

# *Genetic Testing Benefits Collaborative*

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**COLORADO**

Department of Health Care  
Policy & Financing

# *Our Mission*

**Improving** health care access and outcomes for the **people** we serve while demonstrating sound stewardship of financial **resources**



# *What is the Benefits Collaborative Process?*



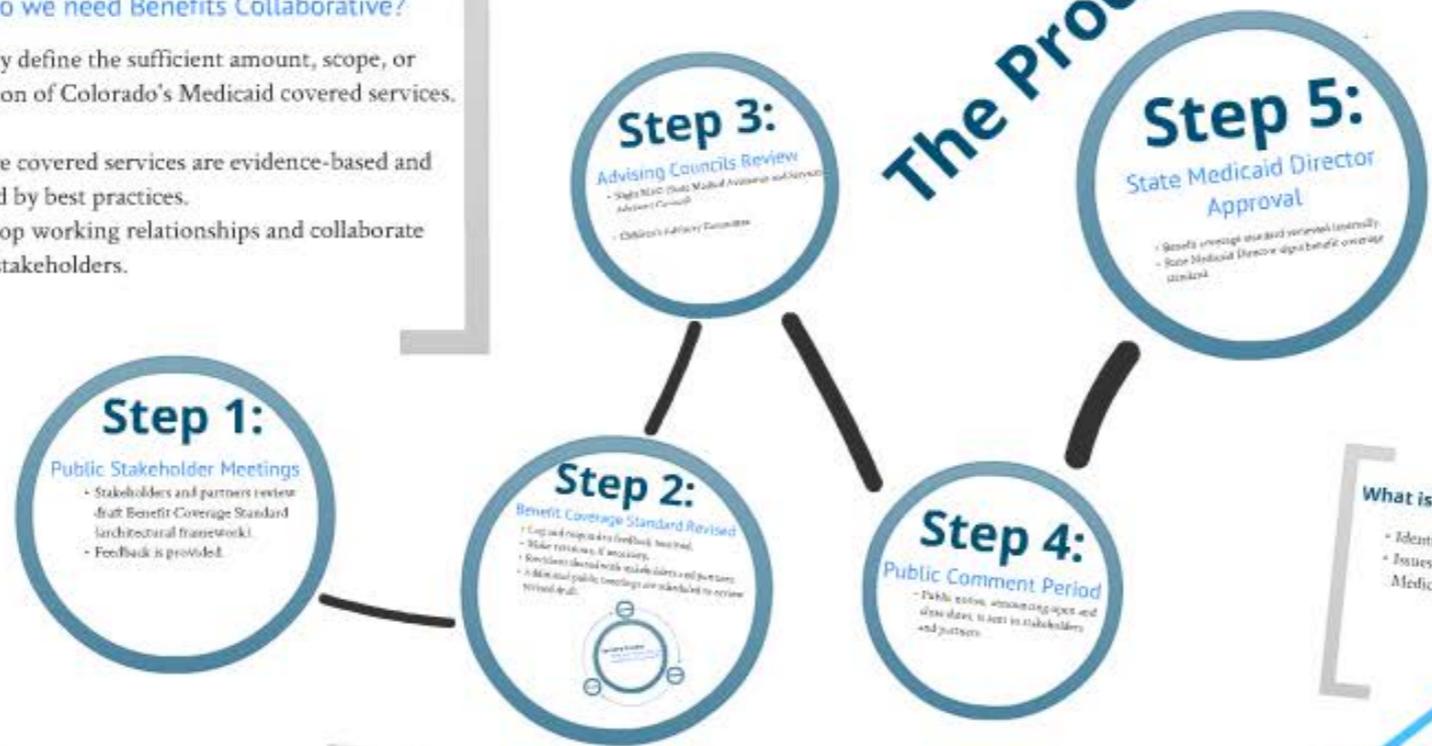
# Benefits Collaborative

## Purpose

Why do we need Benefits Collaborative?

- Clearly define the sufficient amount, scope, or duration of Colorado's Medicaid covered services.
- Ensure covered services are evidence-based and guided by best practices.
- Develop working relationships and collaborate with stakeholders.

## The Process



### Step 1:

- Public Stakeholder Meetings**
- Stakeholders and partners review draft Benefit Coverage Standard architectural framework.
  - Feedback is provided.

### Step 2:

- Benefit Coverage Standard Revised**
- Cap and copay rates (deductible, cost share)
  - State reviews if necessary
  - Beneficiaries shared with stakeholders and partners
  - A final and public meetings are scheduled to review the standard.

### Step 3:

- Advising Councils Review**
- State Medicaid Director, Medicaid Advisory Council, Children's Advisory Committee

### Step 4:

- Public Comment Period**
- Public review, comments, input and ideas shared to assist in stakeholder and partners.

### Step 5:

- State Medicaid Director Approval**
- Benefit coverage standard reviewed internally
  - State Medicaid Director signs benefit coverage standard.

## Coverage Determination vs. Medical Necessity:

**Coverage Determination**

- An agency policy about what is covered for the entire Colorado Medicaid population.
- Example: Weight Loss surgery is covered by Medicaid.

**Medical Necessity**

- Analysis determining if covered service for an individual Colorado Medicaid client.
- Example: Client was in 11 clinically obese, 21 for at least 2 years, and 31 have made a previous attempt to lose weight.

## What is a Benefit Coverage Standard?

- Identifies what is covered by Colorado Medicaid.
- Issues coverage determinations for the Colorado Medicaid program.

## Objective

### Develop Benefit Coverage Standards

- Objective researchers draft the Benefit Coverage Standards according to evidence-based guidelines and best practices.
- Conduct an extensive review of the medical literature.

## The Format:

- Brief Coverage Statement
- Services Addressed in Other Coverage Standards
- Eligible Providers
- Eligible Places of Service
- Eligible Clients
- Covered Services and Limitations
- Non-Covered Services and General Limitations:
- Requirements
- Billing Guidelines
- Definitions
- References



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# Objective

## Develop Benefit Coverage Standards

- Subject matter experts draft the Benefit Coverage Standards according to evidence-based guidelines and best practices.
- Conduct an extensive review of the medical literature.



# What is a Benefit Coverage Standard?

- Identifies what services are covered by Colorado Medicaid.
- Defines the appropriate amount, scope and duration of a covered service.
- States determination of whether a given service is medically necessary.
- Describes the service.
- Lists who is eligible to provide and receive said service and where.



# The Format:

- Brief Coverage Statement
- Services Addressed in Other Coverage Standards
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# Coverage Determination vs. Medical Necessity:

## Coverage Determination

- An agency policy about what is covered for the entire Colorado Medicaid population.
  - Example: Weight Loss surgery is covered by Medicaid.



## Medical Necessity

- Involves authorizing a covered service for an individual Colorado Medicaid client.
  - Example: Client must be 1) clinically obese, 2) for at least 2 years, and 3) have made a previous attempt to lose weight.



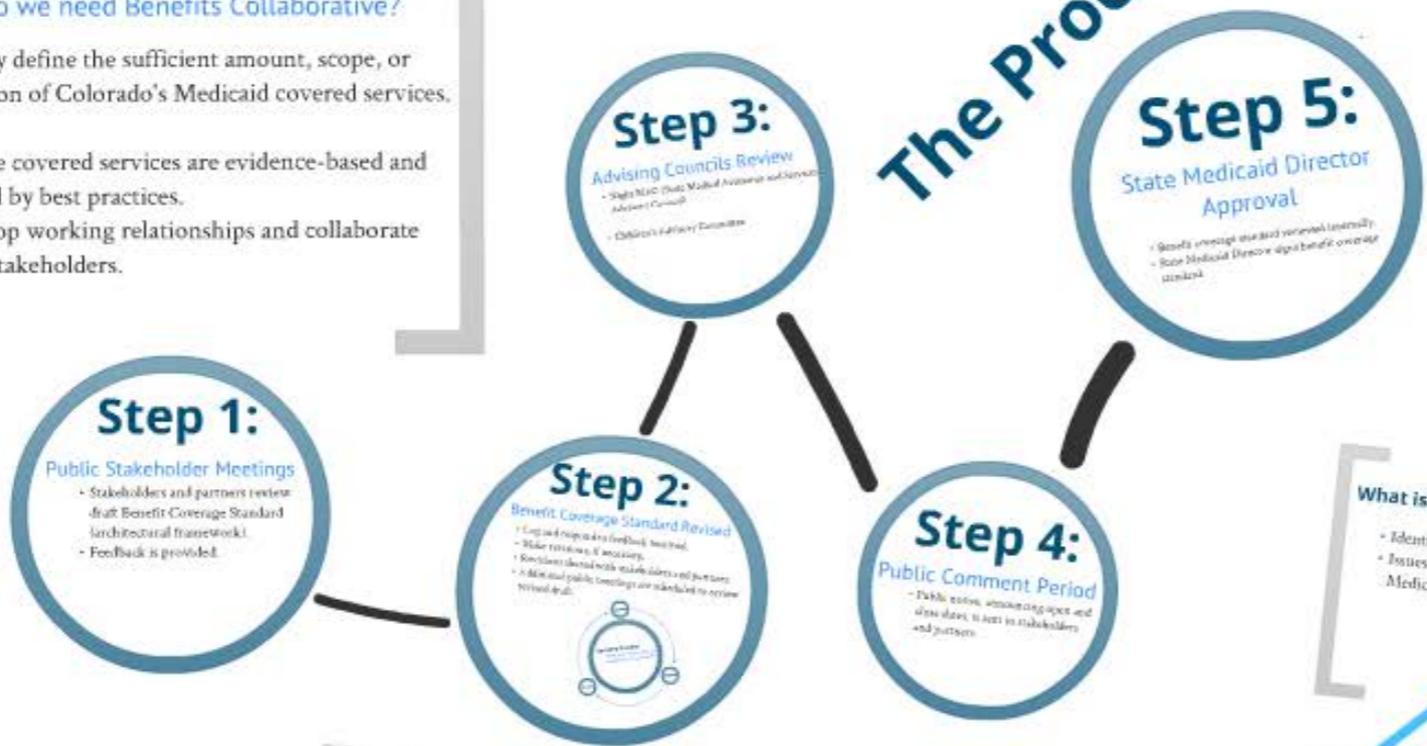
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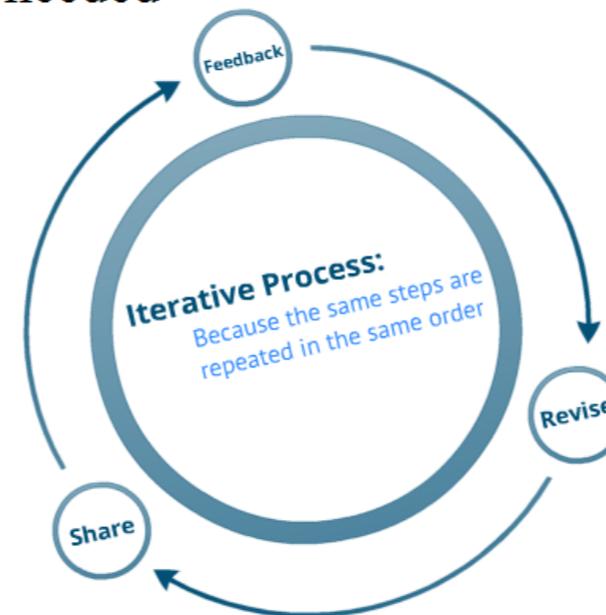
## Public Stakeholder Meetings

- Stakeholders review draft Benefit Coverage Standard
- Feedback is provided

# Step 2:

## Benefit Coverage Standard Revised

- Log and respond to feedback received
- Make revisions, if necessary
- Revisions shared with stakeholders
- Additional public meetings are scheduled to review revised draft if needed



# Step 3:

## Advising Councils Review

- Night MAC (State Medical Assistance and Services Advisory Council)
  - 42 CFR 431.12
- Children's Advisory Committee



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# Step 4:

## Public Comment Period

- Public notice, announcing open and close dates, is sent to stakeholders and partners before the open date.

# Step 5:

## State Medicaid Director Approval

- Benefit Coverage Standard reviewed internally
- State Medicaid Director signs  
Benefit Coverage Standard



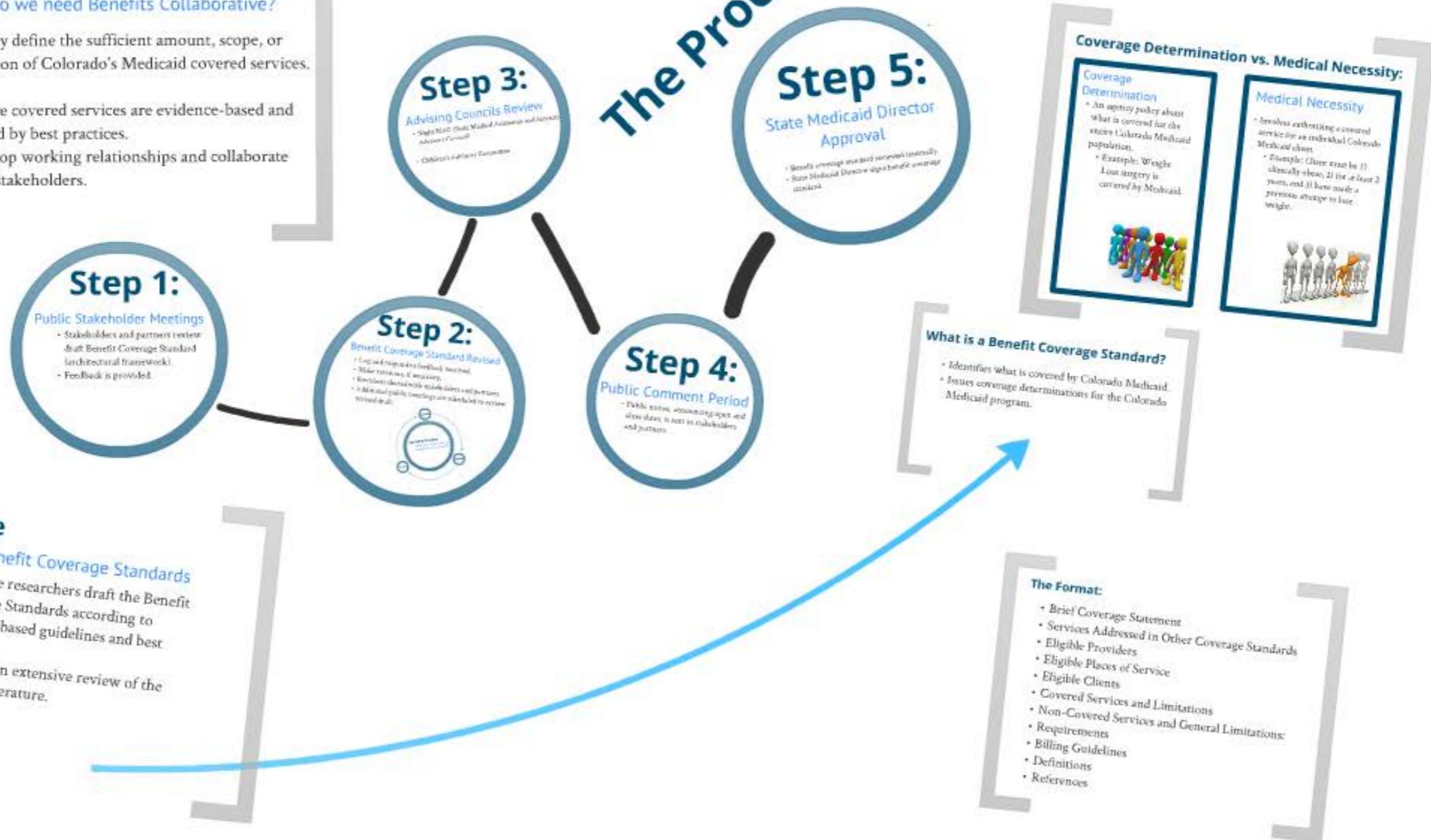
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## The Process



*What's My Role Here  
Today ?*

*How Do I Participate?*



# Your Role

## Participants Are Consultants

Your role is to provide suggestions for policy improvement based on:

- Evidence based research and data
- Peer reviewed literature
- Knowledge of the population we serve



# Guiding Principles

## Policy Suggestions Adopted Will:

- Be guided by recent clinical research and evidence based best practices, wherever possible.
- Be cost effective and establish reasonable limits upon services.
- Promote the health and functioning of Medicaid clients.



# Guiding Principles

What is meant by “recent clinical research” ?

- A body of research based on consistent clinical results that speaks to the efficacy of a treatment.
- Fields of medicine evolve at different rates. Generally, research is considered “recent” when within the last three years.



# Guiding Principles

What is meant by “evidence based best practice” ?

- Best practices are generally defined by professional organizations, representing practitioners who administer the service(s) in question.
- Best practices are typically derived from the type of clinical research already mentioned.



# Guiding Principles

## What is meant by “cost effective” ?

- A service must be effective in relation to its cost.
  - Example: the cost of providing Breast and Cervical Cancer Screening to all clients with a family history is offset by the effectiveness of early detection and the money saved through prevention.

## What “cost effective” does not mean:

- Cost effective does not mean cheap or ineffective.



# Our Role

- To seek out the feedback of the population we serve and those that support them.
- To implement suggested improvements that meet the collaborative's guiding principles.
- To foster understanding in the community about how policy is developing, and why.



# Ground Rules

## Participants Are Asked To:

- Mind E-manners
- Identify Yourself
- Speak Up Here & Share The Air
- Listen for Understanding
- Stay Solution Focused
- Stay Scope Focused



# *Genetic Testing*

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# What are the CDC Guidelines?

CDC Office of Public Health Genomics ranks a list of genomic tests according to their respective levels of evidence and family health history in practice.

Tests are grouped into three ranking categories: **Green** (Tier 1), **Yellow** (Tier 2) and **Red** (Tier 3).

<http://www.cdc.gov/genomics/gtesting>

## Tier 1

- FDA label requires use of test to inform choice or dose of a drug
- CMS covers testing
- Clinical practice guidelines based on systematic review supports testing

## Tier 2

- FDA label mentions biomarkers\*
- CMS coverage with evidence development
- Clinical practice guideline, not based on systematic review, supports use of test
- Clinical practice guideline finds insufficient evidence but does not discourage use of test
- Systematic review, without clinical practice guideline, supports use of test
- Systematic review finds insufficient evidence but does not discourage use of test
- Clinical practice guideline recommends dosage adjustment, but does not address testing

## Tier 3

- FDA label cautions against use
- CMS decision against coverage
- Clinical practice guideline recommends against use of test
- Clinical practice guideline finds insufficient evidence and discourages use of test
- Systematic review recommends against use
- Systematic review finds insufficient evidence and discourages use
- Evidence available only from published studies without systematic reviews, clinical practice guidelines, FDA label or CMS labels coverage decision



# Why has the Department Chosen to use the CDC Guidelines?

- Rigorous methodology used by the CDC
- Tests were assessed for both statistical and clinical validity, as well as the benefit to the client.
- CDC Tier system provides the Department an unbiased test list, which utilizes a peer reviewed process, established in the medical literature.
- Allows the Department to provide medically necessary genetic testing, without delaying client care in order to conduct research.
- The CDC Tiers are easy to follow guidelines which will expand with the scientific breakthroughs in this field.



# Why has the Department Chosen to use the CDC Guidelines?

Previously proposed system (algorithm) unworkable

- Under the old algorithm, ordering providers were required to do more research to determine if a test for a specific client was covered, including:
  - Determining that the chance of genetic abnormality was  $\geq 10\%$  before requesting the test; and
  - Determining if the test is USPSTF or EGAPP recommended; and
- Confusion also existed with regard to how the accompanying ACCE guidelines were evaluated and reported.



# Eligible Providers

The Department requires that genetic testing and test counseling must be provided by Colorado Medicaid enrolled practitioners who can render the service within the scope of their practice, certifications, and licensure.



# Eligible Providers

The Department has received requests to mandate genetic counseling and limit genetic counseling to credentialed genetic counselors; we have not done so for several important reasons:

- Licensure
  - Some states have instituted licensure for genetic counselors. In those states the term “genetic counselor” refers only to a licensed provider.
  - The Colorado Department of Regulatory Agencies (DORA) has not yet instituted such licensure requirements for genetic counselors, which would make such a provision difficult to enforce.



# Eligible Providers (cont.)

- Access to Care
  - Per Title XIX of the Social Security Act, services provided to Medicaid clients must meet state wideness criteria.
  - Mandating that counseling be administered by certified genetic counselors creates an access to care issue for many clients who do not, for example, live along the front range.



# Genetic Counseling

The Department is committed to ensuring that clients receive appropriate counseling and has taken the following actions:

- **Created a new provider type in MMIS**, so that genetic counselors certified through the American Board of Genetic Counselors are now able to enroll with Medicaid and bill for counseling services.
- **Added a provision in the draft standard** that practitioners (such as physicians) who are ordering a genetic test but who are unable to counsel a client regarding genetic testing, must refer the client to a professional who is able to provide counseling services within their scope of practice.



# *Discussion*



*Thank You*



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