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6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

This rulemaking is required as a result of the May 2014 Ninth Circuit Court of Appeals Decision in *Alvarez et al v Betlach*. Litigation challenging AHCCCS coverage of incontinence briefs for members in the ALTCS Program was filed in federal court in 2009 by the Arizona Center for Disability Law. The lawsuit sought to compel AHCCCS to provide incontinence briefs and supplies to members in the Arizona Long Term Care Program who were age 21 years and older and who were incontinent as a result of their disabilities in order to prevent skin breakdown. The current rule applicable to this population limits coverage of incontinence briefs for members age 21 and older to circumstances when medically necessary to treat a medical condition, such as an infection, but not for preventive purposes. The Ninth Circuit Court of Appeals determined that AHCCCS is required to provide coverage of incontinence briefs prescribed for members in the Arizona Long Term Care Program who are 21 years of age and older when medically necessary to prevent skin breakdown and infection.

Although the AHCCCS Administration filed a Petition of Certiorari with the United States Supreme Court, the Court denied the Petition. As a result, AHCCCS must comply with the Ninth Circuit Court of Appeals Decision which expands coverage of incontinence briefs to include preventive purposes for ALTCS members age 21 years and older..

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

A study was not referenced or relied upon when revising the regulations for Incontinence Briefs.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. A summary of the economic, small business, and consumer impact:

The Administration anticipates a moderate to high economic impact on the implementing agency, contractors, small businesses and consumers after consideration of national data of incontinence, based on age and gender, which was applied to the ALTCS population. The AHCCCS Administration estimates utilization of incontinence briefs by members in the Arizona Long Term Care Program who are age 21 years and older and who receive services in a home and community based setting (HCBS) to be approximately 25.3%. Accordingly, it is estimated that approximately 8,158 members in the ALTCS Program who are 21 years of age and over and who receive HCBS services may require incontinence briefs for preventive purposes at an estimated annual cost to the Contractors of \$13M.

Minimal = under \$1M

Moderate = \$1M to \$10M

High = \$10M and above

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

No significant changes were made between the proposed rulemaking and the final rulemaking. Technical changes have been made as recommended by the Governor's Regulatory Review Council staff, such as, the conjunction "and" was added to R9-28-202(B)(1).

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

The following comments were received as of the close of the comment period of May 4, 2015.

Item #	Rule Cite Line #	Comment From and Date rec'd.	Comment	Analysis/ Recommendation
1.	R9-28-206	Theresa McMahan 03/20/15	Are you aware that "Institutional" includes Skilled Nursing Facilities?	Yes. Please refer to A.A.C. R9-28-204. It is Skilled Nursing Facilities and Intermediate Care Facilities
2.	R9-28-206	Theresa McMahan 03/20/15	Exactly what constitutes a "documented medical condition that causes incontinence of bowel and/or bladder"?	The PCP or attending physician who writes the prescription is responsible for making the determination regarding the member's need for incontinence briefs as delineated in the rule.
3.	R9-28-206	Theresa McMahan 03/20/15	Does this include Severe or Profound Intellectual Disability in the absence of another diagnosis?	The PCP or attending physician who writes the prescription is responsible for making the determination regarding the member's need for incontinence briefs as delineated in the rule.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

No other matters are applicable.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

Not applicable.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

Not applicable.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

Not applicable.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 28. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

ARIZONA LONG-TERM CARE SYSTEM

ARTICLE 2. COVERED SERVICES

Section

R9-28-202. ~~Medical~~ Scope of Services

R9-28-206. ALTCS Services that may be Provided to a Member Residing in either an Institutional or HCBS Setting

ARTICLE 2. COVERED SERVICES

R9-28-202. Medical Scope of Services

- A.** The Administration or a contractor shall cover medical services specified in 9 A.A.C. 22, Article 2 for a member, subject to the limitations and exclusions specified in Article 2, unless otherwise specified in this Chapter.
- B.** In addition, for members living in an HCBS setting, incontinence briefs for a member 21 years of age and older, including pull-ups, are covered in order to:
1. Treat a medical condition; and
 2. Prevent skin breakdown when all the following are met:
 - a. The member is incontinent due to a documented medical condition that causes incontinence of bowel and/or bladder,
 - b. The PCP or attending physician has issued a prescription ordering the incontinence briefs,
 - c. Incontinence briefs do not exceed 180 briefs per month unless the prescribing physician presents evidence of medical necessity for more than 180 briefs per month,
 - d. The member obtains incontinence briefs from vendors within the Contractor's network, and
 - e. Prior authorization has been obtained if required by the Administration, Contractor, or Contractor's designee, as appropriate. Contractors shall not require prior authorization more frequently than every twelve months.
- C.** Incontinence brief coverage for a member under age 21 is described under R9-22-212.

R9-28-206. ALTCS Services that may be Provided to a Member Residing in either an Institutional or HCBS Setting

The Administration shall cover the following services if the services are provided to a member within the limitations listed:

1. Occupational and physical therapies, speech and audiology services, and respiratory therapy:
 - a. The duration, scope, and frequency of each therapeutic modality or service is prescribed by the member's primary care provider or attending physician;
 - b. The therapy or service is authorized by the member's contractor or the Administration; and
 - c. The therapy or service is included in the members case management plan;
 - d. AHCCCS will not cover more than 15 outpatient physical therapy visits for the contract year with the exception of the required Medicare coinsurance and deductible payment as described in 9 A.A.C. 29, Article 3.
2. Medical supplies, durable medical equipment, and customized durable medical equipment, which conform with the requirements and limitations of 9 A.A.C. 22, Article 2 and as described under R9-28-202 for persons in HCBS settings;
3. Ventilator dependent services:
 - a. Inpatient or institutional services are limited to services provided in a general hospital, special hospital, NF, or ICF-MR. Services provided in a general or special hospital are included in the hospital's unit tier rate under 9 A.A.C. 22, Article 7;
 - b. A ventilator dependent member may receive the array of home and community based services under R9-28-205 as appropriate.
4. Hospice services:
 - a. Hospice services are covered only for a member who is in the final stages of a terminal illness and has a prognosis of death within six months;
 - b. Covered hospice services for a member are those allowable under 42 CFR 418.202, December 20, 1994, incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments; and
 - c. Covered hospice services do not include:
 - i. Medical services provided that are not related to the terminal illness, or
 - ii. Home delivered meals.
 - d. Medicare is the primary payor of hospice services for a member if applicable.