ARKANSAS REGISTER

Proposed Rule Cover Sheet

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Name of Department Department of Human Services

Agency or Division Name Division of Medical Services

Other Subdivision or Department, If Applicable N/A

Previous Agency Name, If Applicable N/A

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Name of Rule Cell and Gene Therapy (CGT) Model

Newspaper Name Arkansas Democrat Gazette

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Final Date for Public Comment 1/10/26

Location and Time of Public Meeting January 7, 2026 @ 10:00 am; https://us02web.zoom.us/j/83419649641

1. Inpatient Hospital Services (continued)

Long-Acting Reversible Contraceptives (LARC)

Effective for claims with dates of service on or after January 1, 2024, all acute care hospitals will be reimbursed in addition to the per diem rates for Food and Drug Administration approved Long-Acting Reversible Contraceptives (LARCs) to include the IUD and contraceptive implants, and insertion and removal. LARC reimbursement will be the same as found in Attachment 4.19-B page 1v.

Select Carved-Out Drugs from Hospital Settings

Effective for claims with dates of service on or after January 1, 2026, all approved acute care hospitals will be reimbursed in addition to the per diem rates for selected carved-out drugs. Reimbursement will be the same as found in Attachment 4.19-B page 4aa. Approved acute care hospitals are those that have been certified and have appropriate agreements in place to provide the selected carve-out drugs.

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye, or by an optometrist

a. Prescribed Drugs (Continued)

vii. Clotting Factor

a. Pharmacies dispensing Antihemophilic Factor products will be reimbursed at the lesser of methodology plus the established professional dispensing fee. The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) plus zero percent (+0%) or State Actual Acquisition Cost (SAAC).

b. Pharmacies dispensing Antihemophilic Factor products purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B) by pharmacies that carve Medicaid into the 340B Drug Pricing Program shall be reimbursed the lesser of methodology for the allowed ingredient cost shall be the 340B actual invoice price, Wholesale Acquisition Cost (WAC) plus zero percent (+0%) or State Actual Acquisition Cost (SAAC). The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

viii. Drugs Purchased at Nominal Price

Facilities purchasing drugs at Nominal Price (outside of 340B or FSS) shall be reimbursed by their actual acquisition cost.

ix. Physician Administered Drugs

Reimbursement rates for Physician Administered Drugs are a "fee schedule" as determined by the Medicare fee schedule. If the Medicare rate is not available, then other published pricing Average Wholesale Price (AWP) less five percent (-5%) shall be used to determine reimbursement. Under the fee schedule methodology, reimbursement is based on the lesser of the billed charge for each procedure or the maximum allowable for each procedure.

x. Select Carved-Out Drugs from Hospital Settings

Effective for claims with dates of service on or after January 1, 2026, drugs that are reimbursed as a direct reimbursement will be reimbursed based on the provider's Actual Acquisition Cost for the drug, verified by the purchasing invoice.

b. State Upper Limit (SUL) shall apply to certain drugs identified administratively, judicially, or by a federal agency as having a published price exceeding the ingredient cost. The calculated SAAC shall be obtained from actual acquisition costs from multiple resources, if available. Depending on the variance, either the highest acquisition cost, an average of the acquisition costs, or invoice price shall be used in determining a SAAC. When Brand and Generic drugs are available for the same ingredient, reimbursement will be based on the Generic State Actual Acquisition Cost (SAAC).

TOC required

212.100 Scope – Inpatient

~~7-15-12~~1-1-26

"Inpatient hospital services" are defined in the Arkansas Medical Assistance Program as those items and services ordinarily furnished by the hospital for care and treatment of inpatients and are provided under the direction of a licensed practitioner (physician or dentist with staff affiliation) of a facility maintained primarily for treatment and care of injured persons, individuals with disabilities, or sick persons. Such inpatient services must be medically justified, documented, certified and re-certified by the Quality Improvement Organization (QIO) and are payable by Medicaid if provided on a Medicaid covered day.

A "Medicaid covered day" is defined as a day for which the beneficiary is Medicaid eligible, the patient's inpatient benefit has not been exhausted, the patient's inpatient stay is medically necessary, the day is not part of a hospital stay for a non-payable procedure or non-authorized procedure (see Sections 220.000 and 244.000), and the claim is filed on time. (See Section III of this manual for reference to "Timely Filing.")

The following services are covered inpatient hospital services if medically necessary for treatment of the patient and if the date of service is a Medicaid covered day:

A. **Accommodation**
"Accommodation" means the type of room provided for the patient while receiving inpatient hospital services. The Medicaid Program will cover the semi-private room or ward accommodations and intensive care. A private room will only be covered when such accommodations are medically necessary, as certified by the patient's attending physician. Private rooms are considered medically necessary only when the patient's condition requires him or her to be isolated to protect his or her health or welfare, or to protect the health of others.

B. **Operating Room**
Operating room charges for services and supplies associated with surgical procedures are covered inpatient hospital services.

C. **Anesthesia**
Anesthesia charges for services and/or supplies furnished by the hospital are covered inpatient hospital services.

D. **Blood Administration**
Blood, blood components and blood administration charges are covered when not available to the beneficiary from other sources. Hospitals are encouraged to replace blood that is used by a Medicaid beneficiary through his or her friends and relatives, or through the Red Cross whenever possible.

E. **Pharmacy**
Drugs and biologicals furnished by the hospital for the care and treatment of patients are covered inpatient hospital services. Take-home drugs are non-covered inpatient hospital services under the Arkansas Medicaid Program. Designated Cell and Gene Therapy Drugs furnished while a beneficiary is an inpatient in an acute care hospital will be treated as an outpatient hospital service and paid separately from the per diem. See Section 272.104 for prior authorization and special billing guidelines.

F. **Radiology and Laboratory**
The coverage of inpatient hospital services includes the non-physician services related to machine tests, laboratory and radiology procedures provided to inpatients. The hospital where the patient is hospitalized will be responsible for providing or securing these services. The party who furnishes these non-physician services is permitted to bill only the hospital.

If a patient is transferred to another hospital to receive services on an outpatient basis, the cost of the transfer is included in the hospital reimbursement amount. The ambulance company may not bill Medicaid or the beneficiary for the service.

G. **Medical, Surgical and Central Supplies**
Necessary medical and surgical supplies and equipment that are furnished by the hospital for the care and treatment of patients are covered inpatient hospital services. Supplies and equipment for use outside the hospital are not covered by Medicaid.

H. **Physical and Inhalation Therapy**
Physical and inhalation therapy and other necessary services, as well as supply charges for these services that are furnished by the hospital, are covered inpatient hospital services.

I. **Delivery Room**
Delivery room charges for services and supplies associated with obstetrical procedures are covered inpatient hospital services.

J. **Other**
Services other than the non-covered services identified in Section 212.200, which are not specified above.

272.103 Instructions for Prior Approval Letter Acquisition for Special Pharmacy, Therapeutic Agents and Treatments

1-15~~-15~~26

Providers must obtain prior approval, in accordance with the following procedures, for special pharmacy, therapeutic agents and treatments. Approval letters may be obtained by the ordering physician and a copy provided to the hospital; however, the billing provider is ultimately responsible for meeting the documentation requirements for payment.

A. Before treatment begins, the Division of Medical Services (DMS)~~,~~ Medical Director for Clinical Affairs must approve any drug, therapeutic agent or treatment not listed as covered in this provider manual or in official DMS correspondence.

This requirement also applies to any drug, therapeutic agent or treatment with special instructions regarding coverage in the provider manual or in official DMS correspondence.

B. The Medical Director for Clinical Affairs' prior approval is required to ensure approval for medical necessity. Additionally, all other requirements must be met for reimbursement.

1. The provider must submit a history and physical examination with the treatment protocol before beginning the treatment.
2. The provider will be notified by mail of the DMS Medical Director for Clinical Affairs' decision. No prior authorization number is assigned if the request is approved, but a prior approval letter is issued and must be attached to each claim. Any changes in treatment require resubmission and a new approval letter.

Send requests for a prior approval letter for pharmacy and therapeutic agents to the attention of the **Division of Medical Services, Medical Director of Clinical Affairs**.

272.104 ~~Reserved~~Cell and Gene Therapy Drugs When Hospitalization is Required for Administration

1-15~~-15~~26

Effective for claims with dates of service on or after January 1, 2026, all approved acute care hospitals will be reimbursed in addition to the per diem rates for designated cell and gene therapy drugs. Approved hospitals are those that are appropriately certified to provide the services and have contracts in place to administer the designated cell and gene therapy drugs. Hospitals requesting services for a member enrolled in a PASSE organization will be required to follow prior authorization and billing guidelines as below.

Prior Authorization:

A. **See a list of medications that require a prior authorization**.

B. Provider will submit prior authorization request to **Utilization Review**.

C. A Single Case Agreement will be completed for each request.

Billing Guidelines:

A. The Hospital should continue to bill the inpatient stay on an inpatient claim (CMS-1450, formerly UB-04).

B. If the hospital provides the cell and gene therapy, the hospital is to bill the cell and gene therapy drug on an outpatient claim (CMS-1450, formerly UB-04), even though the dates fall within an inpatient stay. Use the identified **Cell and Gene Therapy Drug billing combinations** (Procedure Code, Modifier, and such) on the outpatient claim. Ensure the applicable NDC code is submitted on the claim.

C. Physician charges can be billed for the administration of the drug on a professional claim (CMS-1500), in addition to the physician's evaluation and management charges. When provided by the physician, the cell and gene therapy drug is billed by the physician on the professional claim instead of by the hospital. Use the **Cell and Gene Therapy Drug billing combinations** when submitting the billing codes on the professional claim. Ensure the applicable NDC code is submitted on the claim. A copy of the invoice with actual acquisition cost must be submitted with the claim.

D. The 340-B rules and modifiers to the Cell and Gene Therapy Drug billing code when they apply to the combinations.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Department of Human Services
BOARD/COMMISSION _____
PERSON COMPLETING THIS STATEMENT Andy Morgan
TELEPHONE NO. (501) 320-6540 **EMAIL** andy.morgan@dhs.arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE Cell and Gene Therapy (CGT) Model

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 no, please explain:

   (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 reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

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 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	$868,188	General Revenue	$1,745,405
Federal Funds	$1,953,352	Federal Funds	$3,897,675
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 2,821,540.00	Total	$ 5,643,080.00

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

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or 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**
$ 868,188.00	$ 1,745,405.00

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; **Arkansas Medicaid is joining the Centers for Medicare & Medicaid Innovation (CMMI) cell and gene therapy access model. This model will focus on outcomes-based agreements with manufacturers to improve health outcomes and reduce long-term costs for state Medicaid programs.**

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute; **Medicaid seeks to improve efficiency and quality of care through use of cell and gene therapies as one-time treatments that can transform the lives of people living with rare and severe diseases that are difficult to treat. There may be other models negotiated with manufacturers by CMS. This initial model is for patients with sickle cell disease. This is an optional model and no statute requires rulemaking.**

(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; **Medicaid seeks to promulgate this rule to implement an outcomes-based model for reimbursement of FDA approved medications already required for coverage and accessibility for patients with rare diseases.**

(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; **N/A**

(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; **N/A** 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.

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

Statement of Necessity and Rule Summary
Cell and Gene Therapy (CGT) Model

Statement of Necessity

Arkansas Medicaid joined the Cell and Gene Therapy (CGT) Access Model developed by the Centers for Medicare & Medicaid (CMS) Innovation Center. The CMS Innovation Center develops and implements payment and service delivery models (pilot programs) and conducts Congressionally-mandated demonstrations to support health care transformation and increase access to high-quality care.

The CGT Access Model focuses on outcomes-based agreements with manufacturers to improve health outcomes and reduce long-term costs for state Medicaid programs. Cell and gene therapies are one-time treatments that can transform the lives of people living with rare and severe diseases that are difficult to treat. While there may be other models negotiated with manufacturers by CMS, the initial model is for patients with sickle cell disease. A State Plan Amendment (SPA) will be necessary to allow for the one-time treatments. Reimbursement rate will be no less than actual acquisition cost for the medication.

Summary

Arkansas Medicaid will request a SPA from CMS and take other steps to implement the CGT Access Model. The State Plan Amendment will allow claims for select gene therapy drugs to be reimbursed in addition to the hospital per diem rates for dates of service on or after January 1, 2026. The SPA also will allow for select access model drugs to be carved out of the hospital per diem and to be reimbursed at the provider's Actual Acquisition Cost for the drug, verified by the purchasing invoice. Corresponding updates to the Medicaid Hospital Provider Manual will provide information and billing guidelines for the cell and gene therapy model for sickle cell disease.

NOTICE OF RULE MAKING

The Department of Human Services (DHS) 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. The projected effective date of the rule is March 1, 2026, if approved.

The Division of Medical Services (DMS) seeks an amendment to the Arkansas Medicaid State Plan to implement cell and gene therapies developed through the Centers for Medicare & Medicaid (CMS) Innovation Center. Cell and gene therapies are one-time treatments that can transform the lives of people living with rare and severe diseases that are difficult to treat. The rule will allow claims for select gene therapy drugs, reimbursed at the provider's Actual Acquisition Cost for the drug, verified by the purchasing invoice, in addition to the hospital per diem rates for dates of service on or after January 1, 2026. Corresponding updates to the Medicaid Hospital Provider Manual will provide information and billing guidelines for the cell and gene therapy model for sickle cell diseases. The estimated financial impact is $2,821,540.00 for state fiscal year 2026 and $5,643,080.00 for state fiscal year 2027.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Policy and Rules, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. This notice also shall be posted at the local office of the Division of County Operations (DCO) of DHS in every county in the state. You may also access and download the proposed rule at ar.gov/proposedrules.

Public comments can 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 January 10, 2026. 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 will be held online by remote access. Public comments may be submitted at the hearing. The details for attending the online public hearing appear at ar.gov/dhspublichearings.

If you need this material in a different format, such as large print, contact the Office of Policy and Rules at 501-320-6428. 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. **45022292178**

Elizabeth Pitman, Director
Division of Medical Services