EXHIBIT L

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: State Plan Amendment 2021-0004 Long-Acting Reversible Contraceptives (LARCs); Physician 1-21

DESCRIPTION:

Statement of Necessity

The Division of Medical Services revises the Medicaid State Plan rate methodology for family planning to replace the term Intrauterine Device (IUD) with Long-Acting Reversible Contraceptives (LARCs). This change acknowledges the possible use of other types of LARCs as they become available. This SPA will also update the reimbursement rates for currently covered LARCs.

Rule Summary

Adding language to the State Plan rate methodology for family planning to increase flexibility and to allow for the addition of new LARCs in a timely manner. The updated rates will be based on Wholesale Acquisition Cost.

Making technical corrections to the manuals below:

Section II of the Physician manual.
243.500 Contraception:
- 243.500(B) – replaced Etonogestrel (contraceptive) implant with Contraceptive Implant Systems.
- 243.500(B1) – deleted etonogestrel and replaced "system" with "systems."
- 243.500(C) – deleted the word "prescription"

Section II of the Hospital manual:
216.513 Contraception:
- 216.513(B) – replaced Etonogestrel (contraceptive) implant with Contraceptive Implant Systems.
- 216.513(B1) – deleted etonogestrel and replaced "system" with "systems."
- 216.513(C) – deleted the word "prescription"

Section II of the Rural Health Clinic manual:
217.220 Other Contraceptive Methods:
- Replaced "The Norplant System, its implementation" with "Contraceptive implant systems, their implementations . . ."

Section II of the Nurse Practitioner manual:
214.333 Contraception:

- 214.333(B) – replaced Etonogestrel (contraceptive) implant with Contraceptive Implant Systems.
- 214.333(B1) – deleted etonogestrel and replaced "system" with "systems."
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Section II of the Certified Nurse-Midwife manual:
215.250 Contraception:
- 215.250 (B) – replaced Etonogestrel (contraceptive) implant with Contraceptive Implant Systems.
- 215.250 (B1) – deleted etonogestrel and replaced "system" with "systems."
- 215.250 (C) – deleted the word "prescription"

PUBLIC COMMENT: A public hearing was held on this rule on September 15, 2021. The public comment period expired September 25, 2021. The agency provided the following summary of the public comments it received and its responses to those comments:

Commenter's Name: Nancy Allison, Practice Manager, Creekside Center for Women, on behalf of OB/GYN Provider Medicaid Group #134004002

COMMENT: I am writing on behalf of OB/GYN Provider Medicaid group #134004002 in regards to the August 24, 2021 memorandum with the subject State Plan Amendment 2021-004 Long-Acting Reversible Contraceptives (LARCs); Physician 1-21. We were led to understand that Kyleena 19.5mg Levonorgestrel-Releasing Intrauterine Contraceptive System was also going to be added to the LARCs list that Arkansas Medicaid would reimburse for. Is there an update on that discussion or a date of when it may be added?

RESPONSE: Kyleena is included as part of this SPA. The language has been changed to clarify that all FDA approved IUDs and implants will be included.

Commenter's Name: William J. Mazanec, PharmD, MBA, Account Executive, Organon

COMMENT: The language in 243.500 Contraception

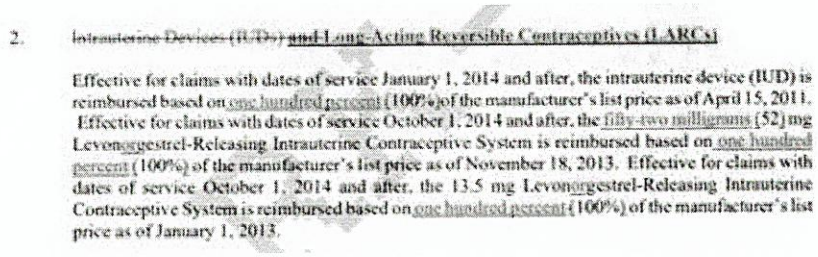
B ~~Etonogestrel~~ Estrogen (contraceptive) Implant System

1. Medicaid covers the ~~etonogestrel~~ estrogen contraceptive implant system, including implants and supplies.

NEXPLANON (etonogestrel implant)

Highlights of Prescribing Information

INDICATIONS AND USAGE section states NEXPLANON is a progestin indicated for use by women to prevent pregnancy. NEXPLANON is not an estrogen.



2. ~~Intrauterine Devices (IUDs) and~~ Long-Acting Reversible Contraceptives (LARCs)

Effective for claims with dates of service January 1, 2014 and after, the intrauterine device (IUD) is reimbursed based on one hundred percent (100%) of the manufacturer's list price as of April 15, 2011. Effective for claims with dates of service October 1, 2014 and after, the fifty-two milligrams (52) mg Levonorgestrel-Releasing Intrauterine Contraceptive System is reimbursed based on one hundred percent (100%) of the manufacturer's list price as of November 18, 2013. Effective for claims with dates of service October 1, 2014 and after, the 13.5 mg Levonorgestrel-Releasing Intrauterine Contraceptive System is reimbursed based on one hundred percent (100%) of the manufacturer's list price as of January 1, 2013.

NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive method and if other LARCs are included in this section NEXPLANON should be included.

RESPONSE: Nexplanon is included as part of this SPA. The language has been changed to clarify that all FDA approved IUDs and implants will be included.

Commenter's Name: Dr. Timothy J. Bell

COMMENT: Please consider adding Kyleena into the approved Medicaid options/fee schedule for patients. This is a LARC (long-acting reversible contraception) as recommended by ACOG. This device has lower levels of hormone and a smaller size to the device that helps several patients that have suffered from cramps or who have never been pregnant, where a larger IUD may cause patient discomfort. Thank you for considering this added product.

RESPONSE: Kyleena is included as part of this SPA. The language has been changed to clarify that all FDA approved IUDs and implants will be included.

Commenter's Name: Brandee Litty, CPPM, Clinic Office Manager, on behalf of Dr. Maureen Flowers and Dr. William Smith, BRMC Urology Clinic

COMMENT: I would like to request on behalf of both my OB/GYN's, Dr. Maureen Flowers and Dr. William Smith that Kyleena be added to the Medicaid fee schedule and ARKids. We serve a rural, low-income area, and we need to be able to provide adequate family planning to all our patients. Please consider adding Kyleena to the fee schedule, so that we are not limiting our patients' care.

RESPONSE: Kyleena is included as part of this SPA. The language has been changed to clarify that all FDA approved IUDs and implants will be included.

The proposed effective date is December 1, 2021.

FINANCIAL IMPACT: The agency indicated that this rule has a financial impact.

Per the agency, the additional cost of this rule is $681,899 for the current fiscal year ($68,190 in general revenue and $613,709 in federal funds) and $1,168,970 for the next fiscal year ($116,897 in general revenue and $1,052,073 in federal funds). The total

estimated cost by fiscal year to state, county, and municipal government to implement this rule is $68,190 for the current fiscal year and $116,897 for the next fiscal year.

The agency indicated that there is a new or increased cost or obligation of at least $100,000 to a private individual, private entity, private business, state government, county government, municipal government, or to 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;

Reimbursements for IUDs and LARCs will be based on Wholesale Acquisition Costs.

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

Reimburse providers for cost of the device.

(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;

Reimbursement is less than cost.

(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;

None.

(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;

None 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; and

N/A

(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.

The Agency monitors State and Federal rules and policies for opportunities to reduce and control cost.

LEGAL AUTHORIZATION: The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically authorized to maintain an indigent medical care program (Arkansas Medicaid). *See* Ark. Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Human Services

DIVISION Division of Medical Services

DIVISION DIRECTOR Elizabeth Pitman

CONTACT PERSON Mac Golden

ADDRESS P. O. Box 1437, Slot S295 Little Rock, AR 72203-1437

PHONE NO. 501-320-6383 **FAX NO.** 501-404-4619 **E-MAIL** Mac.E.Golden@dhs.arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Elizabeth Pitman

PRESENTER E-MAIL Elizabeth.Pitman.@dhs.arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely 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, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? State Plan Amendment 2021-0004 Long-Acting Reversible Contraceptives (LARCs); Physician 1-21; Hospital 3-21; CNM 2-21; Nursepra 3-21; Rurlhlth 2-21

2. What is the subject of the proposed rule? Changing LARC Reimbursement Methodology to Wholesale Acquisition Cost. Updating provider manual verbiage.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☒
   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 ☒
   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 regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
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 ☒ 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 25-10-129

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://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: September 15, 2021
Time: 11:00
Place: Zoom meeting - **https://us02web.zoom.us/j/82736912788**

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
September 25, 2021

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
December 1, 2021

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**

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services

DIVISION Division of Medical Services

PERSON COMPLETING THIS STATEMENT Jason Callan

TELEPHONE 501-320-6540 **FAX** 501-682-8155 **EMAIL:** Jason.Callan@dhs.arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE State Plan Amendment 2021-0004 Long-Acting Reversible Contraceptives (LARCs); Physician 1-21; Hospital 3-21; CNM 2-21; Nursepra 3-21; Rurlhlth 2-21

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☒ No ☐

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

   If an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;

   (b) The reason for adoption of the more costly rule;

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:
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   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$	General Revenue	$
Federal Funds	$	Federal Funds	$
Cash Funds		Cash Funds	

Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$	Total	$

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$ 68,190	General Revenue	$ 116,897
Federal Funds	$ 613,709	Federal Funds	$ 1,052,073
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 681,899	Total	$ 1,168,970

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year
$ _____

Next Fiscal Year
$ _____

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6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year
$ 68,190

Next Fiscal Year
$ 116,897

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7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☒ No ☐

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; **Reimbursement for IUD's and LARC's will be based on Wholesale Acquisition Costs.**

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute**; Reimburse providers for cost of the device.**

(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; **Reimbursement is less than cost.**

(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; **NONE**

(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; **None 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; and **N/A**

(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. **The Agency monitors State and Federal rules and policies for opportunities to reduce and control cost.**

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 December 1, 2021:

The Director of the Division of Medical Services (DMS) revises the Medicaid State Plan by replacing the term Intrauterine Device (IUD) with Long-Acting Reversable Contraceptives (LARCs) to acknowledge the possible use of other types of LARCs as they become available. The revision also revises rate methodology and updates reimbursement rates for currently covered LARCs. Claims with a date of service on and after December 1, 2021, for Long-Acting Reversible Contraceptives will be based on Wholesale Acquisition Costs as of December 1, 2021. Finally, DMS issues technical corrections to Section II of the Physician manual. The annual financial impact will be $1,052,073 (Federal) and $116,897 (State).

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://humanservices.arkansas.gov/do-business-with-dhs/proposed -rules/. 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 September 25, 2021. 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.

A public hearing by remote access only through a Zoom webinar will be held on September 15th, 2021, at 11:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at **https://us02web.zoom.us/j/82736912788**.The webinar ID is 827 3691 2788. If you would like the electronic link, "one-tap" mobile information, listening only dial-in phone numbers, or international phone numbers, please contact ORP at ORP@dhs.arkansas.gov.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-396-6428.

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. 4501960528

Elizabeth Pitman, Director
Division of Medical Services

Statement of Necessity and Rule Summary

State Plan Amendment 2021-0004 Long-Acting Reversible Contraceptives (LARCs);
PHYSICN 1-21; RURLHLTH-2-21, NURSEPRA-3-21, CNM- 2-21, HOSPITAL 3-21

Why is this change necessary? Please provide the circumstances that necessitate the change.

The Division of Medical Services revises the Medicaid State Plan rate methodology for family planning to replace the term Intrauterine Device (IUD) with Long-Acting Reversible Contraceptives (LARC's). This change acknowledges the possible use of other types of LARCs as they become available. This SPA will also update the reimbursement rates for currently covered LARC's.

What is the change? Please provide a summary of the change.

Adding language to the State Plan rate methodology for family planning to increase flexibility and to allow for the addition of new LARCs in a timely manner. The updated rates will be based on Wholesale Acquisition Cost.

Making technical corrections to the manuals below:

Section II of the Physician manual
243.500 Contraception:

- 243.500 (B) -replaced Etonogestrel (contraceptive) implant with Contraceptive Implant Systems.
- 243.500 (B1) – deleted etonogestrel and replaced system with systems.
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Section II of the Certified Nurse-Midwife manual:
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