EXHIBIT K

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: COVID-19 Vaccinations for Home-Bound Medicaid Clients

DESCRIPTION:

Statement of Necessity

The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) approved the administration of the COVID-19 vaccination in a patient's home (or similar setting). The Department of Human Services (DHS), Division of Medical Services (DMS) will cover administration of the COVID-19 vaccination to Arkansas Medicaid clients who are home-bound.

Examples of Medicaid clients eligible for this service include those who face barriers or challenges to obtaining a COVID-19 vaccination and those who might not get vaccinated without this service being provided in their home by designated Medicaid providers. CMS created an infographic to help Medicare providers understand the scope of this service, which Medicaid providers may find helpful.

Summary

To implement this program, Medicaid will authorize Home Health services providers (Provider Type 14) and Pharmacy providers (Provider Type 07/PV) to administer the COVID-19 vaccinations in the home (or similar setting) to eligible Medicaid clients. Home Health and Pharmacy providers will be able to administer the vaccination to current Home Health clients, as well as to those who are not currently in the Home Health Program.

DMS amends the COVID Response Manual to authorize home health providers and pharmacy providers to administer COVID-19 vaccination shots in a client's home or similar location. DMS outlines home administration requirements for those currently receiving home-based services as well as those who do not currently receive home based services. Also, DMS requires specific documentation by the provider and provides directions for billing and payment of claims. These include covered vaccines, procedure codes, and rates. The rule automatically sunsets at the end of the Federal Public Health Emergency. The information also will be issued in an Official Notice published to providers.

<u>PUBLIC COMMENT</u>: A public hearing was held on this rule on December 1, 2021. The public comment period expired on December 13, 2021. The agency indicated that it received no public comments.

This rule was filed on an emergency basis and was reviewed and approved by the Executive Subcommittee on November 9, 2021. The proposed effective date for permanent promulgation is March 1, 2022.

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

Per the agency, the total cost to implement this rule is estimated at \$1,485,578 for the current fiscal year (\$421,607 in general revenue and \$1,063,971 in federal funds) and \$2,228,367 for the next fiscal year (\$632,411 in general revenue and \$1,595,956 in federal funds). The total estimated cost by fiscal year to state, county, and municipal government to implement this rule is \$421,607 for the current fiscal year and \$632,411 for the next fiscal year.

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

The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) approved administration of the COVID-19 vaccination in a patient's home. The Department of Human Services, Division of Medical Services (DHS/DMS) will cover administration of the COVID-19 vaccination to Arkansas Medicaid clients who are home-bound.

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

The purpose is to provide home bound recipients with an opportunity to receive the COVID-19 vaccine.

(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;

The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) approved administration of the COVID-19 vaccination in a patient's home. The Department of Human Services, Division of Medical Services (DHS/DMS) will cover administration of the COVID-19 vaccination to Arkansas Medicaid clients who are home-bound.

(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;

N/A

(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

The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) approved administration of the COVID-19 vaccination in a patient's home. The Department of Human Services, Division of Medical Services (DHS/DMS) will cover administration of the COVID-19 vaccination to Arkansas Medicaid clients who are home-bound.

(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.

DMS will review this rule based on the current state of the Public Health Emergency.

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).

The federal government has approved in-home administration of COVID-19 vaccines for certain "patients that have difficulties leaving their homes or are hard-to-reach." *See* CMS, *Medicare Payment for COVID-19 Vaccination Administration in the Home* (Aug. 2021), <u>https://www.cms.gov/files/document/vaccine-home.pdf;</u> CDC, *Vaccinating Homebound Persons with COVID-19 Vaccine* (Aug. 10. 2021), <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html</u>.

<u>QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS</u> <u>WITH THE ARKANSAS LEGISLATIVE COUNCIL</u>

DEPARTMENT/AGENCY _D	Department of Human Services			
DIVISION <u> </u>	Division of Medical Services			
DIVISION DIRECTOR	Elizabeth Pitman			
CONTACT PERSON <u>N</u>	Mac Golden			
ADDRESS P	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-MAILElizabeth.Pitman@dhs.arkansas.gov				

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 th Floor Little Rock, AR 72201

1.	What is the short title of this rule? <u>COVID-19</u> Vaccinations for Home-Bound Medicaid Clients
2.	What is the subject of the proposed rule? See Attached.
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 🗌
	If yes, what is the effective date of the emergency rule? <u>November 11, 2021</u>
	When does the emergency rule expire? <u>March 11, 2022</u>
	Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?
	Yes \bowtie No \square

5. Is this a new rule? Yes No X If yes, please provide a brief summary explaining the regulation.

Does this repeal an existing rule? Yes \square No \boxtimes 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 I 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. <u>Arkansas Code §§ 20-76-201, 20-77-107, and 25-10-129</u>
- 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: December 1, 2021

Time: 10:00 a.m. <u>https://us02web.zoom.us/j/84119369838</u> Place: webinar ID is **841 1936 9838**

- 10. When does the public comment period expire for permanent promulgation? (Must provide a date.) December 13, 2021
- 11. What is the proposed effective date of this proposed rule? (Must provide a date.) November 11, 2021 (Emergency promulgation); March 1, 2022 (regular promulgation)

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. <u>See Attached.</u>

- 13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). <u>See Attached.</u>
- 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. <u>Arkansas Medical Society</u>, Arkansas

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

PAR	ΓΜΕΝΤ	Department of	Human Services				
IVISION Division of Medical Services							
RSON	COMPL	ETING THIS S	TATEMENT Ja	son Calla	an		19 19 20
EPH	IONE <u>501-</u>	<u>320-6540</u>	FAX 501-682-815	55E	MAIL: Jason.	callan@dhs.	arkansas.gov
comp temer	ly with Arl and file t	x. Code Ann. § 2 wo copies with t	25-15-204(e), plea he questionnaire a	se compl and prope	lete the following sed rules.	ng Financial	Impact
ORT LE	TITLE O	FTHIS	COVID-19 Vacc	ination f	or Home-Boun	d Medicaid (Clients
Does	this propos	sed, amended, or	repealed rule hav	ve a finar	ncial impact?	Yes 🔀	No 🗌
 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 □ 				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 ∑			No 🗌				
If an	agency is p	roposing a more	costly rule, pleas	e state th	e 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)	d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.						
lf the	purpose of t	his rule is to imp	lement a federal ru	le or regu	ulation, please st	tate the follow	ving:
(a)	What is the	cost to impleme	ent the federal rule	e or regu	lation?		
rent	Fiscal Yea	<u>r</u>		Next F	'iscal Year		
	ISIC SON LEPE complement ORT LE Doess Is the econd need In col by th If an (a) (b) (c) (d) (f the (a)	ASON COMPLIA LEPHONE 501- comply with Ark tement and file to ORT TITLE OF LE Does this propose Is the rule based economic, or other need for, conseq In consideration by the agency to If an agency is p (a) How the act (b) The reason (c) Whether there so, please economic (d) Whether there explain. If the purpose of to (a) What is the	ISION Division of Me RSON COMPLETING THIS S EPHONE 501-320-6540 I Comply with Ark. Code Ann. § 2 Eement and file two copies with t ORT TITLE OF THIS E Does this proposed, amended, or Is the rule based on the best reas economic, or other evidence and need for, consequences of, and a In consideration of the alternative by the agency to be the least cost If an agency is proposing a more (a) (b) The reason for adoption of (c) Whether the more costly ruso, please explain; and; (d) Whether the reason is within explain.	ISION Division of Medical Services RSON COMPLETING THIS STATEMENT Ja LEPHONE 501-320-6540 FAX 501-682-813 comply with Ark. Code Ann. § 25-15-204(e), plea gement and file two copies with the questionnaire a ORT TITLE OF THIS COVID-19 Vacc LE COVID-19 Vacc Does this proposed, amended, or repealed rule have Is the rule based on the best reasonably obtainable economic, or other evidence and information avail need for, consequences of, and alternatives to the rule In consideration of the alternatives to this rule, wa by the agency to be the least costly rule considered If an agency is proposing a more costly rule, pleas (a) How the additional benefits of the more costly rule (b) The reason for adoption of the more costly rule (c) Whether the more costly rule is based on the so, please explain; and; (d) Whether the reason is within the scope of the explain. f the purpose of this rule is to implement a federal rule (a) What is the cost to implement the federal rule	ISION Division of Medical Services RSON COMPLETING THIS STATEMENT Jason Calls LEPHONE 501-320-6540 FAX 501-682-8155 F comply with Ark. Code Ann. § 25-15-204(e), please complement and file two copies with the questionnaire and proposed. COVID-19 Vaccination f Does this proposed, amended, or repealed rule have a finance of the evidence and information available commended for, consequences of, and alternatives to the rule? In consideration of the alternatives to this rule, was this rule by the agency to be the least costly rule considered? If an agency is proposing a more costly rule, please state the (a) (b) The reason for adoption of the more costly rule; (c) Whether the more costly rule is based on the interests so, please explain; and; (d) Whether the reason is within the scope of the agency explain. (a) What is the cost to implement the federal rule or regular.	ISION Division of Medical Services ISION Division of Medical Services SSON COMPLETING THIS STATEMENT Jason Callan LEPHONE 501-320-6540 FAX 501-682-8155 EMAIL: Jason. comply with Ark. Code Ann. § 25-15-204(e), please complete the following tement and file two copies with the questionnaire and proposed rules. ORT TITLE OF THIS COVID-19 Vaccination for Home-Bountle COVID-19 Vaccination for Home-Bountle Does this proposed, amended, or repealed rule have a financial impact? 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? In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? 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 benefits of the more costly rule; (b) The reason for adoption of the more costly rule; (c) Whether the more costly rule is based on the interests of public healt so, please explain; and; (d) Whether the reason is within the scope of the agency's statutory auttexplain. (a) What is the cost to implement a federal rule or regulation, please state application.	ISION Division of Medical Services RSON COMPLETING THIS STATEMENT Jason Callan .EPHONE 501-320-6540 FAX 501-682-8155 EMAIL: Jason.callan@dms.i .comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial ement and file two copies with the questionnaire and proposed rules. COVID-19 Vaccination for Home-Bound Medicaid C .comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial ement and file two copies with the questionnaire and proposed rules. ORT TITLE OF THIS .cow TITLE OF THIS COVID-19 Vaccination for Home-Bound Medicaid C .le

General Revenue	\$
Federal Funds	\$
Cash Funds	\$
Special Revenue	\$

\$
\$
\$
\$
\$ <u>\$</u> \$

Other (Identify)	\$	Other (Identify)	\$
Total	\$	Total	\$
(b) What is the	ne additional cost of the state rule?		
Current Fisca	l Year	Next Fiscal Year	<u>r</u>
General Revent Federal Funds Cash Funds Special Revent Other (Identify	\$1,063,971 \$ ne \$	General Revenue Federal Funds Cash Funds Special Revenue Other (Identify)	\$1,595,956 \$
Total	\$1,485,578	Total	\$2,228,367

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
\$	\$

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	Next Fiscal Year		
\$ 421,607	\$ 632,411		
3			

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
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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;

The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) approved administration of the COVID-19 vaccination in a patient's home. The Department of Human Services, Division of Medical Services (DHS/DMS) will cover administration of the COVID-19 vaccination to Arkansas Medicaid clients who are home-bound. (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

The purpose is to provide home bound recipients with an opportunity to receive the COVID-19 vaccine.

- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and
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- (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; N/A
- (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

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 - (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.

DMS will review this rule based on the current state of the Public Health Emergency.

Statement of Necessity and Rule Summary COVID-19 Vaccinations for Home-Bound Medicaid Clients

Statement of Necessity

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Examples of Medicaid clients eligible for this service include those who face barriers or challenges to obtaining a COVID-19 vaccination and those who might not get vaccinated without this service being provided in their home by designated Medicaid providers. CMS created an <u>infographic</u> to help Medicare providers understand the scope of this service, which Medicaid providers may find helpful.

Summary

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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, & 25-10-129.

Effective March 1, 2022:

The Director of the Division of Medical Services (DMS) amends the DMS COVID-19 Response Manual to authorize home health providers and pharmacy providers to administer COVID-19 vaccination shots in a client's home or similar location. DMS outlines the requirements for those currently receiving home-based services as well as those who do not currently receive home based services to receive the COVID-19 vaccine in their home. Also, DMS requires specific documentation by the provider and provides directions for billing and payment of claims. These include covered vaccines, procedure codes, and rates. The rule automatically sunsets at the end of the Federal Public Health Emergency.

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 at <u>https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/</u>. Public comments must be submitted in writing at the above address or at the following email address: <u>ORP@dhs.arkansas.gov</u>. All public comments must be received by DHS no later than December 13, 2021. Please note that public comments, 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 December 1, 2021, at 10:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at <u>https://us02web.zoom.us/j/84119369838</u>. The webinar ID is 841 1936 9838. 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 <u>ORP@dhs.arkansas.gov</u>.

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. 4502035775

Élizabeth Pitman, Director Division of Medical Services