tests and x-rays not performed by the authorizing physician or under his/her direct personal supervision cannot be billed by the physician except for physicians in a Certified Clinical Laboratory group practice. A Certified Clinical Laboratory group practice may only bill for those laboratory and X-Ray Services actually performed or supervised by a physician member of the group or performed by a qualified employee of the group. Payment must shall be made to the authorizing physician or the group practice.

8.660.4.D. Laboratory and X-Ray Services performed by a hospital-based or independent laboratory or x-ray provider and submitted to an unrelated physician for interpretation may only be billed by the laboratory or x-ray provider for the technical component.

8.660.4.E. Practitioner and clinic providers rendering professional interpretation and not direct laboratory or X-Ray Services may only bill the professional component.

8.660.5 REIMBURSEMENT

8.660.5.A. Reimbursement for certified laboratory and X-Ray Services must ~~shall~~ be the lowest of the following:

1. Submitted charges.

2. Fee schedule as determined by the Department.

8.660.5.B. Services rendered by a hospital-based laboratory during an inpatient stay are included in the hospital Diagnosis Related Group or inpatient rate and must ~~shall~~ not be billed or reimbursed separately.

8.660.5.C. Each certified laboratory provider must ~~shall~~ be reimbursed for only those tests performed in the specialties or sub-specialties for which it is certified.

8.660.5.D. Reimbursement for out-of-state certified independent clinical laboratory or X-Ray Services must ~~shall~~ be subject to Department reimbursement rates.

8.660.5.E. The reimbursement methodology at 8.660.5.A - 8.660.5.D does not apply to payments for those services/procedures that are reimbursed under a capitated or contracted agreement accomplished through competitive bid or other arrangement.