DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Hospital 3-19 Spinal Muscular Atrophy Newborn Screening

DESCRIPTION:

Statement of Necessity

Act 2019, No. 58 amended Ark. Code Ann. § 20-15-302 to add spinal muscular atrophy to the list of metabolic diseases for which all newborn infants in the state must be tested. In addition, Act 58 created a new subchapter in the Arkansas Code that requires health benefit plans, including Arkansas Medicaid, to provide coverage for newborn screening for spinal muscular atrophy. The revision in this promulgation of the Medicaid hospital provider manual, section 272.450, procedure code S3620, provides that Arkansas Medicaid will cover the metabolic diseases listed in Ark. Code Ann. § 20-15-302 in the Newborn Metabolic Screening panel. This promulgation implements Act 58.

Summary

Effective January 1, 2020, section 272.450, procedure code S3620, of the Medicaid hospital provider manual will be updated to remove current language that states "all newborn infants shall be tested for phenylketonuria, hypothyroidism, galactosemia, cystic fibrosis, and sickle-cell anemia" as required by Ark. Code Ann. § 20-15-302 and replace these references to specific diseases with a statement providing that all newborns will be tested for "certain metabolic diseases" as required by Ark. Code Ann. § 20-15-302.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on November 4, 2019. The agency received no comments on the proposed rule.

The proposed effective date is January 1, 2020.

FINANCIAL IMPACT: The agency stated that the amended rule has a financial impact.

The agency estimates that the additional cost to implement the rule is \$112,535 for the current fiscal year (\$32,421 in general revenue and \$80,114 in federal funds) and \$225,070 for the next fiscal year (\$63,987 in general revenue and \$161,083 in federal funds).

The total estimated cost by fiscal year to state, county, and municipal government to implement the rule is \$32,421 for the current fiscal year and \$63,987 for the next fiscal year.

The agency stated that there is a new or increased cost or obligation of at least \$100,000 to a private individual, private business, state government, county government, municipal government, or two or more of those entities combined. Accordingly, the agency provided the following written findings:

(1) a statement of the rule's basis and purpose

To comply with Act 58 of the 92nd General Assembly, which requires newborn screenings to include screenings for Spinal Muscular Atrophy.

- (2) the problem the agency seeks to address with this proposed rule, including a statement of whether a rule is required by statute

 To catch this genetic mutation early. Rule required by statute.
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and
 - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs

Early detection provided by these screenings helps the state with medical costs in the long run.

- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule There are no alternatives to the screening at this time.
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule

 No alternatives proposed at this time.
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response

 Newborn screening did not include this test prior to Act 58.
- (7) an agency plan for review of the rule no less than every ten (10) years to determine wither, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives

The agency monitors state and federal rules and policies for opportunities to reduce and control costs.

LEGAL AUTHORIZATION: The proposed revisions are made in light of Act 58 of 2019, sponsored by Representative Julie Mayberry, which required newborn screening for spinal muscular atrophy and mandated that insurance policies cover newborn screening for spinal muscular atrophy. The Act, as codified at Ark. Code Ann. § 23-79-1801(1)(A)(ii), requires all health benefit plans offered, issued, or renewed in the state, including Arkansas Medicaid, to provide spinal muscular atrophy screening by January 1,

2020. The Department of Human Services has the authority to maintain the Arkansas Medicaid program. *See* Ark. Code Ann. § 20-77-107.