DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Changes to the renewal process for Sections 8.100.4.G, 8.100.3.K, and 8.100.3.P.
Rule Number: MSB 19-08-21-A
Division / Contact / Phone: Office of Medicaid Operations / Melissa Torres / 5052

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 19-08-21-A, Revision to the Medical Assistance Rule concerning Changes to the renewal process for Sections 8.100.4.G, 8.100.3.K, and 8.100.3.P.

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) 8.100.4.G, 8.100.3.K, and 8.100.3.P, 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 8.100.3.K with the proposed text beginning at 8.100.3.K through the end of 8.100.3.K. Replace the current text at 8.100.3.P with the proposed text beginning at 8.100.3.P through the end of 8.100.3.P. Replace the current text at 8.100.4.G with the proposed text beginning at 8.100.4.G through the end of 8.100.4.G. This rule is effective March 1, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Changes to the renewal process for Sections 8.100.4.G, 8.100.3.K, and 8.100.3.P.
Rule Number: MSB 19-08-21-A
Division / Contact / Phone: Office of Medicaid Operations / Melissa Torres / 5052

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 change will amend 10 CCR 2505-10 sections 8.100.4.G, 8.100.3.K, and 8.100.3.P based on 42 C.F.R §435.915, §435.916, §435.917, and §435.948, and §435.949 as this pertains to the renewal process for medical assistance. All policy revisions will align with federal regulations for the state to be in compliance with completing redeterminations. There will be new changes to the renewal process for both MAGI and Non-MAGI Programs. Updates will now allow members to receive an eligibility determination using up-to-date information, before issuing a renewal packet to the head of household. When we are able to determine eligibility for all members of the home through interfaces or information within the eligibility system, the household will not receive a renewal packet or be required to submit additional information. These members will receive an approval notice and only be directed to take action if the information used is not accurate. Members who are determined ineligible or if additional verifications are needed at renewal, will receive a renewal packet and be required to review, update, sign the renewal. The signature form will be added to the renewal packet including the member's rights and responsibilities, penalty and perjury language. Changes will also require members who are terminated at renewal for failure to return the signed renewal form or failure to provide requested documentation, to complete a new application after ninety days from the termination date. Members who are terminated at renewal and turn in their application or missing information within ninety days will have a new application date that starts the first of the month in which the renewal is returned. Members will also be given the option to request retro coverage within the 90-day period for any gap in coverage when eligibility is reinstated. Department Eligibility Policy will be updated to reflect these changes in the Colorado Benefits Management System (CBMS). These updates will be added for Medical Assistance programs to increase accurate and timely eligibility renewals ensuring that Colorado provides medical assistance only to members who remain eligible and reduce enrollment of ineligible individuals.
In addition, a new unearned income type of Earned Income tax Credits will be added to policy to align with Medicaid and Child Health Plan Plus rules, CBMS updates are not required for this new unearned income type. Lastly, an update to policy language will be made for the Reasonable Opportunity Period (ROP) for income verification that reduced the ROP from 90 days to 30 days. These updates were previously approved in MSB 20-09-21-A, and the updates are to align with policy, with no CBMS updates required.

2. An emergency rule-making is imperatively necessary

Initial Review	**12/10/21**	Final Adoption	**01/10/22**
Proposed Effective Date	**03/01/22**	Emergency Adoption	

DOCUMENT #08

☐ 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:
   42 C.F.R §435.915, §435.916, §435.917, §435.948, §435.949, and §457.380

4. State Authority for the Rule:

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

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Rule concerning Changes to the renewal process for Sections 8.100.4.G, 8.100.3.K, and 8.100.3.P.
Rule Number: MSB 19-08-21-A
Division / Contact / Phone: Office of Medicaid Operations / Melissa Torres / 5052

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 proposed rule will impact all applicants/members who have reached their redetermination period in MAGI and Non-MAGI Medical Assistance Programs. The rule update will benefit applicants/members who are found eligible at the beginning of their renewal period, by giving eligible members automatic determinations and eliminating the need for applicants/members to review a renewal packet. Ineligible applicants/members will be required to review and update any information on their renewal packet and return it with their missing documentation and a signature form.

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 proposed rule will allow members to receive an accurate and timely eligibility determination by using the renewal review process which contains up-to-date information. This includes providing automatic medical assistance determinations to individuals who remain eligible for MAGI and Non-MAGI Medical assistance programs, which will allow the department to eliminate making payments for ineligible individuals.

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 anticipates that updating the renewal process will not impact costs through caseload changes as these policy changes do not affect a member's eligibility. If a household receives a renewal packet, it will be due to someone in the household not being eligible for Medicaid or CHP+. The Department will take steps to make the signature requirement as easy to complete as possible for members so to not cause disruption in the member's enrollment.

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

The probable costs of this policy include updating the Department's eligibility systems to comply with CMS guidance.

The probable benefits to the policy are the Department would be in compliance with CMS rules.

The probable costs of inaction would be that the Department would be out of compliance with CMS rules which would threaten the Department's ability to receive a federal match for the Departments' programs.

There are no obvious benefits to inaction.

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

   The Department does not have any less costly method of implementing this update for the renewal process

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 the proposed rule that were considered.

8.100 MEDICAL ASSISTANCE ELIGIBILITY

8.100.3. Medical Assistance General Eligibility Requirements

8.100.3.K. Consideration of Income

1. Income or resources of an alien sponsor or an alien sponsor's spouse shall be countable to the sponsored alien effective December 19, 1997. Forms used prior to December 19, 1997, including but not limited to forms I-134 or I-136 are legally unenforceable affidavits of support. The attribution of the income and resources of the sponsor and the sponsor's spouse to the alien will continue until the alien becomes a U.S. citizen or has worked or can be credited with 40 qualifying quarters of work, provided that an alien crediting the quarters to the applicant/client has not received any public benefit during any creditable quarter for any period after December 31, 1996.

    a. Exception: When the sponsored alien is a pregnant woman or a child the income or resources of an alien sponsor or an alien sponsor's spouse will not be countable to the sponsored alien.

2. Income, in general, is the receipt by an individual of a gain or benefit in cash or in kind during a calendar month. Income means any cash, payments, wages, in-kind receipt, inheritance, gift, prize, rents, dividends, interest, etc., that are received by an individual or family.

3. Earned income is payment in cash or in kind for services performed as an employee or from self-employment.

4. Earned in kind income shall be income produced as a result of the performance of services by the applicant/client, for which he/she is compensated in shelter or other items in lieu of wages.

5. Received means "actually" received or legally becomes available, whichever occurs first; the point at which the income first is available to the individual for use. For example, interest income on a savings account is counted when it is credited to the account.

6. All Home Care Allowance (HCA) income paid to a Medical Assistance applicant or member by the HCA recipient to provide home care services is countable earned income.

7. An applicant or member who is a live-In home care provider to a care recipient receiving a Difficulty of Care Payment and who is being determined for a MAGI Medical Assistance program, must meet the following requirements for Difficulty of Care payments to be excluded as countable income:

a. The care provider receiving payments for personal care or supportive services provided to a care recipient must live full-time in the same home with the care recipient; and

b. The care recipient must either

i) receiving personal care or supportive services must be enrolled in Long Term Service Supports (LTSS), with additional services through a Home-Based Services (HCBS) waiver program; or

ii) The care recipient must be enrolled in the Buy-In Program for Working Adults with Disabilities, and receive additional services through the Home and Community Based Services (HCBS) waiver program.

c. Exception: Difficulty of Care Payments are not excluded if the payments are for more than 10 qualified foster individuals under the age of 19 or 5 qualified foster individuals who are over the age of 19

8. Participation in the Workforce Investment Act (WIA) affects eligibility for Medical Assistance as follows:

a. Wages derived from participation in a program carried out under WIA (work experience or on-the-job training) and paid to a caretaker relative is considered countable earned income.

b. Training allowances granted by WIA to a dependent child or a caretaker relative of a dependent child to participate in a training program is exempt.

c. Wages derived from participation in a program carried out the under Workforce Investment Act (WIA) and paid to any dependent child who is applying for or receiving Medical Assistance are exempt in determining eligibility for a period not to exceed six months in each calendar year.

9. An individual involved in a profit-making activity as a sole proprietor, partner in a partnership, independent contractor, or consultant shall be classified as self-employed.

a. To determine the net profit of a self-employed applicant/client deduct the cost of doing business from the gross income. These business expenses include, but are not limited to:

i) the rent of business premises,

ii) wholesale cost of merchandise,

iii) utilities,

iv) taxes,

v) labor, and

vi) upkeep of necessary equipment.

b. The following are not allowed as business expenses:

i) Depreciation of equipment;

1) Exception: For the purpose of calculating MAGI-based income, depreciation of equipment is an allowable business expense if the equipment is not used for capital improvements.

ii) The cost of and payment on the principal of loans for capital asset or durable goods;

iii) Personal expenses such as personal income tax payments, lunches, and transportation to and from work.

c. Appropriate allowances for cost of doing business for Medical Assistance clients who are licensed, certified or approved day care providers are (1) $ 55 for the first child for whom day care is provided, and (2) $ 22 for each additional child. If the client can document a cost of doing business which is greater than the amounts above set forth, the procedure described in A, shall be used.

d. When determining self-employment expenses and distinguishing personal expenses from business expenses it is a requirement to only allow the percentage of the expense that is business related.

10. Self-employment income includes, but is not limited to, the following:

a. Farm income - shall be considered as income in the month it is received. When an individual ceases to farm the land, the self-employment deductions are no longer allowable.

b. Rental income - shall be considered as self-employment income only if the Medical Assistance client actively manages the property at least an average of 20 hours per week.

c. Board (to provide a person with regular meals only) payment shall be considered earned income in the month received to the extent that the board payment exceeds the maximum food stamp allotment for one-person household per boarder and other documentable expenses directly related to the provision of board.

d. Room (to provide a person with lodging only) payments shall be considered earned income in the month received to the extent that the room payment exceeds documentable expenses directly related to the provision of the room.

e. Room and board payments shall be considered earned income in the month received to the extent that the payment for room and board exceeds the food stamp allotment for a one-person household per room and boarder and documentable expenses directly related to the provision of room and board.

11. Unearned income is the gross amount received in cash or kind that is not earned from employment or self-employment. Unearned income includes, but is not limited to, the following:

a. Pensions and other period payments, such as:

i) Private pensions or disability benefits

1) Exception: Refer to section 8.100.4 for treatment of private disability benefits for MAGI Medical Assistance.

ii) Social Security benefits (Retirement, survivors, and disability)

iii) Workers' Compensation payments

iv) Railroad retirement annuities

v) Unemployment insurance payments

vi) Veterans benefits other than Aid and Attendance (A&A) and Unusual Medical Expenses (UME).

vii) Alimony and support payments

viii) Interest, dividends and certain royalties on countable resources

12. For all Medical Assistance categories, the federal Coronavirus Aid, Relief, and Economic Security (CARES) Act and American Rescue Plan (ARP) Act Recovery Rebate, known as the COVID-19 Economic Stimulus, shall be exempt from consideration as income.

13. Federal Pandemic Unemployment Compensation (FPUC) program, which provides an extra $600.00 a week for qualifying individuals, is exempt as countable unearned income for all Medical Assistance categories.

14. Federal Income Tax refunds, Earned Income Tax Credit payments, or Child Tax Credits, areshall be exempt from consideration as income.

8.100.3.P. Redetermination of Eligibility

1. "RA redetermination of eligibility" shall means a case review and necessary verification to determine whether the Medical Assistance Program client member continues to be eligible to receive Medical Assistance.

"Reconsideration period" means the 90-day period following termination of eligibility.

Beginning on as of the case approval date, a redetermination shall be accomplished at least every each 12 months for Title XIX Medical Assistance only cases.

An eligibility site may redetermine eligibility through telephone, mail, or online electronically means.

2. The eligibility site shall promptly redetermine eligibility when:

a. it receives and verifies information which indicates a change in a member'sclient's circumstances which may affect continued eligibility for Medical Assistance; or

b. it receives direction to do so from the Department.

The eligibility site shall redetermine eligibility according to timelines defined by the Department.

3. Ex Parte Review: A redetermination form ~~is not required to~~will not be sent to the member ~~client~~ if all current eligibility requirements can be verified by reviewing information from another assistance program~~,~~ or if this information can be verified though an electronic verification system – this process is referenced as Ex Parte Review.~~., and/or CBMS.~~ The use of telephonic or electronic redeterminations shall be noted in the case record. When applicable, the eligibility site shall redetermine eligibility based solely on information already available. If verification or information is available for any of the three months prior to the redetermination month, and all other eligibility requirements are met, ~~, no request shall be made of the client and~~ then an approval ~~notice of the findings of the review will go to the client. If not all verification or information is available,~~ will be sent for all eligible members of the household who are requesting assistance. This approval notice shall include directions on how to view the information used ~~in~~to determine ~~the eligibility determination. the eligibility site shall only request the additional minimum verification from the client. This procedure is referenced as Ex Parte Review.~~

4. If all required information is not available and/or the information received does not support a finding of eligibility~~make the requesting members eligible, A~~a redetermination form will be ~~sent~~issued to the household at least 30 days prior to the ~~expiration~~end ~~of the eligibility period. , approved by the Department,~~The redetermination form shall be prepopulated with the current information on file and ~~mailed~~ sent to the ~~person~~ household at least 30 days prior to ~~the~~ the ~~first of the month in which completion of eligibility~~ redetermination period ending~~is due~~. As part of the ex parte review, ~~The redetermination form shall be used to inform~~ the member~~client~~ will be informed of ~~the redetermination and~~ any verification needed to determine eligibility.~~, but the form itself cannot be required to be returned~~ the member to return a signed form. ~~. The only verification that can be required at redetermination is the minimum verification needed to complete a redetermination of eligibility.~~

The redetermination form shall direct ~~clients~~ members to verify that the information provided is ~~still~~ accurate or to report any changes to the information. ~~review current information, and to take no action by verifying if the information is still accurate with no changes and/or if there are no changes to reporting changes in the household.~~ Members must~~will also need to~~ complete and the return the redetermination with necessary verifications and the signature form.~~.~~ If a member fails to sign the ~~redetermination~~signature form or comply with any of these requirements, ~~eligibility status shall not be redetermined and~~ the member will be terminated from the program for failure to complete the redetermination process. ~~Eligibility sites and CBMS shall view T~~the absence of ~~requested information and/or a missing or an unsigned signature form~~reported changes from the ~~client~~ member at this redetermination period ~~shall be viewed~~ as ~~a failure to complete the redetermination process.~~confirmation that there have been no changes in the household. ~~This procedure is referenced as automatic reenrollment.~~

The following procedures relate to mail-out redetermination:

a. A Redetermination Form shall be mailed to the ~~client~~ member together with any other forms to be completed;

b. ~~b. When additional~~ Required verification ~~is required to~~ shall be returned by the ~~client~~ member~~, it shall be returned to the eligibility site no later than ten working days after receipt of request;~~Members shall provide requested forms, verifications and information to the eligibility site within 10 working days ~~of receipt~~;

c. When the member~~individual~~ is unable to complete the forms due to physical, mental or emotional disabilities, or other good cause, and has no one to help him/her, the eligibility site shall either assist the ~~client~~ member or refer him/her to a legal or other resource. When initial arrangements or a change in arrangements are being made, an extension of

up to thirty days shall be allowed. The action of the eligibility site in assistance or referral shall be recorded in the case record and CBMS case comments.

d. The redetermination form shall require that a recipient and community spouse of a recipient of HCBS, PACE or institutional services disclose a description of any interest the individual or community spouse has in an annuity or similar financial instrument regardless of whether the annuity is irrevocable or treated as an asset. The redetermination form shall include a statement that the Department shall be a remainder beneficiary for any annuity or similar financial instrument purchased on or after February 8, 2006 for the total amount of Medical Assistance provided to the individual.

e. The eligibility site shall notify in writing the issuer of any annuity or financial instrument that the Department is a preferred remainder beneficiary in the annuity or similar financial instrument for the total amount of Medical Assistance provided to the individual. This notice shall require the issuer to notify the eligibility site when there is a change in the amount of income or principal that is being withdrawn from the annuity.

f. Members who return properly completed redetermination forms and requested information during the ~~redetermination~~reconsideration period shall not be required to submit a new application for eligibility. If redetermination forms and requested information are not returned within 90 days after termination, the member must submit a new application to obtain enrollment in the program. ~~If a redetermination form and the requested information is returned within 90 days after a member's eligibility is terminated, the eligibility site shall accept the information and shall not require the member to complete a new application. This procedure will be referenced as a reconsideration period. A new application will be required after the 90 days.~~

g. ~~-~~For individuals ~~that~~who are determined to be eligible for Medical Assistance within the reconsideration period, the effective date of coverage will be the first day of the month in which the redetermination form was returned. ~~'s coverage lapses during the reconsideration period, the member may request retroactive coverage of up to three months.~~If the member has a gap in coverage due to submitting ~~turning in~~ the redetermination within the reconsideration period, the member can request up to three months in retroactive coverage ~~up to three months~~.

5. When the redetermination verification information is received by the eligibility site, it shall be date stamped. Within ~~ten~~ fifteen working days, the verification information shall be thoroughly reviewed for completeness, accuracy, and consistency. All factors shall be evaluated as to their effect on eligibility at that time. Verifications shall be documented in the case file and CBMS case comments. The case file shall be used as a checklist in the redetermination process, and shall be used to keep track of matters requiring further action. When additional information is needed:

a. due to incomplete information, the request form shall be mailed ~~back~~ to the ~~client~~ member with a letter specifying the items that require completion. The member shall return the completed request form~~, it shall be returned~~ to the eligibility site no later than ten working days. ~~a~~;

b. due to incomplete, inaccurate or inconsistent data, the Medical Assistance ~~client~~ member shall be contacted by telephone or in writing so that the worker may secure the proper information according to timelines defined by the Department.

6. Due to the federal Coronavirus COVID-19 Public Health Emergency, the Department will continue eligibility for all Medical Assistance categories, regardless of a redetermination and/or reported change for these individuals to ensure continuity of eligibility for Medical Assistance coverage.

8.100.4 MAGI Medical Assistance Eligibility [Eff. 01/01/2014]

8.100.4.G. MAGI Covered Groups

1. For MAGI Medical Assistance, any person who is determined to be eligible for Medical Assistance based on MAGI at any time during a calendar month shall be eligible for benefits during the entire month.

2. Children applying for Medical Assistance whose total household income does not exceed 133% of the federal poverty level (MAGI-equivalent) shall be determined financially eligible for Medical Assistance. Refer to the MAGI-Medicaid income guidelines chart available on the Department's website.

    a. Children are eligible for Children's MAGI Medical Assistance through the end of the month in which they turn 19 years old. After turning 19, the individual may be eligible for a different Medical Assistance category.

3. Parents and Caretaker Relatives applying for Medical Assistance whose total household income does not exceed 60% of the federal poverty level (MAGI-equivalent) shall be determined financially eligible for Medical Assistance. Parents or Caretaker Relatives eligible for this category shall have a dependent child in the household.

    a. A dependent child is considered to be living in the home of the parent or caretaker relative as long as the parent or specified relative exercises responsibility for the care and control of the child even if:

        i) The child is under the jurisdiction of the court (for example, receiving probation services);

        ii) Legal custody is held by an agency that does not have physical possession of the child;

        iii) The child is in regular attendance at a school away from home;

        iv) Either the child or the relative is away from the home to receive medical treatment;

        v) Either the child or the relative is temporarily absent from the home;

vi) The child is in voluntary foster care placement for a period not expected to exceed three months. Should the foster care plan change within the three months and the placement become court ordered, the child is no longer considered to be living in the home as of the time the foster care plan is changed.

4. Adults applying for Medical Assistance whose total household income does not exceed 133% of the federal poverty level shall be determined financially eligible for Medical Assistance. This category includes adults who are parents or caretaker relatives of dependent children whose income exceeds the income threshold to qualify for the Parents and Caretaker Relatives MAGI category and who meet all other eligibility criteria.

   a. A dependent child living in the household of a parent or caretaker relative shall have minimum essential coverage, in order for the parent or caretaker relative to be eligible for Medical Assistance under this category. Refer to section 8.100.4.G.3.a on who is considered a dependent child.

   b. Due to the COVID-19 Public Health Emergency an applicant who is not eligible for Medical Assistance but has been impacted through exposure to or potential infection with COVID-19 may be eligible to receive services for COVID-19 testing only. To qualify for this limited benefit, the Applicant must not be enrolled in other health insurance and meet the criteria of citizenship.

5. Pregnant Women whose household income does not exceed 185% of the federal poverty level (MAGI-equivalent) are eligible for the Pregnant Women MAGI Medical Assistance program. Medical Assistance shall be provided to a pregnant woman for a period beginning with the date of application for Medical Assistance through the last day of the month following 60 days from the date the pregnancy ends. Once eligibility has been approved, Medical Assistance coverage will be provided regardless of changes in the woman's financial circumstances once the income verification requirements are met.

   a. A pregnant women's eligibility period will end effective the earliest possible month, if the following occurs:

      i) Fails to provide a reasonable explanation or paper documentation when self-attested income is not reasonably compatible with income information from an electronic data source, by the end of the 30~~90~~ day reasonable opportunity period. This exception only applies the first-time income is verified following an initial eligibility determination or an annual redetermination.

6. A lawfully admitted non-citizen who is pregnant and who has been in the United States for less than five years is eligible for Medical Assistance if she meets all of the other eligibility requirements specified at 8.100.4.G.5 and fits into one of the immigration categories listed in 8.100.3.G.1.g.iii.1-5 and 8.100.3.G.1.g.vi.1-15. This population is referenced as Legal Immigrant Prenatal.

7. A child whose mother is receiving Medical Assistance at the time of the child's birth is continuously eligible for one year. This population is referred to as "Eligible Needy Newborn". This coverage also applies in instances where the mother received Medical Assistance to cover the child's birth through retroactive Medical Assistance. The child is not required to live with the mother receiving Medical Assistance to qualify as an Eligible Needy Newborn.

   a. To receive Medical Assistance under this category, the birth must be reported verbally or in writing to the County Department of Human Services or eligibility site. Information provided shall include the baby's name, date of birth, and mother's name or Medical

Assistance number. A newborn can be reported at any time by any person. Once reported, a newborn meeting the above criteria shall be added to the mother's Medical Assistance case, or his or her own case if the newborn does not reside with the mother, according to timelines defined by the Department. If adopted, the newborn's agent does not need to file an application or provide a Social Security Number or proof of application for a Social Security Number for the newborn

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Eligibility Rules concerning General and Citizenship Eligibility Requirements, Section 8.100.3.G
Rule Number: MSB 21-11-24-B
Division / Contact / Phone: Eligibility Policy / Jennifer VanCleave / 303-866-6204

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 21-12-15-A, Revision to the Medical Assistance Eligibility Rules Concerning General and Citizenship Eligibility Requirements, Section 8.100.3.G

3. This action is an adoption of: <Select One>

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

   Sections(s) OP Pages, 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)? <Select One>

   If yes, state effective date: 11/12/2021

   Is rule to be made permanent? (If yes, please attach notice of hearing). Yes

PUBLICATION INSTRUCTIONS*

Replace the current text at 8.100.3.G with the proposed text beginning at 8.100.3.G through the end of 8.100.3.G. This rule is effective March 1, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Eligibility Rules concerning General and Citizenship Eligibility Requirements, Section 8.100.3.G
Rule Number: MSB 21-11-24-B
Division / Contact / Phone: Eligibility Policy / Jennifer VanCleave / 303-866-6204

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).

   On September 30, 2021, Congress singed the Extending Government Funding and Delivering Emergency Assistance Act (HR 5305) into law. Section 2502 of HR 5305 expanded eligibility to entitlement programs such as Medicaid, to include Afghan evacuees as qualified non-citizens not subject to the five-year bar. The resolution states that a citizen or national of Afghanistan who is paroled into the United States between July 31, 2021 and September 30, 2022; or is paroled into the United States after September 30, 2022 and is either a spouse or child (defined under section 101(b) of the Immigration and Nationality Act 8 U.S.C. 4 1101(b); or is the parent or legal guardian of an individual arriving from Afghanistan in the prescribed date range who was determined to be an unaccompanied child (under 6 U.S.C. 279(g)(2), will considered a qualified non-citizen not subject to the 5 year bar. The population is referred to as Afghan humanitarian parolees.

   Currently, these statuses are already considered qualified non-citizens not subject to the five-year bar for children under the age of 19 and pregnant women. HR 5305 states that all humanitarian parolees arriving from Afghanistan during the specified date ranges should be considered qualified non-citizens not subject to the five-year bar, as long as their parole has not been terminated by the Department of Homeland Security. Individuals with these statuses are not automatically entitled for Medical Assistance, they will still need to apply and meet all categorical requirements to be approved. Their status will also be verified electronically through the Verify Lawful Presence (VLP) interface with the Systematic Alien Verification for Entitlements (SAVE) program per current state and federal rule.

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:

   HR 5305, Section 2502

Initial Review
Proposed Effective Date

Final Adoption
Emergency Adoption

DOCUMENT #

DO NOT PUBLISH THIS PAGE

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2021);
   Section 25.5-4-205, C.R.S. (2021)
   Section 24.4-4-103(6)(a), C.R.S. (2021)

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Title of Rule: Revision to the Medical Assistance Eligibility Rules concerning General and Citizenship Eligibility Requirements, Section 8.100.3.G
Rule Number: MSB 21-11-24-B
Division / Contact / Phone: Eligibility Policy / Jennifer VanCleave / 303-866-6204

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 Governor's Office and the Department of Human Services Office of Refugee Resettlement estimates 1,000 – 2,000 total Afghan evacuees arriving in Colorado, with an estimate of up to half of the total population (approximately 1,000) entering Colorado under the newly established eligible immigration status.

   With the proposed rule change, Afghan humanitarian parolees who arrived during the specified date ranges, will be considered qualified non-citizens not subject to the five-year bar until March 31, 2023, or through the extent of their parole timeframe, whichever is later. They will be eligible for full benefits, rather than only those services necessary to treat an emergency medical condition. Many Afghan refugees will arrive in Colorado with immigration statuses that are already considered qualified non-citizens not subject to the five-year bar for Medical Assistance, and their eligibility will be unaffected by the proposed rule change.

   The Department will also benefit from the proposed change as the rule will align with federal requirements. The Department will also bear the cost of the proposed rule change, as there will be an increase in the number of individuals who will be eligible for Medical Assistance.

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 proposed change will update rule to comply with the requirements put forth in Extending Government Funding and Delivering Emergency Assistance Act (HR 5305), Section 2502. The Department will benefit from compliance with federal regulations. This will ensure that Medical Assistance eligibility will be accurately determined for Afghan evacuees. The proposed change will also expand eligibility for full Medical Assistance benefits to Afghan humanitarian parolees who were previously only eligible for the coverage of services necessary to treat an emergency medical condition.

   The Department, stakeholders, applicants, and providers will benefit from a description of the expanded population eligible for benefits, as well as the date

ranges during which the newly expanded population will be considered qualified non-citizens for Medical Assistance.

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 this policy would increase the Medicaid caseload by up to 1,000 members. The Department anticipates that the total impact of coverage of Medicaid programs for these members will be $4,425,970 in Fiscal Year 2021-2022.

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

   The probable costs of this policy include potentially paying up to $4.4 million for Medicaid services attributable to new members.

   The probable benefits to the policy include staying in compliance with federal laws, as well as providing medical care to individuals in need.

   The probable costs of inaction will be that the Department will be out of compliance with federal laws. This could cause the Department to pay a disallowance to CMS or forfeit the Federal Match the Department receives from the Federal Government.

   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.

   The Department does not have any less costly method of enrolled the 1,000 newly eligible members.

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 no alternative methods for achieving the purpose of the proposed rule, as it is required to come into compliance with federal law.

8.100 MEDICAL ASSISTANCE ELIGIBILITY

8.100.3. Medical Assistance General Eligibility Requirements

8.100.3.G. General and Citizenship Eligibility Requirements

1. To be eligible to receive Medical Assistance, an eligible person shall:

    a. Be a resident of Colorado;

    b. Meet the following requirements while being an inmate, in-patient or resident of a public institution:

        i). The following individuals, if eligible, may be enrolled for Medical Assistance

            1. Patients in a public medical institution

            2. Residents of a Long-Term Care Institution

            3. Prior inmates who have been paroled

            4. Resident of a publicly operated community residence which serves no more than 16 residents

            5. Individuals participating in community corrections programs or residents in community corrections facilities (“halfway houses”) who have freedom of movement and association which includes individuals who:

                a) are not precluded from working outside the facility in employment available to individuals who are not under justice system supervision;

                b) can use community resources (e.g., libraries, grocery stores, recreation, and education) at will;

                c) can seek health care treatment in the broader community to the same or similar extent as other Medicaid enrollees in the state; and/or

                d) are residing at their home, such as house arrest, or another location

ii). Inmates who are incarcerated in a correctional institution such as a city, county, state or federal prison may be enrolled, if eligible, with benefits limited to an in-patient stay of 24 hours or longer in a medical institution.

c. Not be a patient in an institution for tuberculosis or mental disease, unless the person is under 21 years of age or has attained 65 years of age and is eligible for the Medical Assistance Program and is receiving active treatment as an inpatient in a psychiatric facility eligible for Medical Assistance reimbursement. See section 8.100.4.H for special provisions extending Medical Assistance coverage for certain patients who attain age 21 while receiving such inpatient psychiatric services;

d. Meet all financial eligibility requirements of the Medical Assistance Program for which application is being made;

e. Meet the definition of disability or blindness, when applicable. Those definitions appear in this volume at 8.100.1 under Definitions;

f. Meet all other requirements of the Medical Assistance Program for which application is being made; and

g. Fall into one of the following categories:

i) Be a citizen or national of the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, American Samoa or Swain's Island; or

ii) Be a lawfully admitted non-citizen who entered the United States prior to August 22, 1996, or

iii) Be a non-citizen who entered the United States on or after August 22, 1996 and is applying for Medical Assistance benefits to begin no earlier than five years after the non-citizen's date of entry into the United States who falls into one of the following categories:

1) lawfully admitted for permanent residence under the Immigration and Nationality Act (hereafter referred to as the "INA");

2) paroled into the United States for at least one year under 8 U.S.C. § 1182(d)(5); or

3) granted conditional entry under section 203(a)(7) of the INA, as in effect prior to April 1, 1980; or

4) determined by the eligibility site, in accordance with guidelines issued by the U.S. Attorney General, to be a spouse, child, parent of a child, or child of a parent who, in circumstances specifically described in 8 U.S.C. §1641(c), has been battered or subjected to extreme cruelty which necessitates the provision of Medical Assistance (Medicaid); or

iv) Be a non-citizen who arrived in the United States on any date, who falls into one of the following categories:

1) lawfully residing in Colorado and is an honorably discharged military veteran (also includes spouse, unremarried surviving spouse and unmarried, dependent children), or

2) lawfully residing in Colorado and is on active duty (excluding training) in the U.S. Armed Forces (also includes spouse, unremarried surviving spouse and unmarried, dependent children), or

3) granted asylum under section 208 of the INA, or

4) refugee under section 207 of the INA, or

5) deportation withheld under section 243(h) (as in effect prior to September 30, 1996) or section 241(b)(3) (as amended by P.L. 104-208) of the INA, or

6) Cuban or Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980, or

7) an individual who (1) was born in Canada and possesses at least 50 percent American Indian blood, or is a member of an Indian tribe as defined in 25 U.S.C. sec. 5304(e)(2016), or

8) admitted to the U.S. as an Amerasian immigrant pursuant to section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988 (as amended by P.L. 100-461), or

9) lawfully admitted permanent resident who is a Hmong or Highland Lao veteran of the Vietnam conflict, or

10) a victim of a severe form of trafficking in persons, as defined in section 103 of the Victims of Trafficking and Violence Protection Act of 2000, Pub. L.106-386, as amended (22 U.S.C. § 7105(b) (2016)), or

11) An alien who arrived in the United States on or after December 26, 2007 who is an Iraqi special immigrant under section 101(a)(27) of the INA, or

12) An alien who arrived in the United States on or after December 26, 2007 who is an Afghan Special Immigrant under section 101(a)(27) of the INA, or

13) Compact of Free Association (COFA) migrants, including citizens of Micronesia, the Marshall Islands, and Palau, pursuant to section 208 of the Consolidated Appropriations Act of 2021 (in effect December 27, 2020).

v) The statutes listed at sections 8.100.3.G.1.g.iii.1-5 and at 8.100.3.G.1.g.iv.3-11 are incorporated herein by reference. No amendments or later editions are incorporated. These regulations are available for public inspection at the Colorado Department of Health Care Policy and Financing, 1570 Grant Street, Denver, Colorado 80203-1714. Pursuant to C.R.S. 24-4-103(12.5)(b)(2016), 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.

vi) Be a lawfully admitted non-citizen who is a pregnant women or a child under the age of 19 years in the United States who falls into one of the categories listed in 8.100.3.G.1.g.iii or into one of the following categories listed below. These individuals are exempt from the 5-year waiting period:

1) granted temporary resident status in accordance with 8 U.S.C. 1160 or 1255a,or

2) granted Temporary Protected Status (TPS) in accordance with 8 U.S.C 1254a and pending applicants for TPS granted employment authorization,

3) granted employment authorization under 8 CFR 274a.12(c),or

4) Family Unity beneficiary in accordance with section 301 of Pub. L. 101-649, as amended.

5) Deferred Enforced Departure (DED), pursuant to a decision made by the President,

6) granted Deferred Action status (excluding Deferred Action for Childhood Arrivals (DACA)) as described in the Secretary of Homeland Security's June 15,2012 memorandum,

7) granted an administrative stay of removal under 8 CFR 241.6(2016), or

8) Beneficiary of approved visa petition who has a pending application for adjustment of status.

9) Pending an application for asylum under 8 U.S.C. 1158, or for withholding of removal under 8 U.S.C. 1231, or under the Convention Against Torture who-

a) as been granted employment authorization; or

b) Is under the age of 14 and has had an application pending for at least 180 days.

10) granted withholding of removal under the Convention Against Torture,

11) A child who has a pending application for Special Immigrant Juvenile status under 8 U.S.C. 1101(a)(27)(J), or

12) Citizens of Micronesia, the Marshall Islands, and Palau, or

13) is lawfully present American Samoa under the immigration of laws of American Samoa.

14) A non-citizen in a valid nonimmigrant status, as defined in 8 U.S.C. 1101(a)(15) or under 8 U.S.C. 1101(a)(17), or

15) A non-citizen who has been paroled into the United States for less than one year under 8 U.S.C. § 1182(d)(5), except for an individual paroled for prosecution, for deferred inspection or pending removal proceedings.

vii) Be an Afghan Humanitarian Parolee who falls into one of the following categories listed below, as defined in Section 2502 of the Extending Government Funding and Delivering Emergency Assistance Act of 2021 (HR 5305). These individuals are exempt from the 5-year waiting period until March 31, 2023, or through the termination of their parole period, whichever is later:

1) paroled into the United States between July 31, 2021 – September 30, 2022; or

2) paroled into the United States after September 30, 2022, and

a) is the spouse or child of an individual in subparagraph 1 as defined under section 101(b) of the Immigration and Nationality Act (8 U.S.C. 4 1101(b)); or

b) is the parent or legal guardian of an individual in subparagraph 1 who is determined to be an unaccompanied child under 6 U.S.C.279(g)(2).

viii) Exception: The exception to these requirements is that persons who apply for and meet the criteria for one of the categorical Medical Assistance programs, but who are not citizens, and are not eligible non-citizens, according to the criteria set forth in 8.100.3.G.1.g, shall receive Medical Assistance benefits for emergency medical care only. The rules on confidentiality prevent the Department or eligibility site from reporting to the United States Citizenship and Immigration Services persons who have applied for or are receiving assistance. These persons need not select a primary care physician as they are eligible only for emergency medical services.

For non-qualified aliens receiving Medical Assistance emergency only benefits, the following medical conditions will be covered:

An emergency medical condition (including labor and delivery) which manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

1) placing the patient's health in serious jeopardy;

2) serious impairment of bodily function; or

3) serious dysfunction of any bodily organ or part.

A physician shall make a written statement certifying the presence of an emergency medical condition when services are provided and shall indicate that services were for a medical emergency on the claim form. Coverage is limited to care and services that are necessary to treat immediate emergency medical conditions. Coverage does not include prenatal care or follow-up care.

2. For determinations of eligibility for Medical Assistance, legal immigration status must be verified. This requirement applies to a non-citizen individual who meets the criteria of any category defined

at 8.100.3.G(1)(g)(ii) (iii) (iv) ~~or~~ (vi) or (vii) and has declared that he or she has a legal immigration status.

a. The Verify Lawful Presence (VLP) interface will be used to verify immigration status. The VLP interface connects to the Systematic Alien Verification for Entitlements (SAVE) Program to verify legal immigration status.

i) If an automated response from VLP confirms that the information submitted is consistent with VLP data for immigration status verification requirements, no further action is required for the individual and no additional documentation of immigration status is required.

ii) If the VLP cannot automatically confirm the information submitted, the individual will be contacted with a request for additional documents and/or information needed to verify their legal immigration status through the VLP interface. If a response from the VLP interface confirms that the additional documents and/or information received from the individual verifies their legal immigration status, no further action is required for the individual and no additional documentation of immigration status is required.

3. Reasonable Opportunity Period

a. If the verification through the electronic interface is unsuccessful then the applicant will be provided a reasonable opportunity period, of 90 days, to submit documents indicating a legal immigration status, as listed in 8.100.3.G.1.g. The reasonable opportunity period will begin as of the date of the Notice of Action. The required documentation must be received within the reasonable opportunity period.

b If the applicant does not provide the necessary documents within the reasonable opportunity period, then the applicant's Medical Assistance application shall be terminated.

c. The reasonable opportunity period applies to MAGI, Adult and Buy-In Programs.

i) For the purpose of this section only, MAGI Programs for persons covered pursuant to 8.100.4.G or 8.100.4.I. include the following:

Commonly Used Program Name	Rule Citation
Children's Medical Assistance	8.100.4.G.2
Parent and Caretaker Relative Medical Assistance	8.100.4.G.3
Adult Medical Assistance	8.100.4.G.4
Pregnant Women Medical Assistance	8.100.4.G.5
Legal Immigrant Prenatal Medical Assistance	8.100.4.G.6
Transitional Medical Assistance	8.100.4.I.1-5

ii) For the purpose of this section only, Adult and Buy-In Programs for persons covered pursuant to 8.100.3.F, 8.100.6.P, 8.100.6.Q, or 8.715. include the following:

Commonly Used Program Name	Rule Citation

Old Age Pension A (OAP-A)	8.100.3.F.1.c
Old Age Pension B (OAP-B)	8.100.3.F.1.c
Qualified Disabled Widow/Widower	8.100.3.F.1.e
Pickle	8.100.3.F.1.e
Long-Term Care	8.100.3.F.1.f-h
Medicaid Buy-In Program for Working Adults with Disabilities	8.100.6.P
Medicaid Buy-In Program for Children with Disabilities	8.100.6.Q
Breast and Cervical Cancer Program (BCCP)	8.715

Title of Rule: Revision to the Medical Assistance Act Rule Concerning Preferred Drug List (PDL) and New Drug Determinations, Section 8.800.16.B
Rule Number: MSB 21-11-24-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 21-11-24-A, Revision to the Medical Assistance Act Rule Concerning Preferred Drug List (PDL) and New Drug Determinations, Section 8.800.16.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) 8.800.16.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 8.800.16.B with the proposed text beginning at 8.800.16.B through the end of 8.800.16.B. This rule is effective March 1, 2022.

*to be completed by MSB Board Coordinator

DO NOT PUBLISH THIS PAGE

Title of Rule: Revision to the Medical Assistance Act Rule Concerning Preferred Drug List (PDL) and New Drug Determinations, Section 8.800.16.B
Rule Number: MSB 21-11-24-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).

   This proposed rule change will clarify that when a new drug becomes available and falls into a Drug Class that is already on the PDL, that the Department will determine whether it's Preferred or Non-preferred within a specified timeframe.

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:

   N/A

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2021);
   Section 25.5-1-108, C.R.S. (2021)

Initial Review Final Adoption **01/14/22**
Proposed Effective Date **03/30/22** Emergency Adoption

DOCUMENT #04

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Title of Rule: Revision to the Medical Assistance Act Rule Concerning Preferred Drug List (PDL) and New Drug Determinations, Section 8.800.16.B
Rule Number: MSB 21-11-24-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.

   Members will benefit from the proposed rule by ensuring that they receive drugs that are new to the market in a timely manner. There are no costs of the proposed rule.

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

   Quantitatively, drugs that are new to the market will be designated as Preferred or Non-preferred within a specified timeframe, which in some cases may increase the speed at which new drugs are available to members. Qualitatively, the Department will ensure that members receive drugs that are new to market in a timely manner.

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 of the proposed rule.

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

   There are no probable costs of the proposed rule and there are no benefits of inaction. The benefit of action is that the Department will ensure that members receive drugs that are new to the market in a timely manner.

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.

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Not applicable.

8.800 PHARMACEUTICALS

8.800.16 PREFERRED DRUG LIST

8.800.16.A. ESTABLISHING THE PREFERRED DRUG LIST

1. To develop and maintain the PDL, the Department shall take the following steps:

   a. Determine which drugs and Drug Classes shall be reviewed for inclusion on the PDL.

   b. Refer selected drugs and Drug Classes to the P&T Committee for clinical reviews performed without consideration of drug cost-effectiveness. The P&T Committee shall make recommendations pursuant to 10 C.C.R. 2505-10, Section 8.800.17.C.

   c. Make recommendations to the Medical Director based on evaluations of relevant criteria, including but not limited to:

      i) Drug safety;

      ii) Drug efficacy;

      iii) The recommendations of the P&T Committee;

      iv) Public comments received by the Department before a drug or Drug Class is reviewed at the relevant P&T Committee meeting;

      v) Cost-effectiveness; and

      vi) Scientific evidence, standards of practice and other relevant drug information for such evaluation.

2. After the P&T Committee meets, the Medical Director shall review the recommendations of the P&T Committee and the Department and determine whether a reviewed drug is designated a Preferred Drug or a Non-preferred Drug.

3. After the Medical Director has designated a reviewed drug as Preferred or Non-preferred, the Department shall refer that drug to the DUR Board for recommendations on prior authorization criteria.

4. After the DUR Board meets, the Medical Director shall review the recommendations of the P&T Committee, the DUR Board and the Department and determine the efficacy, safety and appropriate prior authorization criteria for Preferred and Non-preferred Drugs to ensure the health and safety of members.

5. The Department shall provide public notice of PDL updates at least ten days before such changes take effect.

6. Drug Classes included on the PDL shall be reviewed at least annually.

8.800.16.B. NEW DRUGS

1. Notwithstanding any other provision of this section, a new drug entity, including new generic drugs and new drug product dosage forms of existing drug entities, in a Drug Class already included on the PDL:

   a. Shall be subject to a preliminary evaluation by the Department within 30 days from when the drug is available on the market; and~~automatically designated a Non-preferred Drug; unless~~

   b. The Department shall designate the new drug as Preferred or Non-preferred upon completion of the preliminary evaluation. ~~A preliminary evaluation by the Department finds that a new drug must be designated a Preferred Drug because it is medically necessary.~~

2. The Preferred or Non-preferred designation for a new drug shall continue until the relevant Drug Class is reviewed and the designation is changed pursuant to Section 8.800.16.A.

3. New drug prior authorization information is addressed in Section 8.800.7.D.

8.800.16.C. EXCLUSION OF DRUGS, DRUG CLASSES OR INDIVIDUALS FROM THE PDL

1. The following exclusions are intended to promote good health outcomes and clinically appropriate drug utilization and to protect the most vulnerable Medical Assistance Program members.

2. After reviewing the recommendations of the P&T Committee and the Department, the Medical Director may, notwithstanding any other provision of this section and to the extent allowed by federal and state law:

   a. Exclude drugs or Drug Classes from consideration for inclusion on the PDL.

   b. Determine continuity of care protocols that exempt Medical Assistance Program members stabilized on specified Non-preferred Drugs from prior authorization requirements.

   c. Exclude specific Medical Assistance Program populations from prior authorization requirements for all Non-preferred Drugs.

3. Individual Medical Assistance Program members shall be exempted, on an annual basis, from prior authorization requirements for all Non-preferred Drugs if:

   a. A member meets clinical criteria recommended by the Department and P&T Committee and approved by the Medical Director; and

   b. A member's physician submits a request for exemption and meets the criteria for approval.

8.800.16.D. AUTHORITY OF THE EXECUTIVE DIRECTOR

1. The decisions of the Medical Director, made under the authority of this section, shall be implemented by the Department at the sole discretion of the Executive Director.

2. If the Medical Director position is unfilled, the duties and obligations of that position, as described in this section, shall be performed by the Executive Director.

8.800.16.E. SUPPLEMENTAL REBATES

1. The Department may enter into supplemental rebate agreements with drug manufacturers for Preferred Drugs. The Department may contract with a vendor and/or join a purchasing pool to obtain and manage the supplemental rebates.