### DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

<u>SUBJECT</u>: ARKids First-B-2-19, Certified Nurse Midwife-1-18, Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)-1-19, Dental-1-18, Nurse Practitioner-3-18, Pharmacy 1-19, and Physician-3-18

**<u>DESCRIPTION</u>**: The rule revisions are being made to comply with Acts 651, 652, and 959 of 2019 and to add informational language concerning the availability of tobacco cessation counseling as follows:

- ARKids First-B: Section 222.750 is revised to include a new section containing health education.
- Certified Nurse-Midwife: Pursuant to Act 959, section 272.452 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol does not require prior authorization. Revisions also include new billing information for Tobacco Cessation counseling services.
- Child Health Services/Early and Periodic Screening, Diagnosis, and Treatment: Sections 215.290 and 252.100 are revised to include counseling visits concerning tobacco cessation.
- Dental: Pursuant to Act 959, section 214.100 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol does not require prior authorization. Pursuant to Acts 651 and 959, revisions also reflect increased product coverage and the full scope of available coverage and new billing information for Tobacco Cessation counseling services.
- Nurse Practitioner: Pursuant to Act 959, section 252.454 is revised to reflect that
  coverage of tobacco cessation products either prescribed or initiated through
  statewide pharmacist protocol does not require prior authorization. Revisions also
  include new billing information for Tobacco Cessation counseling services.
- Pharmacy:
  - Pursuant to Act 652, sections 201.100 and 211.000 are revised to reflect the new protocol for reimbursement and coverage of vaccines and immunizations for beneficiaries age seven (7) years of age to age eighteen (18) years of age.
  - Pursuant to Act 959, section 241.000 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol does not require prior authorization. Pursuant to Acts 651 and 959, revisions also reflect increased product coverage and the full scope of available coverage.
- Physician/Independent Lab/CRNA/Radiation Therapy Center:
  - Pursuant to Act 959, section 257.000 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol does not require prior authorization. Pursuant to Acts 651 and 959, revisions also reflect increased product coverage and the full

- scope of available coverage and new billing information for Tobacco Cessation counseling services.
- Pursuant to Act 959, section 292.900 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol does not require prior authorization. Revisions also include the exempt procedure codes from PCP referral for Tobacco Cessation.

**PUBLIC COMMENT:** No public hearing was held on this rule. The public comment period expired on November 25, 2019. The agency indicated that it received no public comments.

Per the agency, this rule does not require CMS approval.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following questions and received the following responses:

QUESTION #1: The proposed revisions allow children under 18 to receive tobacco cessation counseling if a parent or guardian smokes. Is this required by statute or was it a policy decision? **RESPONSE:** This was a policy decision.

QUESTION #2: In light of Ark. Code Ann. § 17-92-101(17)(A)(i)(c) and (e), why do the proposed rules require prescription orders for vaccines and immunizations given to adults 19 years of age and older? I am specifically referring to the Pharmacy provider manual, section 211.000 (the last sentence in the paragraph directly following the discussion of over-the-counter items). **RESPONSE:** Thank you for catching that. DHS is removing the referenced phrase from the manual.

The proposed effective date is February 1, 2020.

**<u>FINANCIAL IMPACT</u>**: The agency stated that this rule will have no financial impact.

**LEGAL AUTHORIZATION:** The Department of Human Services has the authority to administer and maintain Arkansas Medicaid. *See* Ark. Code Ann. § 20-77-107. These rules implement Acts 651, 652, and 959 of 2019. Act 651, sponsored by Representative Les Eaves, authorizes physicians and pharmacists to initiate therapy and administer or dispense nicotine replacement therapy products. Act 652, sponsored by Representative Jimmy Gazaway, allows children between the ages of seven and eighteen, with parental consent, to be vaccinated or immunized pursuant to a general written protocol rather than patient-specific orders. Act 959, sponsored by Representative Andrew Collins, requires Arkansas Medicaid to cover FDA-approved tobacco cessation medications and allows physicians and pharmacists to provide these products to eligible Medicaid beneficiaries without prior authorization.

# QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

ENCY Department of Human Services
dical Services
OR Janet Mann
I Isaac Linam
Slot S295, Little Rock, AR 72203-1437
70 FAX NO. 501-404-4619 E-MAIL isaac.linam@dhs.arkansas.gov
TER AT COMMITTEE MEETING Janet Mann
[L janet.mann@dhs.arkansas.gov
OR Janet Mann  I Isaac Linam  Slot S295, Little Rock, AR 72203-1437  70 FAX NO. 501-404-4619 E-MAIL isaac.linam@dhs.arkansas.go  FER AT COMMITTEE MEETING Janet Mann

#### **INSTRUCTIONS**

- A. Please make copies of this form for future use.
- B. Please answer each question <u>completely</u> using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Jessica C. Sutton Administrative Rules Review Section Arkansas Legislative Council Bureau of Legislative Research One Capitol Mall, 5<sup>th</sup> Floor Little Rock, AR 72201

\* ARKids First-B-2-19, Certified Nurse Midwife-1-18, Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)-1-19, Dental-1-18, Nurse Practitioner-3-18, Pharmacy 1-19, and Physician-3-18 1. What is the short title of this rule? DMS provider manuals are being revised to comply with Act 651, Act 652, and What is the subject of the proposed rule?

Act 959. Also, adding Tobacco Cessation Counseling information. 2. 3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No X If yes, please provide the federal rule, regulation, and/or statute citation. 4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes No x If yes, what is the effective date of the emergency rule? When does the emergency rule expire? Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No

5.	Is this a new rule? Yes No If yes, please provide a brief summary explaining the rule.
	Does this repeal an existing rule? Yes No X If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.
	Is this an amendment to an existing rule? Yes X No If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."
	See attached.
6.	Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation.
	Arkansas Code §§ 20-76-201, 20-77-107, and 25-109-129
7.	What is the purpose of this proposed rule? Why is it necessary? See attached.
8.	Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). https://medicaid.mmis.arkansas.gov/general/comment/comment.aspx
9.	Will a public hearing be held on this proposed rule? Yes NoX If yes, please complete the following:
	Date:
	Time:
	Place:
10.	When does the public comment period expire for permanent promulgation? (Must provide a date. November 25, 2019
11.	What is the proposed effective date of this proposed rule? (Must provide a date.)  February 1, 2020
12.	Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. See attached.
13.	Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). See attached.

14.	Please give the names of persons, groups, or organizations that you expect to comment on these
	rules? Please provide their position (for or against) if known.

Unknown

#### NOTICE OF RULE MAKING

The Director of the Division of Medical Services of the Department of Human Services announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§ 20-76-201, 20-77-107, and 25-10-129.

Effective February 1, 2020, Division of Medical Services (DMS) provider manuals are being revised to comply with Acts 2019 Nos. 651, 652, and 959. The purpose of these Acts is to increase services and medications to Medicaid eligible beneficiaries. Act 651 authorizes physicians and pharmacists to initiate therapy and administer or dispense both drugs that include naloxone and nicotine replacement therapy products. Act 652 amends the definition of "practice of pharmacy" to allow vaccines and immunizations to be given to a person from seven (7) years of age to eighteen (18) years of age under a general written protocol. Act 959 increases coverage without the requirement of prior authorization for medications approved by the US Federal Drug Administration (FDA) for tobacco cessation in the Arkansas Medicaid Program and for other purposes. Tobacco cessation utilizes a community-based strategy which includes efforts to challenge conventional thinking, advocate for policies, and change the social norms around tobacco use for Arkansas's youth and adults through the facilitation of a statewide coalition. Adding information about the tobacco cessation program to Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), ARKids First-B, Nurse Practitioner, Certified Nurse Midwife, and Dental provider manuals should help save lives, diminish suffering, cut health-related and economic costs, and conserve public and private dollars.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Rules Promulgation, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule on the Medicaid website at https://medicaid.mmis.arkansas.gov/General/Comment/Comment.aspx. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than November 25. 2019. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-320-6266.

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin. 4501888131 EL

Janet Mann, Director

Division of Medical Services

### FINANCIAL IMPACT STATEMENT

## PLEASE ANSWER ALL QUESTIONS COMPLETELY

	PARTMENT Department of Human Services		
DIV	VISION Division of Medical Services		
PEF	RSON COMPLETING THIS STATEME	ENT Brian Jones	
TEI	RSON COMPLETING THIS STATEME LEPHONE NO. 501-537-2064 FAX N	O. 501-404-4619	EMAIL: brian.jones@dhs.arkansas.gov
	comply with Ark. Code Ann. § 25-15-204(ement and file two copies with the question		
SHO	ORT TITLE OF THIS RULE ARKids First-B-2-19,	CNM-1-18, EPSDT-1-19, De	ntal-1-18, Nurse Practitioner-3-18, Pharmacy-1-19, and Physician-3-18
1.	Does this proposed, amended, or repeatives No x	led rule have a f	inancial impact?
2.	Is the rule based on the best reasonably evidence and information available conthe rule?  Yes × No	cerning the need	ntific, technical, economic, or other d for, consequences of, and alternatives to
3.	In consideration of the alternatives to the least costly rule considered? Yes	nis rule, was this	rule determined by the agency to be the
	If an agency is proposing a more costly	rule, please stat	e the following:
	(a) How the additional benefits of the n	nore costly rule	justify its additional cost;
	(b) The reason for adoption of the more	costly rule;	
	(c) Whether the more costly rule is base if so, please explain; and	ed on the interes	ts of public health, safety, or welfare, and
	(d) Whether the reason is within the scorexplain.	ope of the agenc	y's statutory authority, and if so, please
4.	If the purpose of this rule is to implement	a federal rule or	regulation, please state the following:
	(a) What is the cost to implement the fed	eral rule or regul	ation?
	<b>Current Fiscal Year</b>	<u>Ne</u>	xt Fiscal Year
	General Revenue	Ge	neral Revenue
	Federal Funds	Fee	deral Funds
	Cash FundsSpecial Revenue	Ca	sh Fundsecial Revenue
	Special Revenue	Spe	ecial Revenue

Total		Total	
		10111	
(L) What is the additional		1.0	
(b) What is the additional	cost of the state ru	ne?	
Current Fiscal Year		Next Fiscal Year	
General Revenue Federal Funds	\$0	General Revenue	\$0
Federal Funds	\$0	Federal Funds	\$0
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Cash Funds Special Revenue Other (Identify)		Cash Funds Special Revenue Other (Identify)	
Total	\$0	Total	\$0
and explain how they are a  Current Fiscal Year	ffected.	Identify the entity(ies) subject to  Next Fiscal Yea	
\$		\$	
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What is the total estimated implement this rule? Is thi is affected.	cost by fiscal yea	r to state, county, and municipal grogram or grant? Please explain Next Fiscal Yea	government how the gov
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What is the total estimated implement this rule? Is thi is affected.  Current Fiscal Year  \$	cost by fiscal years the cost of the property of the cost of the c	r to state, county, and municipal a rogram or grant? Please explain have a stions #5 and #6 above, is there a usand dollars (\$100,000) per year ate government, county governm	government how the government so a private

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously

with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is 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;
- (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;
- (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;
- (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; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, 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.

#### Statement of Necessity and Rule Summary

ARKids First-B; Certified Nurse-Midwife; Early and Periodic Screening, Diagnosis and Treatment (EPSDT); Dental; Nurse Practitioner; Pharmacy, and Physician/Independent Lab/CRNA/Radiation Therapy Center

#### Statement of Necessity

Effective February 1, 2020, Division of Medical Services (DMS) provider manuals are being revised to comply with Acts 2019 Nos. 651, 652, and 959. The purpose of these Acts is to increase services and medications to Medicaid eligible beneficiaries. Act 651 authorizes physicians and pharmacists to initiate therapy and administer or dispense both drugs that include naloxone and nicotine replacement therapy products. Act 652 amends the definition of "practice of pharmacy" to allow vaccines and immunizations to be given to a person from seven (7) years of age to eighteen (18) years of age under a general written protocol. Act 959 increases coverage without the requirement of prior authorization for medications approved by the US Federal Drug Administration (FDA) for tobacco cessation in the Arkansas Medicaid Program and for other purposes. Tobacco cessation utilizes a community-based strategy which includes efforts to challenge conventional thinking, advocate for policies, and change the social norms around tobacco use for Arkansas's youth and adults through the facilitation of a statewide coalition. Adding information about the tobacco cessation program to Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), ARKids First-B, Nurse Practitioner, Certified Nurse Midwife, and Dental provider manuals should help save lives, diminish suffering, cut health-related and economic costs, and conserve public and private dollars.

#### **Rule Summary**

The proposed effective date for the rule revisions is February 1, 2020. The rule revisions are being made to comply with Acts 2019, Nos. 651, 652, and 959, and to add informational language concerning the availability of tobacco cessation counseling as follows:

- <u>ARKids First-B</u> Section 222.750 is revised to include a new section containing health education.
- <u>Certified Nurse-Midwife</u> Pursuant to Act 959, section 272.452 is revised to reflect that coverage
  of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol
  do not require prior authorization. Revisions also include new billing information for Tobacco
  Cessation counseling services.
- Child Health Services/Early and Periodic Screening, Diagnosis, and Treatment:
  - Section 215.290 is revised to include counseling visits concerning tobacco cessation.
  - Section 252.100 is revised to include counseling visits concerning tobacco cessation.
- <u>Dental</u> Pursuant to Act 959, section 214.100 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol do not require prior authorization. Pursuant to Acts 651 and 959, revisions also reflect increased product coverage and the full scope of available coverage and new billing information for Tobacco Cessation counseling services.

 <u>Nurse Practitioner</u> - Pursuant to Act 959, section 252.454 is revised to reflect that coverage of tobacco cessation products either prescribed or initiated through statewide pharmacist protocol do not require prior authorization. Revisions also include new billing information for Tobacco Cessation counseling services.

#### • Pharmacy:

- Pursuant to Act 652, sections 201.100 and 211.000 are revised to reflect the new protocol for reimbursement and coverage of vaccines and immunizations for beneficiaries age seven (7) years of age to age eighteen (18) years of age.
- Pursuant to Act 959, section 241.000 is revised to reflect that coverage of tobacco
  cessation products either prescribed or initiated through statewide pharmacist protocol do
  not require prior authorization. Pursuant to Acts 651 and 959, revisions also reflect
  increased product coverage and the full scope of available coverage.

#### • Physician/Independent Lab/CRNA/Radiation Therapy Center:

- Pursuant to Act 959, section 257.000 is revised to reflect that coverage of tobacco
  cessation products either prescribed or initiated through statewide pharmacist protocol do
  not require prior authorization. Pursuant to Acts 651 and 959, revisions also reflect
  increased product coverage and the full scope of available coverage and new billing
  information for Tobacco Cessation counseling services.
- Pursuant to Act 959, section 292.900 is revised to reflect that coverage of tobacco
  cessation products either prescribed or initiated through statewide pharmacist protocol do
  not require prior authorization. Revisions also include the exempt procedure codes from
  PCP referral for Tobacco Cessation.

# Stricken language would be deleted from and underlined language would be added to present law. Act 959 of the Regular Session

1	State of Arkansas  As Engrossed: H3/4/19  92nd General Assembly  As Engrossed: H3/4/19
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3	Regular Session, 2019 HOUSE BILL 1555
4	Dry Domensortations & Collins Claud & Davis France D. Frances Commun. Harde I. Johnson
5	By: Representatives A. Collins, Cloud, A. Davis, Eaves, D. Ferguson, Gazaway, Hawks, L. Johnson,
6	Lundstrum, Magie
7 8	By: Senators Irvin, Bond, M. Johnson
9	For An Act To Be Entitled
10	AN ACT TO INCREASE COVERAGE FOR MEDICATIONS APPROVED
11	BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR
12	TOBACCO CESSATION IN THE ARKANSAS MEDICALD PROGRAM;
13	AND FOR OTHER PURPOSES.
14	THE TON CHIEF TONICOLD.
15	
16	Subtitle
17	TO INCREASE COVERAGE FOR MEDICATIONS
18	APPROVED BY THE UNITED STATES FOOD AND
19	DRUG ADMINISTRATION FOR TOBACCO CESSATION
20	IN THE ARKANSAS MEDICAID PROGRAM.
21	
22	
23	BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
24	
25	SECTION 1. DO NOT CODIFY. Legislative findings and intent.
26	(a) The General Assembly finds that:
27	(1) Arkansas has the third-highest rate of adult smokers in the
28	United States;
29	(2) Arkansas has the third-highest rate of new lung cancer
30	diagnoses in the United States;
31	(3) One-third (1/3) of all cancer-related deaths are tied to the
32	use of tobacco; and
33	(4) The Arkansas Healthcare Transparency Initiative, the
34	statewide all-payer claims database, projects that the annual cost of tobacco
35	use to the Arkansas Medicaid Program to be approximately seven hundred
36	ninety-five million dollars (\$795,000,000).



As Engrossed: H3/4/19 HB1555

1	(b) It is the intent of this section to lower the rate of adult
2	smokers in Arkansas and to reduce costs of treatment related to tobacco use-
3	related illness by increasing coverage in the Arkansas Medicaid Program for
4	medications approved by the United States Food and Drug Administration for
5	tobacco cessation.
6	
7	SECTION 2. Arkansas Code Title 20, Chapter 77, Subchapter 1, is
8	amended to add an additional section to read as follows:
9	20-77-135. Medications approved by the United States Food and Drug
10	Administration for tobacco cessation coverage.
11	(a) The Department of Human Services shall ensure that the Arkansas
12	Medicaid Program covers for medications approved by the United States Food
13	and Drug Administration for tobacco cessation, including without limitation:
14	(1) Nicotine replacement therapy patches;
15	(2) Nicotine replacement therapy gum;
16	(3) Nicotine replacement therapy lozenges;
17	(4) Nicotine replacement therapy nasal spray;
18	(5) Nicotine replacement therapy inhalers;
19	(6) Bupropion; and
20	(7) Varenicline.
21	(b) Prior authorization shall not be required for coverage of
22	medications described in subsection (a) of this section.
23	
24	/s/A. Collins
25	
26	ADDROGUED - 1/10/10
27	APPROVED: 4/12/19
28 29	
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