

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Clinical Trials Attestation SPA and Provider Manual Updates & REPEALS:
Crippled Children’s State Plan; PUB 407 – Notice of Privacy Practices

DESCRIPTION:

Statement of Necessity

The Center for Medicaid and CHIP Services (CMCS) issued a State Medicaid Director Letter outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to states and territories and with respect to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial on or after January 1, 2022.

Rule Summary

Added new State Plan pages to comply with new requirements.

Revised Sections 210.100, 212.200, and 215.300 by deleting the word, “experimental” from non-covered services.

Added Section 215.301 to the Hospital Manual to clarify the Indications and Limitations of Coverage for Medicaid. Effective July 1, 2023, for items and services furnished on or after January 1, 2022, Medicaid shall cover the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Providers must submit a Medicaid attestation form to Medicaid for each beneficiary participating in a clinical trial. Instructions for submitting the form and a link to it is provided. All other Medicaid rules apply.

- Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicaid beneficiaries (for example, there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:
 - The investigational item or service itself, unless otherwise covered outside of the clinical trial;
 - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (for example, monthly CT scans for a condition usually requiring only a single scan); and
 - Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.
- Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (for example, conventional care);
- Items or services required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.

Updated Section IV of the Arkansas Medicaid Provider Manuals is revised to add the definition of Routine Standard of Care Associated with qualifying Clinical Trials, and to revise the definition of “Investigational Product” acknowledging coverage of routine standard of care associated with qualifying clinical trials. The definition of “Medical Necessity” is revised to delete the word “experimental” and correct a typo.

Repeals pursuant to the Governor’s Executive Order 23-02:

- (1) Crippled Children’s State Plan; and
- (2) PUB 407 - Notice of Privacy Practices.

PUBLIC COMMENT: A public hearing was held on this rule on July 12, 2023. The public comment period expired on July 17, 2023. The agency indicated that it received no public comments.

The proposed effective date is October 1, 2023.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

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).

With respect to items and services furnished on or after January 1, 2022, the Social Security Act requires states to provide coverage for “routine patient costs” associated with a “qualifying clinical trial.” 42 U.S.C. § 1396d(gg); *see also* P.L. 116-260, div. CC, tit. II, § 210(e) (Dec. 27, 2020) (establishing effective date of January 1, 2022). The Centers for Medicare and Medicaid Services (CMS) issued a State Medicaid Director Letter on April 13, 2022, outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. *See* Ctrs. for Medicare & Medicaid Servs., State Medicaid Director Letter (Apr. 13, 2022), <https://www.medicaid.gov/sites/default/files/2022-04/smd21005.pdf>.

**QUESTIONNAIRE FOR FILING PROPOSED RULES WITH
THE ARKANSAS LEGISLATIVE COUNCIL**

DEPARTMENT _____
 BOARD/COMMISSION _____
 BOARD/COMMISSION DIRECTOR _____
 CONTACT PERSON _____
 ADDRESS _____
 PHONE NO. _____ EMAIL _____
 NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING _____
 PRESENTER EMAIL(S) _____

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

1. What is the official title of this rule?

2. What is the subject of the proposed rule? _____
3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes No

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes No

4. Is this rule being filed for permanent promulgation? Yes No

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes No

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire? _____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes No

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes No

If yes, please provide the state statute and/or rule citation.

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes No

If yes, please list the rules being repealed.

If no, please explain.

8. Is this a new rule? Yes No

Does this repeal an existing rule? Yes No

If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes No

If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes No

If yes, please provide the year of the act(s) and act number(s).

11. What is the reason for this proposed rule? Why is it necessary?

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

13. Will a public hearing be held on this proposed rule? Yes No

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. _____

15. What is the proposed effective date for this rule? _____

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

19. Is the rule expected to be controversial? Yes No

If yes, please explain.

NOTICE OF RULE MAKING

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. The proposed effective date of the rule is October 1, 2023.

To comply with new Medicaid requirements applicable to all states, the Director of the Medical Services issues a Clinical Trials Attestation SPA and updates Provider Manuals accordingly. The new Medicaid requirements assure coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial. The Centers for Medicare and Medicaid Services approved the SPA retroactive to January 1, 2022.

Sections 210.100, 212.200, and 215.300 of the Hospital Manual are revised to delete the word, “experimental”. Section 215.301 is added to the Hospital Manual to clarify the Indications and Limitations of Coverage. For items and services furnished on or after January 1, 2022. Medicaid covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Providers must submit a Medicaid attestation form to Medicaid for each beneficiary participating in a clinical trial. All other Medicaid rules apply. Section IV of the Arkansas Medicaid Provider Manuals is revised to add the definition of Routine Standard of Care Associated with qualifying Clinical Trials, and to revise the definition of “Investigational Product” acknowledging coverage of routine standard of care associated with qualifying clinical trials. The definition of “Medical Necessity” is revised to delete the word “experimental” and correct a typo.

There are no changes to Early Periodic Screening, Diagnosis, and Treatment services (EPSDT). DHS assures continued access to EPSDT services in compliance with 42 C.F.R §440.345.

There is no anticipated fiscal impact for this change.

Pursuant to the Governor’s Executive Order 23-02, DHS repeals the following two rules as part of this promulgation: (1) Crippled Children’s State Plan, and (2) PUB 407 - Notice of Privacy Practices.

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 ar.gov/dhs-proposed-rules. 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.

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 July 17, 2023. 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 Wednesday July 12th at 10:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at <https://us02web.zoom.us/j/81443121136>. The webinar ID is 814 4312 1136. 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 501-320-6428.

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. 4502100209


Elizabeth Pittman, Director
Division of Medical Services

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT _____
BOARD/COMMISSION _____
PERSON COMPLETING THIS STATEMENT _____
TELEPHONE NO. _____ **EMAIL** _____

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 _____

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

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

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

Current Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

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

\$ _____

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

\$ _____

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;
- (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 Clinical Trials Attestation SPA (2022-0029) and Provider Manual updates

Statement of Necessity:

The Center for Medicaid and CHIP Services (CMCS) issued a State Medicaid Director Letter outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to states and territories and with respect to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial on or after January 1, 2022.

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 - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (for example, monthly CT scans for a condition usually requiring only a single scan); and
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 - Items or services that are typically provided absent a clinical trial (for example, conventional care);
 - Items or services required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent), the

- clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
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Repeals pursuant to the Governor’s Executive Order 23-02:

- (1) Crippled Children's State Plan; and
- (2) PUB 407 - Notice of Privacy Practices.

Additional documents:

<https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf>

TOC required**210.100 Introduction****4-15-1510-
1-23**

The Medical Assistance (Medicaid) Program helps eligible individuals obtain necessary medical care.

- A. Medicaid coverage is based on medical necessity.
 - 1. See Section IV of this manual for the Medicaid Program's definition of medical necessity.
 - 2. Some examples of services that are not medically necessary are treatments or procedures that are cosmetic ~~or experimental~~ or that the medical profession does not generally accept as a standard of care (e.g., an inpatient admission to treat a condition that requires only outpatient treatment).
- B. Medicaid denies coverage of services that are not medically necessary. Denial for lack of medical necessity is done in several ways.
 - 1. When Arkansas Medicaid's Division of Medical Services' Medical Director for Clinical Affairs determines that a service is never medically necessary, the Division of Medical Services (DMS) enters the service's procedure code, revenue code and/or diagnosis code into the Medicaid Management Information System (MMIS) as non-payable, which automatically prevents payment.
 - 2. A number of services are covered only with the Program's prior approval or prior authorization. One of the reasons for requiring prior approval of payment or prior authorization for a service is that some services are not always medically necessary and Medicaid wants its own medical professionals to review the case record before making payment or before the service is provided.
 - 3. Lastly, Medicaid retrospectively reviews medical records of services for which claims have been paid in order to verify that the medical record supports the service(s) for which Medicaid paid and to confirm or refute the medical necessity of the services documented in the record.
- C. Unless a service's medical necessity or lack of medical necessity has been established by statute or regulation, medical necessity determinations are made by the Arkansas Medicaid Program's Medical Director, by the Program's Quality Improvement Organizations (QIO) and/or by other qualified professionals or entities authorized and designated by the Division of Medical Services.
- D. When Arkansas Medicaid's Division of Medical Services' Medical Director for Clinical Affairs, QIO or other designee determines – whether prospectively, concurrently or retrospectively – that a hospital service is not medically necessary, Medicaid covers neither the hospital service nor any related physician services.

212.200 Exclusions – Inpatient**40-1-1510-
1-23**

The following items are not covered as inpatient hospital services:

- A. Beauty shop
- B. Cot for visitors
- C. Meals for visitors

- D. Television
- E. Telephone
- F. Guest tray
- G. Private duty nurse
- H. Take-home drugs and supplies
- I. Services not reasonable or necessary for the treatment of an illness or injury
- J. Private room (unless physician certifies that it is medically necessary or unless no semi-private rooms are available)
- K. Autopsies

Medicaid does not cover services that are cosmetic, ~~experimental~~, not medically necessary, or that are not generally accepted by the medical profession. Medicaid does not cover services that are not documented by diagnoses that certify medical necessity. Arkansas Medicaid has identified some ICD diagnosis codes that do not certify medical necessity. See Sections 272.460 and 272.470 for diagnosis codes that are not covered by Arkansas Medicaid.

215.300 Non-Covered Services

~~40-14510-1-23~~

Medicaid does not cover services that are cosmetic, ~~experimental~~, not medically necessary or that are not generally accepted by the medical profession. Medicaid does not cover services that are not documented by diagnoses that certify medical necessity. Arkansas Medicaid has identified some ICD diagnosis codes that do not certify medical necessity. See Sections 272.460 and 272.470 for diagnosis codes that are not covered by Arkansas Medicaid.

215.301 Routine Standard of Care Associated with Qualifying Clinical Trials

10-1-23

Effective for items and services furnished on or after 01/01/2022, Medicaid covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

In and out of state providers must submit the **Medicaid attestation form** for all members participating in a clinical trial to the Utilization Review Section of the Division of Medical Services. (Contact Information is listed on the **Medicaid attestation form**.)

All other Medicaid rules apply.

Routine costs of a clinical trial are defined as:

Items and services that are otherwise generally available to Medicaid clients (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- A. The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- B. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- C. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- A. Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- B. Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- C. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.

MARKYUP

SECTION IV - GLOSSARY

400.000

710-1-230

AAFP	American Academy of Family Physicians
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ABESPA	Arkansas Board of Examiners in Speech-Language Pathology and Audiology
ABHSCI	Adult Behavioral Health Services for Community Independence
ACD	Augmentative Communication Device
ACIP	Advisory Committee on Immunization Practices
ACES	Arkansas Client Eligibility System
ACS	Alternative Community Services
ADDT	Adult Developmental Day Treatment
ADE	Arkansas Department of Education
ADH	Arkansas Department of Health
ADL	Activities of Daily Living
AFDC	Aid to Families with Dependent Children (cash assistance program replaced by the Transitional Employment Assistance (TEA) program)
AHEC	Area Health Education Centers
ALF	Assisted Living Facilities
ALS	Advance Life Support
ALTE	Apparent Life-Threatening Events
AMA	American Medical Association
APD	Adults with Physical Disabilities
ARS	Arkansas Rehabilitation Services
ASC	Ambulatory Surgical Centers
ASHA	American Speech-Language-Hearing Association
BIPA	Benefits Improvement and Protection Act
BLS	Basic Life Support
CARF	Commission on Accreditation of Rehabilitation Facilities
CCRC	Children's Case Review Committee
CFA	One Counseling and Fiscal Agent
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CMHC	Community Mental Health Center
CMS	Centers for Medicare and Medicaid Services
COA	Council on Accreditation
CON	Certification of Need

CPT	Physicians' Current Procedural Terminology
CRNA	Certified Registered Nurse Anesthetist
CSHCN	Children with Special Health Care Needs
CSWE	Council on Social Work Education
D&E	Diagnosis and Evaluation
DAAS	Division of Aging and Adult Services
DBS	Division of Blind Services (currently named Division of Services for the Blind)
DCFS	Division of Children and Family Services
DCO	Division of County Operations
DD	Developmentally Disabled
DDS	Developmental Disabilities Services
DHS	Department of Human Services
DLS	Daily Living Skills
DME	Durable Medical Equipment
DMHS	Division of Mental Health Services
DMS	Division of Medical Services (Medicaid)
DOS	Date of Service
DRG	Diagnosis Related Group
DRS	Developmental Rehabilitative Services
DDSCES	Developmental Disabilities Services Community and Employment Support
DSB	Division of Services for the Blind (formerly Division of Blind Services)
DSH	Disproportionate Share Hospital
DURC	Drug Utilization Review Committees
DYS	Division of Youth Services
EIDT	Early Intervention Day Treatment
EAC	Estimated Acquisition Cost
EFT	Electronic Funds Transfer
EIN	Employer Identification Number
EOB	Explanation of Benefits
EOMB	Explanation of Medicaid Benefits. EOMB may also refer to Explanation of Medicare Benefits.
EPSDT	Early and Periodic Screening, Diagnosis, and Treatment
ESC	Education Services Cooperative
FEIN	Federal Employee Identification Number
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
GME	Graduate Medical Education
GUL	Generic Upper Limit

HCBS	Home and Community Based Services
HCPCS	Healthcare Common Procedure Coding System
HDC	Human Development Center
HHS	The Federal Department of Health and Human Services
HIC Number	Health Insurance Claim Number
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
IADL	Instrumental Activities of Daily Living
ICD	International Classification of Diseases
ICF/IID	Intermediate Care Facility for Individuals with Intellectual Disabilities
ICN	Internal Control Number
IDEA	Individuals with Disabilities Education Act
IDG	Interdisciplinary Group
IEP	Individualized Educational Program
IFSP	Individualized Family Service Plan
IMD	Institution for Mental Diseases
IPP	Individual Program Plan
IUD	Intrauterine Devices
JCAHO	Joint Commission on Accreditation of Healthcare Organization
LAC	Licensed Associate Counselor
LCSW	Licensed Certified Social Worker
LEA	Local Education Agencies
LMFT	Licensed Marriage and Family Therapist
LPC	Licensed Professional Counselor
LPE	Licensed Psychological Examiner
LSPS	Licensed School Psychology Specialist
LTC	Long Term Care
MAC	Maximum Allowable Cost
MAPS	Multi-agency Plan of Services
MART	Medicaid Agency Review Team
MEI	Medicare Economic Index
MMIS	Medicaid Management Information System
MNIL	Medically Needy Income Limit
MPPPP	Medicaid Prudent Pharmaceutical Purchasing Program
MSA	Metropolitan Statistical Area
MUMP	Medicaid Utilization Management Program
NBCOT	National Board for Certification of Occupational Therapy
NCATE	North Central Accreditation for Teacher Education

NDC	National Drug Code
NET	Non-Emergency Transportation Services
NF	Nursing Facility
NPI	National Provider Identifier
OBRA	Omnibus Budget Reconciliation Act
OHCDSD	Organized Health Care Delivery System
OBHS	Outpatient Behavioral Health Services
OTC	Over the Counter
PA	Prior Authorization
PAC	Provider Assistance Center
PASSE	Provider-led Arkansas Shared Savings Entity Program
PCP	Primary Care Physician
PERS	Personal Emergency Response Systems
PHS	Public Health Services
PIM	Provider Information Memorandum
PL	Public Law
POC	Plan of Care
POS	Place of Service
PPS	Prospective Payment System
PRN	Pro Re Nata or "As Needed"
PRO	Professional Review Organization
ProDUR	Prospective Drug Utilization Review
QIDP	Qualified Intellectual Disabilities Professional
QMB	Qualified Medicare Beneficiary
RA	Remittance Advice. Also called Remittance and Status Report
RFP	Request for Proposal
RHC	Rural Health Clinic
BID	Beneficiary Identification Number
RSPD	Rehabilitative Services for Persons with Physical Disabilities
RSYC	Rehabilitative Services for Youth and Children
RTC	Residential Treatment Centers
RTP	Return to Provider
RTU	Residential Treatment Units
SBMH	School-Based Mental Health Services
SD	Spend Down
SFY	State Fiscal Year
SMB	Special Low-Income Qualified Medicare Beneficiaries
SNF	Skilled Nursing Facility

SSA	Social Security Administration
SSI	Supplemental Security Income
SURS	Surveillance and Utilization Review Subsystem
TCM	Targeted Case Management
TEA	Transitional Employment Assistance
TEFRA	Tax Equity and Fiscal Responsibility Act
TOS	Type of Service
TPL	Third Party Liability
UPL	Upper Payment Limit
UR	Utilization Review
VFC	Vaccines for Children
VRS	Voice Response System
Accommodation	A type of hospital room, e.g., private, semiprivate, ward, etc.
Activities of Daily Living (ADL)	Personal tasks that are ordinarily performed daily and include eating, mobility/transfer, dressing, bathing, toileting, and grooming
Adjudicate	To determine whether a claim is to be paid or denied
Adjustments	Transactions to correct claims paid in error or to adjust payments from a retroactive change
Admission	Actual entry and continuous stay of the beneficiary as an inpatient to an institutional facility
Affiliates	Persons having an overt or covert relationship such that any individual directly or indirectly controls or has the power to control another individual
Agency	The Division of Medical Services
Aid Category	A designation within SSI or state regulations under which a person may be eligible for public assistance
Aid to Families with Dependent Children (AFDC)	A Medicaid eligibility category
Allowed Amount	The maximum amount Medicaid will pay for a service as billed before applying beneficiary coinsurance or co-pay, previous TPL payment, spend down liability, or other deducted charges
American Medical Association (AMA)	National association of physicians
Ancillary Services	Services available to a patient other than room and board. For example: pharmacy, X-ray, lab, and central supplies
Arkansas Client Eligibility System (ACES)	A state computer system in which data is entered to update assistance eligibility information and beneficiary files
Attending Physician	<i>See Performing Physician.</i>
Automated Eligibility Verification Claims Submission (AEVCS)	Online system for providers to verify eligibility of beneficiaries and submit claims to fiscal agent
Base Charge	A set amount allowed for a participating provider according to specialty

Beneficiary	Person who meets the Medicaid eligibility requirements, receives an ID card, and is eligible for Medicaid services (formerly recipient)
Benefits	Services available under the Arkansas Medicaid Program
Billed Amount	The amount billed to Medicaid for a rendered service
Buy-In	A process whereby the state enters into an agreement with the Medicaid/Medicare and the Social Security Administration to obtain Medicare Part B (and part A when needed) for Medicaid beneficiaries who are also eligible for Medicare. The state pays the monthly Medicare premium(s) on behalf of the beneficiary.
Care Plan	<i>See Plan of Care (POC).</i>
Case Head	An adult responsible for an AFDC or Medicaid child
Categorically Needy	All individuals receiving financial assistance under the state's approved plan under Title I, IV-A, X, XIV, and XVI of the Social Security Act or in need under the state's standards for financial eligibility in such a plan
Centers for Medicare and Medicaid Services	Federal agency that administers federal Medicaid funding
Child Health Services	Arkansas Medicaid's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program
Children with Chronic Health Conditions (CHC)	A Title V Children with Special Health Care Needs Program administered by the Arkansas Division of Developmental Disabilities Services to provide medical care and service coordination to children with chronic physical illnesses or disabilities.
Claim	A request for payment for services rendered
Claim Detail	<i>See Line Item.</i>
Clinic	(1) A facility for diagnosis and treatment of outpatients. (2) A group practice in which several physicians work together
Coinsurance	The portion of allowed charges the patient is responsible for under Medicare. This may be covered by other insurance, such as Medi-Pak or Medicaid (if entitled). This also refers to the portion of a Medicaid covered inpatient hospital stay for which the beneficiary is responsible.
Contract	Written agreement between a provider of medical services and the Arkansas Division of Medical Services. A contract must be signed by each provider of services participating in the Medicaid Program.
Co-pay	The portion of the maximum allowable (either that of Medicaid or a third-party payer) that the insured or beneficiary must pay
Cosmetic Surgery	Any surgical procedure directed at improving appearance but not medically necessary
Covered Service	Service which is within the scope of the Arkansas Medicaid Program
Current Procedural Terminology	A listing published annually by AMA consisting of current medical terms and the corresponding procedure codes used for reporting medical services and procedures performed by physicians
Credit Claim	A claim transaction which has a negative effect on a previously processed claim.

Crossover Claim	A claim for which both Titles XVIII (Medicare) and XIX (Medicaid) are liable for reimbursement of services provided to a beneficiary entitled to benefits under both programs
Date of Service	Date or dates on which a beneficiary receives a covered service. Documentation of services and units received must be in the beneficiary's record for each date of service.
Deductible	The amount the Medicare beneficiary must pay toward covered benefits before Medicare or insurance payment can be made for additional benefits. Medicare Part A and Part B deductibles are paid by Medicaid within the program limits.
Debit Claim	A claim transaction which has a positive effect on a previously processed claim
Denial	A claim for which payment is disallowed
Department of Health and Human Services (HHS)	Federal health and human services agency
Department of Human Services (DHS)	State human services agency
Dependent	A spouse or child of the individual who is entitled to benefits under the Medicaid Program
Diagnosis	The identity of a condition, cause, or disease
Diagnostic Admission	Admission to a hospital primarily for the purpose of diagnosis
Disallow	To subtract a portion of a billed charge that exceeds the Medicaid maximum or to deny an entire charge because Medicaid pays Medicare Part A and B deductibles subject to program limitations for eligible beneficiaries
Discounts	<p>A discount is defined as the lowest available price charged by a provider to a client or third-party payer, including any discount, for a specific service during a specific period by an individual provider. If a Medicaid provider offers a professional or volume discount to any customer, claims submitted to Medicaid must reflect the same discount.</p> <p>Example: If a laboratory provider charges a private physician or clinic a discounted rate for services, the charge submitted to Medicaid for the same service must not exceed the discounted price charged to the physician or clinic. Medicaid must be given the benefit of discounts and price concessions the lab gives any of its customers.</p>
Duplicate Claim	A claim that has been submitted or paid previously or a claim that is identical to a claim in process
Durable Medical Equipment	Equipment that (1) can withstand repeated use and (2) is used to serve a medical purpose. Examples include a wheelchair or hospital bed.
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)	A federally mandated Medicaid program for eligible individuals under the age of twenty-one (21). See <i>Child Health Services</i> .
Education Accreditation	When an individual is required to possess a bachelor's degree, master's degree, or a Ph.D. degree in a specific profession. The degree must be from a program accredited by an organization that is approved by the Council for Higher Education Accreditation (CHEA).

Electronic Signature	An electronic or digital method executed or adopted by a party with the intent to be bound by or to authenticate a record, which is: (a) Unique to the person using it; (b) Capable of verification; (c) Under the sole control of the person using it; and (d) Linked to data in such a manner that if the data are changed the electronic signature is invalidated. An Electronic Signature method must be approved by the DHS Chief Information Officer or his or her designee before it will be accepted. A list of approved electronic signature methods will be posted on the state Medicaid website.
Eligible	(1) To be qualified for Medicaid benefits. (2) An individual who is qualified for benefits
Eligibility File	A file containing individual records for all persons who are eligible or have been eligible for Medicaid
Emergency Services	Inpatient or outpatient hospital services that a prudent layperson with an average knowledge of health and medicine would reasonably believe are necessary to prevent death or serious impairment of health and which, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services. Source: 42 U.S. Code of Federal Regulations (42 CFR) and §424.101.
Error Code	A numeric code indicating the type of error found in processing a claim also known as an "Explanation of Benefits (EOB) code" or a "HIPAA Explanation of Benefits (HEOB) code"
Estimated Acquisition Cost	The estimated amount a pharmacy actually pays to obtain a drug
Experimental Surgery	Any surgical procedure considered experimental in nature
Explanation of Medicaid Benefits (EOMB)	A statement mailed once per month to selected beneficiaries to allow them to confirm the Medicaid service which they received
Family Planning Services	Any medically approved diagnosis, treatment, counseling, drugs, supplies, or devices prescribed or furnished by a physician, nurse practitioner, certified nurse-midwife, pharmacy, hospital, family planning clinic, rural health clinic (RHC), Federally Qualified Health Center (FQHC), or the Department of Health to individuals of child-bearing age for purposes of enabling such individuals freedom to determine the number and spacing of their children.
Field Audit	An activity performed whereby a provider's facilities, procedures, records, and books are audited for compliance with Medicaid regulations and standards. A field audit may be conducted on a routine basis, or on a special basis announced or unannounced.
Fiscal Agent	An organization authorized by the State of Arkansas to process Medicaid claims
Fiscal Agent Intermediary	A private business firm which has entered into a contract with the Arkansas Department of Human Services to process Medicaid claims
Fiscal Year	The twelve-month period between settlements of financial accounts
Generic Upper Limit (GUL)	The maximum drug cost that may be used to compute reimbursement for specified multiple-source drugs unless the provisions for a Generic Upper Limit override have been met. The Generic Upper Limit may be established or revised by the Centers for Medicare and Medicaid Services (CMS) or by the State Medicaid Agency.

Group	Two (2) or more persons. If a service is a “group” therapy or other group service, there must be two (2) or more persons present and receiving the service.
Group Practice	A medical practice in which several practitioners render and bill for services under a single pay-to provider identification number
Healthcare Common Procedure Coding System (HCPCS)	Federally defined procedure codes
Health Insurance Claim Number	Number assigned to Medicare beneficiaries and individuals eligible for SSI
Hospital	An institution that meets the following qualifications: <ul style="list-style-type: none"> • Provides diagnostic and rehabilitation services to inpatients • Maintains clinical records on all patients • Has by-laws with respect to its staff of physicians • Requires each patient to be under the care of a physician, dentist, or certified nurse-midwife • Provides 24-hour nursing service • Has a hospital utilization review plan in effect • Is licensed by the State • Meets other health and safety requirements set by the Secretary of Health and Human Services
Hospital-Based Physician	A physician who is a hospital employee and is paid for services by the hospital
ID Card	An identification card issued to Medicaid beneficiaries and ARKids First-B participants containing encoded data that permits a provider to access the card-holder’s eligibility information
Individual	A single person as distinguished from a group. If a service is an “individual” therapy or service, there may be only one (1) person present who is receiving the service.
Inpatient	A patient, admitted to a hospital or skilled nursing facility, who occupies a bed and receives inpatient services.
In-Process Claim (Pending Claim)	A claim that suspends during system processing for suspected error conditions such as: all processing requirements appear not to be met. These conditions must be reviewed by the Arkansas Medicaid fiscal agent or DMS and resolved before processing of the claim can be completed. <i>See Suspended Claim.</i>
Inquiry	A request for information
Institutional Care	Care in an authorized private, non-profit, public, or state institution or facility. Such facilities include schools for the deaf, or blind and institutions for individuals with disabilities.
Instrumental Activities of Daily Living (IADL)	Tasks which are ordinarily performed on a daily or weekly basis and include meal preparation, housework, laundry, shopping, taking medications, and travel/transportation
Intensive Care	Isolated and constant observation care to patients critically ill or injured

Interim Billing	A claim for less than the full length of an inpatient hospital stay. Also, a claim that is billed for services provided to a particular date even though services continue beyond that date. It may or may not be the final bill for a particular beneficiary's services.
Internal Control Number (ICN)	The unique 13-digit claim number that appears on a Remittance Advice
International Classification of Diseases	A diagnosis coding system used by medical providers to identify a patient's diagnosis or diagnoses on medical records and claims
Investigational Product	Any product that is considered investigational or experimental and that is not approved by the Food and Drug Administration. The Arkansas Medicaid Program does not cover investigational products <u>but does cover routine standard of care associated with qualifying clinical trials.</u>
Julian Date	Chronological date of the year, 001 through 365 or 366, preceded on a claims number (ICN) by a two-digit-year designation. Claim number example: 03231 (August 19, 2003).
Length of Stay	Period of time a patient is in the hospital. Also, the number of days covered by Medicaid within a single inpatient stay.
Limited Services Provider Agreement	An agreement for a specific period of time not to exceed twelve (12) months, which must be renewed in order for the provider to continue to participate in the Title XIX Program.
Line Item	A service provided to a beneficiary. A claim may be made up of one (1) or more line items for the same beneficiary. Also called a claim detail.
Long Term Care (LTC)	An office within the Arkansas Division of Medical Services responsible for nursing facilities
Long Term Care Facility	A nursing facility
Maximum Allowable Cost (MAC)	The maximum drug cost which may be reimbursed for specified multi-source drugs. This term is interchangeable with generic upper limit.
Medicaid Provider Number	A unique identifying number assigned to each provider of services in the Arkansas Medicaid Program, required for identification purposes
Medicaid Management Information System (MMIS)	The automated system utilized to process Medicaid claims
Medical Assistance Section	A section within the Arkansas Division of Medical Services responsible for administering the Arkansas Medical Assistance Program
Medically Needy	Individuals whose income and resources exceed the levels for assistance established under a state or federal plan for categorically needy, but are insufficient to meet costs of health and medical services

Medical Necessity	All Medicaid benefits are based upon medical necessity. A service is “medically necessary” if it is reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that endanger life, cause suffering or pain, result in illness or injury, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction and if there is no other equally effective (although more conservative or less costly) course of treatment available or suitable for the beneficiary requesting the service. For this purpose, a “course of treatment” may include mere observation or (where appropriate) no treatment at all. The determination of medical necessity may be made by the Medical Director for the Medicaid Program or by the Medicaid Program Quality Improvement Organization (QIO). Coverage may be denied if a service is not medically necessary in accordance with the preceding criteria or is generally regarded by the medical profession as experimental, inappropriate, or ineffective using unless objective clinical evidence demonstrates circumstances making the service necessary.
Mis-Utilization	Any usage of the Medicaid Program by any of its providers or beneficiaries which is not in conformance with both State and Federal regulations and laws (including, but not limited to, fraud, abuse, and defects in level and quality of care)
National Drug Code	The unique 11-digit number assigned to drugs which identifies the manufacturer, drug, strength, and package size of each drug
National Provider Identifier (NPI)	A standardized unique health identifier for health care providers for use in the health care system in connection with standard transactions for all covered entities. Established by the Centers for Medicare & Medicaid Services, HHS, in compliance with HIPAA Administrative Simplification – 45 CFR Part 162.
Non-Covered Services	Services not medically necessary, services provided for the personal convenience of the patient or services not covered under the Medicaid Program
Nonpatient	An individual who receives services, such as laboratory tests, performed by a hospital, but who is not a patient of the hospital
Nurse Practitioner	A professional nurse with credentials that meet the requirements for licensure as a nurse practitioner in the State of Arkansas
Outpatient	A patient receiving medical services, but not admitted as an inpatient to a hospital
Over-Utilization	Any over usage of the Medicaid Program by any of its providers or beneficiaries not in conformance with professional judgment and both State and Federal regulations and laws (including, but not limited to, fraud and abuse)
Participant	A provider of services who: (1) provides the service, (2) submits the claim and (3) accepts Medicaid’s reimbursement for the services provided as payment in full
Patient	A person under the treatment or care of a physician or surgeon, or in a hospital
Payment	Reimbursement to the provider of services for rendering a Medicaid-covered benefit
Pay-to Provider	A person, organization, or institution authorized to receive payment for services provided to Medicaid beneficiaries by a person or persons who are a part of the entity

Pay-to Provider Number	A unique identifying number assigned to each pay-to provider of services (Clinic/Group/Facility) in the Arkansas Medicaid Program or the pay-to provider group's assigned National Provider Identifier (NPI). Medicaid reports provider payments to the Internal Revenue Service under the Employer Identification Number "Tax ID" linked in the Medicaid Provider File to the pay-to provider identification number.
Per Diem	A daily rate paid to institutional providers
Performing Physician	The physician providing, supervising, or both, a medical service and claiming primary responsibility for ensuring that services are delivered as billed
Person	Any natural person, company, firm, association, corporation, or other legal entity
Place of Service (POS)	A nationally approved two-digit numeric code denoting the location of the patient receiving services
Plan of Care	A document utilized by a provider to plan, direct, or deliver care to a patient to meet specific measurable goals; also called care plan, service plan, or treatment plan
Postpayment Utilization Review	The review of services, documentation, and practice after payment
Practitioner	An individual who practices in a health or medical service profession
Prepayment Utilization Review	The review of services, documentation, and practice patterns before payment
Prescription	A health care professional's legal order for a drug which, in accordance with federal or state statutes, may not be obtained otherwise; also, an order for a particular Medicaid covered service
Prescription Drug (RX)	A drug which, in accordance with federal or state statutes, may not be obtained without a valid prescription
Primary Care Physician (PCP)	A physician responsible for the management of a beneficiary's total medical care. Selected by the beneficiary to provide primary care services and health education. The PCP will monitor on an ongoing basis the beneficiary's condition, health care needs and service delivery, be responsible for locating, coordinating, and monitoring medical and rehabilitation services on behalf of the beneficiary, and refer the beneficiary for most specialty services, hospital care, and other services.
Prior Approval	The approval for coverage and reimbursement of specific services prior to furnishing services for a specified beneficiary of Medicaid. The request for prior approval must be made to the Medical Director of the Division of Medical Services for review of required documentation and justification for provision of service.
Prior Authorization (PA)	The approval by the Arkansas Division of Medical Services, or a designee of the Division of Medical Services, for specified services for a specified beneficiary to a specified provider before the requested services may be performed and before payment will be made. Prior authorization does not guarantee reimbursement.
Procedure Code	A five-digit numeric or alpha numeric code to identify medical services and procedures on medical claims
Professional Component	A physician's interpretation or supervision and interpretation of laboratory, X-ray, or machine test procedures

Profile	A detailed view of an individual provider's charges to Medicaid for health care services or a detailed view of a beneficiary's usage of health care services
Provider	A person, organization, or institution enrolled to provide and be reimbursed for health or medical care services authorized under the State Title XIX Medicaid Program
Provider Identification Number	A unique identifying number assigned to each provider of services in the Arkansas Medicaid Program or the provider's assigned National Provider Identifier (NPI), when applicable, that is required for identification purposes
Provider Relations	The activity within the Medicaid Program which handles all relationships with Medicaid providers
Quality Assurance	Determination of quality and appropriateness of services rendered
Quality Improvement Organization	A Quality Improvement Organization (QIO) is a federally mandated review organization required of each state's Title XIX (Medicaid) program. The QIO monitors hospital and physician services billed to the state's Medicare intermediary and the Medicaid program to assure high quality, medical necessity, and appropriate care for each patient's needs.
Railroad Claim Number	The number issued by the Railroad Retirement Board to control payments of annuities and pensions under the Railroad Retirement Act. The claim number begins with a one- to three-letter alphabetic prefix denoting the type of payment, followed by six (6) or nine (9) numeric digits.
Referral	An authorization from a Medicaid enrolled provider to a second Medicaid enrolled provider. The receiving provider is expected to exercise independent professional judgment and discretion, to the extent permitted by laws and rules governing the practice of the receiving practitioner, and to develop and deliver medically necessary services covered by the Medicaid program. The provider making the referral may be a physician or another qualified practitioner acting within the scope of practice permitted by laws or rules. Medicaid requires documentation of the referral in the beneficiary's medical record, regardless of the means the referring provider makes the referral. Medicaid requires the receiving provider to document the referral also, and to correspond with the referring provider regarding the case when appropriate and when the referring provider so requests.
Reimbursement	The amount of money remitted to a provider
Rejected Claim	A claim for which payment is refused
Relative Value	A weighting scale used to relate the worth of one (1) surgical procedure to any other. This evaluation, expressed in units, is based upon the skill, time, and the experience of the physician in its performance.
Remittance	A remittance advice
Remittance Advice (RA)	A notice sent to providers advising the status of claims received, including paid, denied, in-process, and adjusted claims. It includes year-to-date payment summaries and other financial information.
Reported Charge	The total amount submitted in a claim detail by a provider of services for reimbursement
Retroactive Medicaid Eligibility	Medicaid eligibility which may begin up to three (3) months prior to the date of application provided all eligibility factors are met in those months
Returned Claim	A claim which is returned by the Medicaid Program to the provider for correction or change to allow it to be processed properly

Routine Standard of Care Associated with Qualifying Clinical Trials

Effective for items and services furnished on or after 01/01/2022, Medicaid covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicaid rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicaid beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

The investigational item or service, itself unless otherwise covered outside of the clinical trial;

- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.

Sanction	Any corrective action taken against a provider
Screening	The use of quick, simple, medical procedures carried out among large groups of people to sort out apparently well persons from those who may have a disease or abnormality and to identify those in need of more definitive examination or treatment
Signature	The person's original signature or initials. The person's signature or initials may also be recorded by an electronic or digital method, executed, or adopted by the person with the intent to be bound by or to authenticate a record. An electronic signature must comply with Arkansas Code Annotated § 25-31-101-105, including verification through an electronic signature verification company and data links invalidating the electronic signature if the data is changed.
Single State Agency	The state agency authorized to administer or supervise the administration of the Medicaid Program on a statewide basis
Skilled Nursing Facility (SNF)	A nursing home, or a distinct part of a facility, licensed by the Office of Long-Term Care as meeting the Skilled Nursing Facility Federal/State licensure and certification regulations. A health facility which provides skilled nursing care and supportive care on a 24-hour basis to residents whose primary need is for availability of skilled nursing care on an extended basis.

Social Security Administration (SSA)	A federal agency which makes disability and blindness determinations for the Secretary of the HHS
Social Security Claim Number	The account number used by SSA to identify the individual on whose earnings SSA benefits are being paid. It is the Social Security Account Number followed by a suffix, sometimes as many as three (3) characters, designating the type of beneficiary (e.g., wife, widow, child, etc.).
Source of Care	A hospital, clinic, physician, or other facility which provides services to a beneficiary under the Medicaid Program
Specialty	The specialized area of practice of a physician or dentist
Spend Down (SD)	The amount of money a beneficiary must pay toward medical expenses when income exceeds the Medicaid financial guidelines. A component of the medically needy program allows an individual or family whose income is over the medically needy income limit (MNIL) to use medical bills to spend excess income down to the MNIL. The individual(s) will have a spend down liability. The spend down column of the remittance advice indicates the amount which the provider may bill the beneficiary. The spend down liability occurs only on the first day of Medicaid eligibility.
Status Report	A remittance advice
Supplemental Security Income (SSI)	A program administered by the Social Security Administration. This program replaced previous state administered programs for aged, blind, or individuals with disabilities (except in Guam, Puerto Rico, and the Virgin Islands). This term may also refer to the Bureau of Supplemental Security Income within SSA which administers the program.
Suspended Claim	An "In-Process Claim" which must be reviewed and resolved
Suspension from Participation	An exclusion from participation for a specified period
Suspension of Payments	The withholding of all payments due to a provider until the resolution of a matter in dispute between the provider and the state agency
Termination from Participation	A permanent exclusion from participation in the Title XIX Program
Third Party Liability (TPL)	A condition whereby a person or an organization, other than the beneficiary or the state agency, is responsible for all or some portion of the costs for health or medical services incurred by the Medicaid beneficiary (e.g., a health insurance company, a casualty insurance company, or another person in the case of an accident, etc.).
Utilization Review (UR)	The section of the Arkansas Division of Medical Services which performs the monitoring and controlling of the quantity and quality of health care services delivered under the Medicaid Program
Void	A transaction which deletes
Voice Response System (VRS)	Voice-activated system to request prior authorization for prescription drugs and for PCP assignment and change
Ward	An accommodation of five (5) or more beds
Withholding of Payments	A reduction or adjustment of the amounts paid to a provider on pending and subsequently due payments
Worker's Compensation	A type of Third-Party Liability for medical services rendered as the result of an on-the-job accident or injury to a beneficiary for which the employer's insurance company may be obligated under the Worker's Compensation Act

State/Territory: Arkansas**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: 01/01/2022 _____

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)X Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.**Qualifying Clinical Trial – Section 1905(gg)(2)**X A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).**Coverage Determination – Section 1905(gg)(3)**X A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN: 2023-0009
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Effective Date 01/01/2022

State/Territory:

Arkansas**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****MEDICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: X

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1) X Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.**Qualifying Clinical Trial – Section 1905(gg)(2)** X A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).**Coverage Determination – Section 1905(gg)(3)** X A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

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TOC required**210.100 Introduction**

10-1-23

The Medical Assistance (Medicaid) Program helps eligible individuals obtain necessary medical care.

- A. Medicaid coverage is based on medical necessity.
 - 1. See Section IV of this manual for the Medicaid Program's definition of medical necessity.
 - 2. Some examples of services that are not medically necessary are treatments or procedures that are cosmetic or that the medical profession does not generally accept as a standard of care (e.g., an inpatient admission to treat a condition that requires only outpatient treatment).
- B. Medicaid denies coverage of services that are not medically necessary. Denial for lack of medical necessity is done in several ways.
 - 1. When Arkansas Medicaid's Division of Medical Services' Medical Director for Clinical Affairs determines that a service is never medically necessary, the Division of Medical Services (DMS) enters the service's procedure code, revenue code and/or diagnosis code into the Medicaid Management Information System (MMIS) as non-payable, which automatically prevents payment.
 - 2. A number of services are covered only with the Program's prior approval or prior authorization. One of the reasons for requiring prior approval of payment or prior authorization for a service is that some services are not always medically necessary and Medicaid wants its own medical professionals to review the case record before making payment or before the service is provided.
 - 3. Lastly, Medicaid retrospectively reviews medical records of services for which claims have been paid in order to verify that the medical record supports the service(s) for which Medicaid paid and to confirm or refute the medical necessity of the services documented in the record.
- C. Unless a service's medical necessity or lack of medical necessity has been established by statute or regulation, medical necessity determinations are made by the Arkansas Medicaid Program's Medical Director, by the Program's Quality Improvement Organizations (QIO) and/or by other qualified professionals or entities authorized and designated by the Division of Medical Services.
- D. When Arkansas Medicaid's Division of Medical Services' Medical Director for Clinical Affairs, QIO or other designee determines – whether prospectively, concurrently or retrospectively – that a hospital service is not medically necessary, Medicaid covers neither the hospital service nor any related physician services.

212.200 Exclusions – Inpatient

10-1-23

The following items are not covered as inpatient hospital services:

- A. Beauty shop
- B. Cot for visitors
- C. Meals for visitors
- D. Television

- E. Telephone
- F. Guest tray
- G. Private duty nurse
- H. Take-home drugs and supplies
- I. Services not reasonable or necessary for the treatment of an illness or injury
- J. Private room (unless physician certifies that it is medically necessary or unless no semi-private rooms are available)
- K. Autopsies

Medicaid does not cover services that are cosmetic, not medically necessary, or that are not generally accepted by the medical profession. Medicaid does not cover services that are not documented by diagnoses that certify medical necessity. Arkansas Medicaid has identified some ICD diagnosis codes that do not certify medical necessity. See Sections 272.460 and 272.470 for diagnosis codes that are not covered by Arkansas Medicaid.

215.300 Non-Covered Services

10-1-23

Medicaid does not cover services that are cosmetic, not medically necessary or that are not generally accepted by the medical profession. Medicaid does not cover services that are not documented by diagnoses that certify medical necessity. Arkansas Medicaid has identified some ICD diagnosis codes that do not certify medical necessity. See Sections 272.460 and 272.470 for diagnosis codes that are not covered by Arkansas Medicaid.

215.301 Routine Standard of Care Associated with Qualifying Clinical Trials

10-1-23

Effective for items and services furnished on or after 01/01/2022, Medicaid covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

In and out of state providers must submit the [Medicaid attestation form](#) for all members participating in a clinical trial to the Utilization Review Section of the Division of Medical Services. (Contact Information is listed on the [Medicaid attestation form](#).)

All other Medicaid rules apply.

Routine costs of a clinical trial are defined as:

Items and services that are otherwise generally available to Medicaid clients (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- A. The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- B. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- C. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- A. Items or services that are typically provided absent a clinical trial (e.g., conventional care);

- B. Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- C. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.

PROPOSED

SECTION IV - GLOSSARY

400.000

10-1-23

AAFP	American Academy of Family Physicians
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ABESPA	Arkansas Board of Examiners in Speech-Language Pathology and Audiology
ABHSCI	Adult Behavioral Health Services for Community Independence
ACD	Augmentative Communication Device
ACIP	Advisory Committee on Immunization Practices
ACES	Arkansas Client Eligibility System
ACS	Alternative Community Services
ADDT	Adult Developmental Day Treatment
ADE	Arkansas Department of Education
ADH	Arkansas Department of Health
ADL	Activities of Daily Living
AFDC	Aid to Families with Dependent Children (cash assistance program replaced by the Transitional Employment Assistance (TEA) program)
AHEC	Area Health Education Centers
ALF	Assisted Living Facilities
ALS	Advance Life Support
ALTE	Apparent Life-Threatening Events
AMA	American Medical Association
APD	Adults with Physical Disabilities
ARS	Arkansas Rehabilitation Services
ASC	Ambulatory Surgical Centers
ASHA	American Speech-Language-Hearing Association
BIPA	Benefits Improvement and Protection Act
BLS	Basic Life Support
CARF	Commission on Accreditation of Rehabilitation Facilities
CCRC	Children's Case Review Committee
CFA	One Counseling and Fiscal Agent
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CMHC	Community Mental Health Center
CMS	Centers for Medicare and Medicaid Services
COA	Council on Accreditation
CON	Certification of Need

CPT	Physicians' Current Procedural Terminology
CRNA	Certified Registered Nurse Anesthetist
CSHCN	Children with Special Health Care Needs
CSWE	Council on Social Work Education
D&E	Diagnosis and Evaluation
DAAS	Division of Aging and Adult Services
DBS	Division of Blind Services (currently named Division of Services for the Blind)
DCFS	Division of Children and Family Services
DCO	Division of County Operations
DD	Developmentally Disabled
DDS	Developmental Disabilities Services
DHS	Department of Human Services
DLS	Daily Living Skills
DME	Durable Medical Equipment
DMHS	Division of Mental Health Services
DMS	Division of Medical Services (Medicaid)
DOS	Date of Service
DRG	Diagnosis Related Group
DRS	Developmental Rehabilitative Services
DDSCES	Developmental Disabilities Services Community and Employment Support
DSB	Division of Services for the Blind (formerly Division of Blind Services)
DSH	Disproportionate Share Hospital
DURC	Drug Utilization Review Committees
DYS	Division of Youth Services
EIDT	Early Intervention Day Treatment
EAC	Estimated Acquisition Cost
EFT	Electronic Funds Transfer
EIN	Employer Identification Number
EOB	Explanation of Benefits
EOMB	Explanation of Medicaid Benefits. EOMB may also refer to Explanation of Medicare Benefits.
EPSDT	Early and Periodic Screening, Diagnosis, and Treatment
ESC	Education Services Cooperative
FEIN	Federal Employee Identification Number
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
GME	Graduate Medical Education
GUL	Generic Upper Limit

HCBS	Home and Community Based Services
HCPCS	Healthcare Common Procedure Coding System
HDC	Human Development Center
HHS	The Federal Department of Health and Human Services
HIC Number	Health Insurance Claim Number
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
IADL	Instrumental Activities of Daily Living
ICD	International Classification of Diseases
ICF/IID	Intermediate Care Facility for Individuals with Intellectual Disabilities
ICN	Internal Control Number
IDEA	Individuals with Disabilities Education Act
IDG	Interdisciplinary Group
IEP	Individualized Educational Program
IFSP	Individualized Family Service Plan
IMD	Institution for Mental Diseases
IPP	Individual Program Plan
IUD	Intrauterine Devices
JCAHO	Joint Commission on Accreditation of Healthcare Organization
LAC	Licensed Associate Counselor
LCSW	Licensed Certified Social Worker
LEA	Local Education Agencies
LMFT	Licensed Marriage and Family Therapist
LPC	Licensed Professional Counselor
LPE	Licensed Psychological Examiner
LSPS	Licensed School Psychology Specialist
LTC	Long Term Care
MAC	Maximum Allowable Cost
MAPS	Multi-agency Plan of Services
MART	Medicaid Agency Review Team
MEI	Medicare Economic Index
MMIS	Medicaid Management Information System
MNIL	Medically Needy Income Limit
MPPPP	Medicaid Prudent Pharmaceutical Purchasing Program
MSA	Metropolitan Statistical Area
MUMP	Medicaid Utilization Management Program
NBCOT	National Board for Certification of Occupational Therapy
NCATE	North Central Accreditation for Teacher Education

NDC	National Drug Code
NET	Non-Emergency Transportation Services
NF	Nursing Facility
NPI	National Provider Identifier
OBRA	Omnibus Budget Reconciliation Act
OHCDSD	Organized Health Care Delivery System
OBHS	Outpatient Behavioral Health Services
OTC	Over the Counter
PA	Prior Authorization
PAC	Provider Assistance Center
PASSE	Provider-led Arkansas Shared Savings Entity Program
PCP	Primary Care Physician
PERS	Personal Emergency Response Systems
PHS	Public Health Services
PIM	Provider Information Memorandum
PL	Public Law
POC	Plan of Care
POS	Place of Service
PPS	Prospective Payment System
PRN	Pro Re Nata or "As Needed"
PRO	Professional Review Organization
ProDUR	Prospective Drug Utilization Review
QIDP	Qualified Intellectual Disabilities Professional
QMB	Qualified Medicare Beneficiary
RA	Remittance Advice. Also called Remittance and Status Report
RFP	Request for Proposal
RHC	Rural Health Clinic
BID	Beneficiary Identification Number
RSPD	Rehabilitative Services for Persons with Physical Disabilities
RSYC	Rehabilitative Services for Youth and Children
RTC	Residential Treatment Centers
RTP	Return to Provider
RTU	Residential Treatment Units
SBMH	School-Based Mental Health Services
SD	Spend Down
SFY	State Fiscal Year
SMB	Special Low-Income Qualified Medicare Beneficiaries
SNF	Skilled Nursing Facility

SSA	Social Security Administration
SSI	Supplemental Security Income
SURS	Surveillance and Utilization Review Subsystem
TCM	Targeted Case Management
TEA	Transitional Employment Assistance
TEFRA	Tax Equity and Fiscal Responsibility Act
TOS	Type of Service
TPL	Third Party Liability
UPL	Upper Payment Limit
UR	Utilization Review
VFC	Vaccines for Children
VRS	Voice Response System
Accommodation	A type of hospital room, e.g., private, semiprivate, ward, etc.
Activities of Daily Living (ADL)	Personal tasks that are ordinarily performed daily and include eating, mobility/transfer, dressing, bathing, toileting, and grooming
Adjudicate	To determine whether a claim is to be paid or denied
Adjustments	Transactions to correct claims paid in error or to adjust payments from a retroactive change
Admission	Actual entry and continuous stay of the beneficiary as an inpatient to an institutional facility
Affiliates	Persons having an overt or covert relationship such that any individual directly or indirectly controls or has the power to control another individual
Agency	The Division of Medical Services
Aid Category	A designation within SSI or state regulations under which a person may be eligible for public assistance
Aid to Families with Dependent Children (AFDC)	A Medicaid eligibility category
Allowed Amount	The maximum amount Medicaid will pay for a service as billed before applying beneficiary coinsurance or co-pay, previous TPL payment, spend down liability, or other deducted charges
American Medical Association (AMA)	National association of physicians
Ancillary Services	Services available to a patient other than room and board. For example: pharmacy, X-ray, lab, and central supplies
Arkansas Client Eligibility System (ACES)	A state computer system in which data is entered to update assistance eligibility information and beneficiary files
Attending Physician	<i>See Performing Physician.</i>
Automated Eligibility Verification Claims Submission (AEVCS)	Online system for providers to verify eligibility of beneficiaries and submit claims to fiscal agent
Base Charge	A set amount allowed for a participating provider according to specialty

Beneficiary	Person who meets the Medicaid eligibility requirements, receives an ID card, and is eligible for Medicaid services (formerly recipient)
Benefits	Services available under the Arkansas Medicaid Program
Billed Amount	The amount billed to Medicaid for a rendered service
Buy-In	A process whereby the state enters into an agreement with the Medicaid/Medicare and the Social Security Administration to obtain Medicare Part B (and part A when needed) for Medicaid beneficiaries who are also eligible for Medicare. The state pays the monthly Medicare premium(s) on behalf of the beneficiary.
Care Plan	<i>See Plan of Care (POC).</i>
Case Head	An adult responsible for an AFDC or Medicaid child
Categorically Needy	All individuals receiving financial assistance under the state's approved plan under Title I, IV-A, X, XIV, and XVI of the Social Security Act or in need under the state's standards for financial eligibility in such a plan
Centers for Medicare and Medicaid Services	Federal agency that administers federal Medicaid funding
Child Health Services	Arkansas Medicaid's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program
Children with Chronic Health Conditions (CHC)	A Title V Children with Special Health Care Needs Program administered by the Arkansas Division of Developmental Disabilities Services to provide medical care and service coordination to children with chronic physical illnesses or disabilities.
Claim	A request for payment for services rendered
Claim Detail	<i>See Line Item.</i>
Clinic	(1) A facility for diagnosis and treatment of outpatients. (2) A group practice in which several physicians work together
Coinsurance	The portion of allowed charges the patient is responsible for under Medicare. This may be covered by other insurance, such as Medi-Pak or Medicaid (if entitled). This also refers to the portion of a Medicaid covered inpatient hospital stay for which the beneficiary is responsible.
Contract	Written agreement between a provider of medical services and the Arkansas Division of Medical Services. A contract must be signed by each provider of services participating in the Medicaid Program.
Co-pay	The portion of the maximum allowable (either that of Medicaid or a third-party payer) that the insured or beneficiary must pay
Cosmetic Surgery	Any surgical procedure directed at improving appearance but not medically necessary
Covered Service	Service which is within the scope of the Arkansas Medicaid Program
Current Procedural Terminology	A listing published annually by AMA consisting of current medical terms and the corresponding procedure codes used for reporting medical services and procedures performed by physicians
Credit Claim	A claim transaction which has a negative effect on a previously processed claim.

Crossover Claim	A claim for which both Titles XVIII (Medicare) and XIX (Medicaid) are liable for reimbursement of services provided to a beneficiary entitled to benefits under both programs
Date of Service	Date or dates on which a beneficiary receives a covered service. Documentation of services and units received must be in the beneficiary's record for each date of service.
Deductible	The amount the Medicare beneficiary must pay toward covered benefits before Medicare or insurance payment can be made for additional benefits. Medicare Part A and Part B deductibles are paid by Medicaid within the program limits.
Debit Claim	A claim transaction which has a positive effect on a previously processed claim
Denial	A claim for which payment is disallowed
Department of Health and Human Services (HHS)	Federal health and human services agency
Department of Human Services (DHS)	State human services agency
Dependent	A spouse or child of the individual who is entitled to benefits under the Medicaid Program
Diagnosis	The identity of a condition, cause, or disease
Diagnostic Admission	Admission to a hospital primarily for the purpose of diagnosis
Disallow	To subtract a portion of a billed charge that exceeds the Medicaid maximum or to deny an entire charge because Medicaid pays Medicare Part A and B deductibles subject to program limitations for eligible beneficiaries
Discounts	<p>A discount is defined as the lowest available price charged by a provider to a client or third-party payer, including any discount, for a specific service during a specific period by an individual provider. If a Medicaid provider offers a professional or volume discount to any customer, claims submitted to Medicaid must reflect the same discount.</p> <p>Example: If a laboratory provider charges a private physician or clinic a discounted rate for services, the charge submitted to Medicaid for the same service must not exceed the discounted price charged to the physician or clinic. Medicaid must be given the benefit of discounts and price concessions the lab gives any of its customers.</p>
Duplicate Claim	A claim that has been submitted or paid previously or a claim that is identical to a claim in process
Durable Medical Equipment	Equipment that (1) can withstand repeated use and (2) is used to serve a medical purpose. Examples include a wheelchair or hospital bed.
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)	A federally mandated Medicaid program for eligible individuals under the age of twenty-one (21). See <i>Child Health Services</i> .
Education Accreditation	When an individual is required to possess a bachelor's degree, master's degree, or a Ph.D. degree in a specific profession. The degree must be from a program accredited by an organization that is approved by the Council for Higher Education Accreditation (CHEA).

Electronic Signature	An electronic or digital method executed or adopted by a party with the intent to be bound by or to authenticate a record, which is: (a) Unique to the person using it; (b) Capable of verification; (c) Under the sole control of the person using it; and (d) Linked to data in such a manner that if the data are changed the electronic signature is invalidated. An Electronic Signature method must be approved by the DHS Chief Information Officer or his or her designee before it will be accepted. A list of approved electronic signature methods will be posted on the state Medicaid website.
Eligible	(1) To be qualified for Medicaid benefits. (2) An individual who is qualified for benefits
Eligibility File	A file containing individual records for all persons who are eligible or have been eligible for Medicaid
Emergency Services	Inpatient or outpatient hospital services that a prudent layperson with an average knowledge of health and medicine would reasonably believe are necessary to prevent death or serious impairment of health and which, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services. Source: 42 U.S. Code of Federal Regulations (42 CFR) and §424.101.
Error Code	A numeric code indicating the type of error found in processing a claim also known as an "Explanation of Benefits (EOB) code" or a "HIPAA Explanation of Benefits (HEOB) code"
Estimated Acquisition Cost	The estimated amount a pharmacy actually pays to obtain a drug
Experimental Surgery	Any surgical procedure considered experimental in nature
Explanation of Medicaid Benefits (EOMB)	A statement mailed once per month to selected beneficiaries to allow them to confirm the Medicaid service which they received
Family Planning Services	Any medically approved diagnosis, treatment, counseling, drugs, supplies, or devices prescribed or furnished by a physician, nurse practitioner, certified nurse-midwife, pharmacy, hospital, family planning clinic, rural health clinic (RHC), Federally Qualified Health Center (FQHC), or the Department of Health to individuals of child-bearing age for purposes of enabling such individuals freedom to determine the number and spacing of their children.
Field Audit	An activity performed whereby a provider's facilities, procedures, records, and books are audited for compliance with Medicaid regulations and standards. A field audit may be conducted on a routine basis, or on a special basis announced or unannounced.
Fiscal Agent	An organization authorized by the State of Arkansas to process Medicaid claims
Fiscal Agent Intermediary	A private business firm which has entered into a contract with the Arkansas Department of Human Services to process Medicaid claims
Fiscal Year	The twelve-month period between settlements of financial accounts
Generic Upper Limit (GUL)	The maximum drug cost that may be used to compute reimbursement for specified multiple-source drugs unless the provisions for a Generic Upper Limit override have been met. The Generic Upper Limit may be established or revised by the Centers for Medicare and Medicaid Services (CMS) or by the State Medicaid Agency.

Group	Two (2) or more persons. If a service is a “group” therapy or other group service, there must be two (2) or more persons present and receiving the service.
Group Practice	A medical practice in which several practitioners render and bill for services under a single pay-to provider identification number
Healthcare Common Procedure Coding System (HCPCS)	Federally defined procedure codes
Health Insurance Claim Number	Number assigned to Medicare beneficiaries and individuals eligible for SSI
Hospital	An institution that meets the following qualifications: <ul style="list-style-type: none"> • Provides diagnostic and rehabilitation services to inpatients • Maintains clinical records on all patients • Has by-laws with respect to its staff of physicians • Requires each patient to be under the care of a physician, dentist, or certified nurse-midwife • Provides 24-hour nursing service • Has a hospital utilization review plan in effect • Is licensed by the State • Meets other health and safety requirements set by the Secretary of Health and Human Services
Hospital-Based Physician	A physician who is a hospital employee and is paid for services by the hospital
ID Card	An identification card issued to Medicaid beneficiaries and ARKids First-B participants containing encoded data that permits a provider to access the card-holder’s eligibility information
Individual	A single person as distinguished from a group. If a service is an “individual” therapy or service, there may be only one (1) person present who is receiving the service.
Inpatient	A patient, admitted to a hospital or skilled nursing facility, who occupies a bed and receives inpatient services.
In-Process Claim (Pending Claim)	A claim that suspends during system processing for suspected error conditions such as: all processing requirements appear not to be met. These conditions must be reviewed by the Arkansas Medicaid fiscal agent or DMS and resolved before processing of the claim can be completed. <i>See Suspended Claim.</i>
Inquiry	A request for information
Institutional Care	Care in an authorized private, non-profit, public, or state institution or facility. Such facilities include schools for the deaf, or blind and institutions for individuals with disabilities.
Instrumental Activities of Daily Living (IADL)	Tasks which are ordinarily performed on a daily or weekly basis and include meal preparation, housework, laundry, shopping, taking medications, and travel/transportation
Intensive Care	Isolated and constant observation care to patients critically ill or injured

Interim Billing	A claim for less than the full length of an inpatient hospital stay. Also, a claim that is billed for services provided to a particular date even though services continue beyond that date. It may or may not be the final bill for a particular beneficiary's services.
Internal Control Number (ICN)	The unique 13-digit claim number that appears on a Remittance Advice
International Classification of Diseases	A diagnosis coding system used by medical providers to identify a patient's diagnosis or diagnoses on medical records and claims
Investigational Product	Any product that is considered investigational or experimental and that is not approved by the Food and Drug Administration. The Arkansas Medicaid Program does not cover investigational products but does cover routine standard of care associated with qualifying clinical trials.
Julian Date	Chronological date of the year, 001 through 365 or 366, preceded on a claims number (ICN) by a two-digit-year designation. Claim number example: 03231 (August 19, 2003).
Length of Stay	Period of time a patient is in the hospital. Also, the number of days covered by Medicaid within a single inpatient stay.
Limited Services Provider Agreement	An agreement for a specific period of time not to exceed twelve (12) months, which must be renewed in order for the provider to continue to participate in the Title XIX Program.
Line Item	A service provided to a beneficiary. A claim may be made up of one (1) or more line items for the same beneficiary. Also called a claim detail.
Long Term Care (LTC)	An office within the Arkansas Division of Medical Services responsible for nursing facilities
Long Term Care Facility	A nursing facility
Maximum Allowable Cost (MAC)	The maximum drug cost which may be reimbursed for specified multi-source drugs. This term is interchangeable with generic upper limit.
Medicaid Provider Number	A unique identifying number assigned to each provider of services in the Arkansas Medicaid Program, required for identification purposes
Medicaid Management Information System (MMIS)	The automated system utilized to process Medicaid claims
Medical Assistance Section	A section within the Arkansas Division of Medical Services responsible for administering the Arkansas Medical Assistance Program
Medically Needy	Individuals whose income and resources exceed the levels for assistance established under a state or federal plan for categorically needy, but are insufficient to meet costs of health and medical services

Medical Necessity	All Medicaid benefits are based upon medical necessity. A service is “medically necessary” if it is reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that endanger life, cause suffering or pain, result in illness or injury, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction and if there is no other equally effective (although more conservative or less costly) course of treatment available or suitable for the beneficiary requesting the service. For this purpose, a “course of treatment” may include mere observation or (where appropriate) no treatment at all. The determination of medical necessity may be made by the Medical Director for the Medicaid Program or by the Medicaid Program Quality Improvement Organization (QIO). Coverage may be denied if a service is not medically necessary in accordance with the preceding criteria or is generally regarded by the medical profession as inappropriate or ineffective unless objective clinical evidence demonstrates circumstances making the service necessary.
Mis-Utilization	Any usage of the Medicaid Program by any of its providers or beneficiaries which is not in conformance with both State and Federal regulations and laws (including, but not limited to, fraud, abuse, and defects in level and quality of care)
National Drug Code	The unique 11-digit number assigned to drugs which identifies the manufacturer, drug, strength, and package size of each drug
National Provider Identifier (NPI)	A standardized unique health identifier for health care providers for use in the health care system in connection with standard transactions for all covered entities. Established by the Centers for Medicare & Medicaid Services, HHS, in compliance with HIPAA Administrative Simplification – 45 CFR Part 162.
Non-Covered Services	Services not medically necessary, services provided for the personal convenience of the patient or services not covered under the Medicaid Program
Nonpatient	An individual who receives services, such as laboratory tests, performed by a hospital, but who is not a patient of the hospital
Nurse Practitioner	A professional nurse with credentials that meet the requirements for licensure as a nurse practitioner in the State of Arkansas
Outpatient	A patient receiving medical services, but not admitted as an inpatient to a hospital
Over-Utilization	Any over usage of the Medicaid Program by any of its providers or beneficiaries not in conformance with professional judgment and both State and Federal regulations and laws (including, but not limited to, fraud and abuse)
Participant	A provider of services who: (1) provides the service, (2) submits the claim and (3) accepts Medicaid’s reimbursement for the services provided as payment in full
Patient	A person under the treatment or care of a physician or surgeon, or in a hospital
Payment	Reimbursement to the provider of services for rendering a Medicaid-covered benefit
Pay-to Provider	A person, organization, or institution authorized to receive payment for services provided to Medicaid beneficiaries by a person or persons who are a part of the entity

Pay-to Provider Number	A unique identifying number assigned to each pay-to provider of services (Clinic/Group/Facility) in the Arkansas Medicaid Program or the pay-to provider group's assigned National Provider Identifier (NPI). Medicaid reports provider payments to the Internal Revenue Service under the Employer Identification Number "Tax ID" linked in the Medicaid Provider File to the pay-to provider identification number.
Per Diem	A daily rate paid to institutional providers
Performing Physician	The physician providing, supervising, or both, a medical service and claiming primary responsibility for ensuring that services are delivered as billed
Person	Any natural person, company, firm, association, corporation, or other legal entity
Place of Service (POS)	A nationally approved two-digit numeric code denoting the location of the patient receiving services
Plan of Care	A document utilized by a provider to plan, direct, or deliver care to a patient to meet specific measurable goals; also called care plan, service plan, or treatment plan
Postpayment Utilization Review	The review of services, documentation, and practice after payment
Practitioner	An individual who practices in a health or medical service profession
Prepayment Utilization Review	The review of services, documentation, and practice patterns before payment
Prescription	A health care professional's legal order for a drug which, in accordance with federal or state statutes, may not be obtained otherwise; also, an order for a particular Medicaid covered service
Prescription Drug (RX)	A drug which, in accordance with federal or state statutes, may not be obtained without a valid prescription
Primary Care Physician (PCP)	A physician responsible for the management of a beneficiary's total medical care. Selected by the beneficiary to provide primary care services and health education. The PCP will monitor on an ongoing basis the beneficiary's condition, health care needs and service delivery, be responsible for locating, coordinating, and monitoring medical and rehabilitation services on behalf of the beneficiary, and refer the beneficiary for most specialty services, hospital care, and other services.
Prior Approval	The approval for coverage and reimbursement of specific services prior to furnishing services for a specified beneficiary of Medicaid. The request for prior approval must be made to the Medical Director of the Division of Medical Services for review of required documentation and justification for provision of service.
Prior Authorization (PA)	The approval by the Arkansas Division of Medical Services, or a designee of the Division of Medical Services, for specified services for a specified beneficiary to a specified provider before the requested services may be performed and before payment will be made. Prior authorization does not guarantee reimbursement.
Procedure Code	A five-digit numeric or alpha numeric code to identify medical services and procedures on medical claims
Professional Component	A physician's interpretation or supervision and interpretation of laboratory, X-ray, or machine test procedures

Profile	A detailed view of an individual provider's charges to Medicaid for health care services or a detailed view of a beneficiary's usage of health care services
Provider	A person, organization, or institution enrolled to provide and be reimbursed for health or medical care services authorized under the State Title XIX Medicaid Program
Provider Identification Number	A unique identifying number assigned to each provider of services in the Arkansas Medicaid Program or the provider's assigned National Provider Identifier (NPI), when applicable, that is required for identification purposes
Provider Relations	The activity within the Medicaid Program which handles all relationships with Medicaid providers
Quality Assurance	Determination of quality and appropriateness of services rendered
Quality Improvement Organization	A Quality Improvement Organization (QIO) is a federally mandated review organization required of each state's Title XIX (Medicaid) program. The QIO monitors hospital and physician services billed to the state's Medicare intermediary and the Medicaid program to assure high quality, medical necessity, and appropriate care for each patient's needs.
Railroad Claim Number	The number issued by the Railroad Retirement Board to control payments of annuities and pensions under the Railroad Retirement Act. The claim number begins with a one- to three-letter alphabetic prefix denoting the type of payment, followed by six (6) or nine (9) numeric digits.
Referral	An authorization from a Medicaid enrolled provider to a second Medicaid enrolled provider. The receiving provider is expected to exercise independent professional judgment and discretion, to the extent permitted by laws and rules governing the practice of the receiving practitioner, and to develop and deliver medically necessary services covered by the Medicaid program. The provider making the referral may be a physician or another qualified practitioner acting within the scope of practice permitted by laws or rules. Medicaid requires documentation of the referral in the beneficiary's medical record, regardless of the means the referring provider makes the referral. Medicaid requires the receiving provider to document the referral also, and to correspond with the referring provider regarding the case when appropriate and when the referring provider so requests.
Reimbursement	The amount of money remitted to a provider
Rejected Claim	A claim for which payment is refused
Relative Value	A weighting scale used to relate the worth of one (1) surgical procedure to any other. This evaluation, expressed in units, is based upon the skill, time, and the experience of the physician in its performance.
Remittance	A remittance advice
Remittance Advice (RA)	A notice sent to providers advising the status of claims received, including paid, denied, in-process, and adjusted claims. It includes year-to-date payment summaries and other financial information.
Reported Charge	The total amount submitted in a claim detail by a provider of services for reimbursement
Retroactive Medicaid Eligibility	Medicaid eligibility which may begin up to three (3) months prior to the date of application provided all eligibility factors are met in those months
Returned Claim	A claim which is returned by the Medicaid Program to the provider for correction or change to allow it to be processed properly

Routine Standard of Care Associated with Qualifying Clinical Trials	<p>Effective for items and services furnished on or after 01/01/2022, Medicaid covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicaid rules apply.</p> <p>Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicaid beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:</p> <p>The investigational item or service, itself unless otherwise covered outside of the clinical trial;</p> <ul style="list-style-type: none"> • Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and • Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial. <p>Routine costs in clinical trials include:</p> <ul style="list-style-type: none"> • Items or services that are typically provided absent a clinical trial (e.g., conventional care); • Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and • Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.
Sanction	Any corrective action taken against a provider
Screening	The use of quick, simple, medical procedures carried out among large groups of people to sort out apparently well persons from those who may have a disease or abnormality and to identify those in need of more definitive examination or treatment
Signature	The person's original signature or initials. The person's signature or initials may also be recorded by an electronic or digital method, executed, or adopted by the person with the intent to be bound by or to authenticate a record. An electronic signature must comply with Arkansas Code Annotated § 25-31-101-105, including verification through an electronic signature verification company and data links invalidating the electronic signature if the data is changed.
Single State Agency	The state agency authorized to administer or supervise the administration of the Medicaid Program on a statewide basis
Skilled Nursing Facility (SNF)	A nursing home, or a distinct part of a facility, licensed by the Office of Long-Term Care as meeting the Skilled Nursing Facility Federal/State licensure and certification regulations. A health facility which provides skilled nursing care and supportive care on a 24-hour basis to residents whose primary need is for availability of skilled nursing care on an extended basis.

Social Security Administration (SSA)	A federal agency which makes disability and blindness determinations for the Secretary of the HHS
Social Security Claim Number	The account number used by SSA to identify the individual on whose earnings SSA benefits are being paid. It is the Social Security Account Number followed by a suffix, sometimes as many as three (3) characters, designating the type of beneficiary (e.g., wife, widow, child, etc.).
Source of Care	A hospital, clinic, physician, or other facility which provides services to a beneficiary under the Medicaid Program
Specialty	The specialized area of practice of a physician or dentist
Spend Down (SD)	The amount of money a beneficiary must pay toward medical expenses when income exceeds the Medicaid financial guidelines. A component of the medically needy program allows an individual or family whose income is over the medically needy income limit (MNIL) to use medical bills to spend excess income down to the MNIL. The individual(s) will have a spend down liability. The spend down column of the remittance advice indicates the amount which the provider may bill the beneficiary. The spend down liability occurs only on the first day of Medicaid eligibility.
Status Report	A remittance advice
Supplemental Security Income (SSI)	A program administered by the Social Security Administration. This program replaced previous state administered programs for aged, blind, or individuals with disabilities (except in Guam, Puerto Rico, and the Virgin Islands). This term may also refer to the Bureau of Supplemental Security Income within SSA which administers the program.
Suspended Claim	An "In-Process Claim" which must be reviewed and resolved
Suspension from Participation	An exclusion from participation for a specified period
Suspension of Payments	The withholding of all payments due to a provider until the resolution of a matter in dispute between the provider and the state agency
Termination from Participation	A permanent exclusion from participation in the Title XIX Program
Third Party Liability (TPL)	A condition whereby a person or an organization, other than the beneficiary or the state agency, is responsible for all or some portion of the costs for health or medical services incurred by the Medicaid beneficiary (e.g., a health insurance company, a casualty insurance company, or another person in the case of an accident, etc.).
Utilization Review (UR)	The section of the Arkansas Division of Medical Services which performs the monitoring and controlling of the quantity and quality of health care services delivered under the Medicaid Program
Void	A transaction which deletes
Voice Response System (VRS)	Voice-activated system to request prior authorization for prescription drugs and for PCP assignment and change
Ward	An accommodation of five (5) or more beds
Withholding of Payments	A reduction or adjustment of the amounts paid to a provider on pending and subsequently due payments
Worker's Compensation	A type of Third-Party Liability for medical services rendered as the result of an on-the-job accident or injury to a beneficiary for which the employer's insurance company may be obligated under the Worker's Compensation Act

State/Territory: Arkansas**AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: 01/01/2022

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN: 2023-0009
Supersedes TN: New Page

Approval Date: 5/10/2023
Effective Date 01/01/2022

State/Territory:
Arkansas

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

*The state needs to check each assurance below.

Provided: X

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

 X Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

Qualifying Clinical Trial – Section 1905(gg)(2)

 X A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

Coverage Determination – Section 1905(gg)(3)

 X A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN: 2023-0009
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Approval Date: 5/10/2023
Effective Date 01/01/2022

Medicaid Section 1135 Waiver of SPA Submission Requirements Template

A state or territory may request a Section 1135 SPA process waiver(s) if the President has declared a major disaster or an emergency under the Stafford Act, or an emergency under the National Emergencies Act, and the Secretary of the Department of Health and Human Services has declared a public health emergency. The Centers for Medicare and Medicaid Services (CMS) will review the state's request to determine whether the section 1135 waiver request will help the state or territory ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicaid program.

Note: State Medicaid Agencies must request separate section 1135 waiver authority for each Emergency Relief SPA submitted. Agencies may not request section 1135 waiver authority for a SPA that includes any changes that restrict or limit payment, services, or eligibility, or otherwise burden beneficiaries and providers.

State: **Arkansas**

SPA Number: **2023-0009**

The agency seeks the following under section 1135(b)(5) of the Social Security Act (check all that apply):

- Submission Deadlines:** Pursuant to section 1135 (b)(5) of the Act, allows modification of the requirement to submit the SPA by the last day of a quarter, in order to obtain a SPA effective date during that quarter (applicable only for quarters in which the emergency or disaster declaration is in effect) - 42 C.F.R. § 430.20
- Public notice requirements:** Pursuant to section 1135 (b)(5) of the Act, allows a modification of public notice requirements that would otherwise be applicable to SPA submissions. These requirements may include those specified in 42 C.F.R. § 440.386 (Alternative Benefit Plans), 42 C.F.R. § 447.57(c) (premiums and cost sharing), and 42 C.F.R. § 447.205 (public notice of changes in statewide methods and standards for setting payment rates). Requested modifications are as follows:

- Tribal Consultation:** Pursuant to section 1135 (b)(5) of the Act, allows modification of the required Tribal consultation timelines specified in the Medicaid state plan per section 1902(a)(73) of the Act. Requested modifications are as follows:

PRA Disclosure Statement Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond

to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 # 75). Public burden for all of the collection of information requirements under this control number is estimated to take up to 1 hour per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

PROPOSED

SMD # 21-005

**RE: UPDATED: Mandatory Medicaid
Coverage of Routine Patient Costs
Furnished in Connection with
Participation in Qualifying Clinical
Trials**

April 13, 2022

Dear State Medicaid Director:

The Center for Medicaid and CHIP Services (CMCS) is issuing this State Medicaid Director Letter outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to states and territories with respect to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial on or after January 1, 2022.

Background

Historically, the Medicaid statute and its implementing regulations did not specify a clear requirement for coverage of routine costs associated with clinical trials, even if those routine costs were for items and services that ordinarily would be covered by a state's Medicaid program. Therefore, states (including the territories, unless otherwise noted) have had the flexibility to limit or exclude coverage for routine costs associated with clinical trials by defining medical necessity criteria, provider qualifications and limits on the amount, duration, and scope of services. Some states historically have determined that all services provided to a Medicaid beneficiary participating in a clinical trial were considered "experimental," and therefore not covered by Medicaid. On the other hand, we explained in guidance regarding dually eligible Medicare and Medicaid beneficiaries issued on October 30, 2000, that Medicaid may pay for otherwise covered services that are routine costs for clinical trials, provided all applicable requirements are met, including third party liability requirements.¹ To date, this State Medicaid Director Letter is the only guidance we have issued addressing Medicaid coverage of routine costs for clinical trials.

Mandatory Services

Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act (the Act), by adding to the definition of medical assistance a new benefit at section 1905(a)(30) for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries

¹ <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd103000.pdf>

in qualifying clinical trials, subject to further provisions in a new section 1905(gg). Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage also referred to as alternative benefit plans, or ABPs with respect to items and services furnished on or after January 1, 2022.

Pursuant to section 1905(a)(30) and 1905(gg)(1) of the Act, the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act. Such routine services and costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service. Some examples of routine costs in a clinical trial could include otherwise covered physician services or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

Items and Services Not Covered Under the New Mandatory Benefit²

As described under section 1905(gg)(1) of the Act, routine patient costs within the meaning of section 1905(a)(30) of the Act do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

Similarly, routine patient cost does not include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project. For example, if a beneficiary has a condition that typically requires monitoring through an annual medical imaging scan and the beneficiary is participating in a clinical trial with a protocol that requires monthly medical imaging scans only to collect data on the effects of the investigational item or service, the additional monthly scans for purposes of clinical trial data collection would not be included in the beneficiary's routine patient costs to the extent they are not used for the direct clinical management of the beneficiary or are not otherwise covered under the state plan, waiver, or demonstration project.

Qualifying Clinical Trial

Section 1905(gg)(2) of the Act defines the term “qualifying clinical trial” for purposes of section 1905(a)(30) of the Act as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition, and is described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act. Therefore, to meet the statutory definition, the “qualifying clinical trial” must also be one or more of the following:

² This section has been updated.

- A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:
 - The National Institutes of Health (NIH);
 - The Centers for Disease Control and Prevention (CDC);
 - The Agency for Health Care Research and Quality (AHRQ);
 - The Centers for Medicare & Medicaid Services (CMS);
 - A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs;
 - A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants³;
- A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
 - The Department of Energy
 - The Department of Veterans Affairs
 - The Department of Defense;
- A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or
- A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

Coverage Determination Requirements

As provided in section 1905(gg)(3) of the Act, a determination with respect to coverage under section 1905(a)(30) of the Act for a beneficiary participating in a qualifying clinical trial must be expedited and completed within 72 hours and must be made without regard to the geographic location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the qualifying clinical trial. This means that states must review and adjust, as necessary, any existing utilization management processes to ensure a coverage determination is completed within 72 hours. We interpret the geographic location or network affiliation requirement to mean that a state or territory may not deny coverage of routine patient costs based on where the clinical trial is conducted, including out of state, or based on whether the principal investigator or provider treating the beneficiary in connection with the clinical trial is outside of the network of the beneficiary's Medicaid managed care plan, if applicable. In the latter case, if a positive coverage determination is made, the state may either pay for the covered services on a fee-for-service basis as outside the scope of the managed care contract or require the managed care plan to cover the services out-of-network when the coverage requirement applies.

³ While Section 210 of the Consolidated Appropriations Act references a qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants, NIH has clarified that no such guidelines exist.

Coverage must also be based on an attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator and be made using a streamlined uniform form developed for state use by the Secretary, which is currently under development, and that will include the option to reference information regarding the qualifying clinical trial that is publicly available on a website maintained by the Secretary, such as clinicaltrials.gov. Further, coverage determinations must not require submission of the protocols of the qualifying clinical trial or any other documentation that may be proprietary or determined by the Secretary to be burdensome.

States that use a managed care delivery system must either cover the costs as required outside the scope of its managed care contracts or specify the applicable requirements in their managed care plan contracts and adjust capitation rates as appropriate for items and services furnished to Medicaid beneficiaries on or after January 1, 2022.

Exemption of Additional Expenditures from Payment Limits for Territories

Section 210 amended section 1108(g)(4) of the Act to include a new subparagraph (B), providing that expenditures for routine patient costs, as defined in section 1905(gg)(1), will not be taken into account in applying the allotment caps for the territories under 1108(f) of the Act. This provision is also effective for items and services furnished on or after January 1, 2022.

Exception for State Legislation⁴

States that require legislative changes to implement coverage of routine patient costs as specified in section 1905(a)(30) of the Act will not be regarded as failing to comply with the requirements newly added by section 210, solely on the basis of their failure to meet these requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the state legislature that begins after December 27, 2020, the date of enactment of the Consolidated Appropriations Act, 2021. For states that have a two-year legislative session, each year of the session is considered a separate regular session of the state legislature for purposes of this exception.

Essentially, this provision provides for an extension to the required start date of the new coverage requirement if the only reason the state cannot come into compliance by January 1, 2022 is due to lack of state legislation that is needed to meet the requirement. Not all states will be able to seek this extension, because it depends on the timing of the state's first regular legislative session that began after the date of enactment of the Consolidated Appropriations Act, 2021. If the Secretary determines that state legislation is needed to bring the state plan into compliance with the new coverage requirement, the Secretary will not consider the state to be out of compliance with the new coverage requirement solely on the basis of a failure to enact the required state legislation before the first day of the first calendar quarter beginning after the close of the first regular session of the state's legislature that begins after December 27, 2020. If a state's first regular legislative session beginning after December 27, 2020, was the calendar year that began on January 1, 2021, and ended on December 31, 2021, the state would not be able to seek this extension because it would have had only until December 31, 2021, to enact any required legislation, and the first day of the first calendar quarter that begins after that date is January 1, 2022 – the effective date for this provision.

⁴ This section has been updated.

If, however, a state's first regular legislative session beginning after December 27, 2020, does not end until on or after January 1, 2022, and the Secretary determines that legislation was necessary to meet the new coverage requirement, but the necessary legislative authorization was not obtained, the state could seek to delay compliance with the new coverage requirement until the first day of the first calendar quarter after the legislative session ends. Such a state is expected to come into compliance with the new coverage requirement by the first day of the first calendar quarter after the end of the legislative session. If a state has a two-year legislative session, each year of the session shall be considered to be a separate regular session of the state legislature for purposes of this extension. This means that a state would not have a longer extension if it has a two-year legislative session; such a state is treated like a state with a one-year legislative session, and any applicable extension ends on the first day of the first calendar quarter following the end of the first year of the two-year session.

CMS will grant an extension based on legislative delay only if the timing of the state's legislative session is the only reason that a state cannot meet the requirement, and only when the first regular legislative session that began after December 27, 2020, ends on or after January 1, 2022, as discussed above. States should submit requests for the legislative delay extension on or before January 1, 2022, to the Regional SPA/Waiver mailbox that is currently used for Medicaid SPA submissions. If the state is participating in the pilot for the new "One CMS Portal," the request for the legislative delay extension should be submitted via the portal. The request should include documentation to support that the state's first regular legislative session that began after December 27, 2020, did not end until on or after January 1, 2022, that state legislation is needed to come into compliance with the new coverage requirement, and that the legislative delay is the only reason the state cannot come into compliance as of January 1, 2022. States may, but are not required to, use the following format for their legislative delay extension submission:

_____ [Insert name of state] requests an exception based on the need for legislative authority to cover the benefit described in section 1905(a)(30) of the Social Security Act, and submits documentation to support that the state's first regular legislative session that began after December 27, 2020, will not end until on or after January 1, 2022. [Describe the documentation that is attached or that accompanies the request and include information about the state's legislative calendar so CMS can determine the state's compliance date.]

States that are granted an extension due to legislative delay will still need to follow the state plan amendment (SPA) submission requirements below and submit a SPA consistent with the extended compliance deadline.

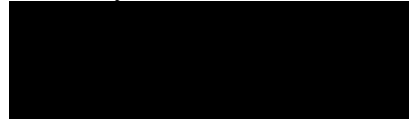
State Plan Amendments

States will need to submit a new SPA at section 3.1A and 3.1B to effectuate this new coverage requirement under section 1905(a)(30), effective with respect to items and services furnished on or after January 1, 2022, unless the exception for state legislation described above applies. Additionally, a state will need to submit a SPA at section 4.19(b) to describe payment methodologies that will be used to pay service providers. Changes in methods and standards for payments associated with the 4.19(b) SPA are subject to the public notice requirements at 42 CFR §447.205, which must be issued at least one day prior to the effective date of the proposed

changes. These SPAs are needed to ensure that the state is appropriately covering and paying for routine patient costs of items and services for beneficiaries enrolled in qualifying clinical trials, as newly required under amendments made by section 210. Similarly, states will need to submit ABP SPAs to add this coverage to their ABPs. ABP SPA public notice requirements under 42 CFR §440.386 must be followed. CMS is available for technical assistance on SPA submissions. States using a managed care delivery system should also evaluate their managed care plan contracts and capitation rates to determine the need for potential revisions with respect to items and services furnished to Medicaid beneficiaries on or after January 1, 2022, such as whether to carve out such costs so the state would provide them outside the scope of the contract or include appropriate amounts in capitation rates to cover an obligation to cover the out of network costs.

For additional information, please contact Kirsten Jensen, Director, Division of Benefits and Coverage, at Kirsten.Jensen@cms.hhs.gov.

Sincerely,

A solid black rectangular box used to redact the signature of Daniel Tsai.

Daniel Tsai
Deputy Administrator and Director

RULES SUBMITTED FOR REPEAL

Rule #1: Crippled Children's State Plan

Rule #2: PUB-407- Notice of Privacy Practices

FINAL RULE
Change

ARKANSAS STATE PLAN
CRIPPLED CHILDREN'S SECTION

(Revised April 1985)

REPEALED

STATE OF ARKANSAS
Department of Human Services
Division of Social Services
Crippled Children's Section
P. O. Box 1437
Little Rock, Arkansas 72203

Phone: 371-2277

REPEALED

ARKANSAS CRIPPLED CHILDREN'S SECTION
STATE PLAN
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REPEALED

STATE PLAN

ARKANSAS CRIPPLED CHILDREN'S SECTION

CRIPPLED CHILD - DEFINITION

- * A crippled child is an individual under 18 years of age who has a crippling physical defect (either congenital or acquired) or other condition calculated to produce such physical defects which may be benefitted by surgical or other medical procedures to the extent that the patient is able to achieve maximum physical and social function. In the cases of individuals with cystic fibrosis, CCS will provide both inpatient and outpatient treatment at Arkansas Children's Hospital for those 18 and older. Medication will be authorized up to the individuals 21st birthday. No medication or equipment will be purchased for the 21 and over age group unless special funds are provided.

Crippled Children's Services does not assume the responsibility for patients who have already been physically restored to the maximum extent possible or to those who require basically custodial care or institutionalized persons.

LEGAL BASIS

The legal basis for the operation of the Crippled Children's Program is vested in Arkansas Law 280 of 1939.

REPEALED

DESIGNATION OF STATE AGENCY

The Arkansas State Legislature has designated Arkansas Social Services, a Division of the Department of Human Services, with the responsibility for administration of Crippled Children's Services.

SEPARATE ORGANIZATIONAL UNIT

Crippled Children's Services is a separate organizational unit in the Office of Medical Services, Division of Social Services, Department of Human Services.

Crippled Children's services are provided statewide.

REVIEW AND APPROVAL OF STATE PLAN

The CCS State Plan is submitted to the State Health Planning Development Agency for review and approval.

Pursuant to Act 14 of 1965, the State Plan is filed through the Administrative Procedures, as required in the legislation.

FUNDING

CCS is funded by state and federal funds. Federal funds are provided under Title V, and the allotment is based on a formula for a fixed amount. The state funds are appropriated by the Arkansas Legislature and used to provide direct medical services for eligible children.

MEDICAL DIRECTOR

The Medical Director will be a physician licensed to practice in the State of Arkansas.

MERIT SYSTEM - PERSONNEL

All employees of the Crippled Children's Section will be certified by the Arkansas Merit System.

STANDARDS RELATING TO PERSONNEL AND FACILITIES

Health professionals providing patient services and diagnostic and treatment facilities for CCS' patients are required to meet state licensing or certification laws, and are in substantial accordance with national standards, as accepted by the Secretary. Standards prescribed by the Secretary.

REPEALED

USE OF SUBPROFESSIONAL STAFF AND VOLUNTEERS

Crippled Children's Section will make an effort to train and use subprofessional staff, with a particular emphasis on employment of persons of low income. Volunteers are used at many CCS field clinics.

USE OF OPTOMETRIST

Where payment is authorized under the plan for services which an optometrist is licensed to perform, the individual for whom such payment is authorized may, to the extent practicable, obtain such service from an optometrist licensed to perform such services, except where such services are rendered in a clinic, or another appropriate institution which does not have an arrangement with optometrists so licensed.

COOPERATION WITH OTHER AGENCIES AND GROUPS

Crippled Children's Services will cooperate and coordinate with medical, health, nursing, educational, welfare groups and organizations, and with any State agency charged with administering state laws providing for vocational rehabilitation of physically handicapped children.

CONFIDENTIAL INFORMATION

All information obtained by the County Social Services and Central Office staff, as to personal facts and circumstances relating to patients, will be held to be confidential and will not be divulged without the individual's or parent's signed consent, except as will be necessary to provide appropriate treatment to individual patients.

EARLY IDENTIFICATION OF CHILDREN IN NEED OF HEALTH CARE SERVICES

Crippled Children's Services recognizes the importance of early identification of children in need of health care services to correct or ameliorate defects or chronic conditions that would lead to crippling.

An informative pamphlet describing the services available through CCS has been distributed throughout the state. Specific case finding activities are accomplished through referrals from private physicians, the local health department, schools, and EPSDT screening.

REFERRALS FOR CRIPPLED CHILDREN'S SERVICES

Any interested person or organization may refer a child for diagnosis and recommendation for treatment.

If possible, the referring party should submit a brief abstract of medical history to assist in routing the patient for examination and/or treatment, and in determining eligibility.

A release from the previous attending physician may be requested, but this release is not required for a preliminary examination and is not mandatory before active treatment is instituted.

APPLICATION FOR CRIPPLED CHILDREN'S SERVICES

- * Applications for Crippled Children's Services are completed by a worker in the County Social Services Office in the child's county of residence or by a hospital social worker who has been provided with the forms and instructed in filling them out.
- * It is required that a new reapplication be completed annually to review the family's financial and social status. This will be sent to the family to be filled out and returned to the CCS Office. If the financial status has changed, new financial verification must be provided to CCS by the close of the second month of the change. In the event of a move to another county, a reapplication must be completed within one month of the move. All changes of address must be reported immediately to the CCS Office.

The parent, legal guardian, or emancipated individuals under 18 years of age must complete, or supply information to complete the application. The signature of the parent, guardian, or emancipated individual under 18 constitutes authority for the Division to determine eligibility and to arrange for any recommended services or treatment within the scope of the Program.

APPLICATION FOR CRIPPLED CHILDREN'S SERVICES (continued)

In addition to the SS-800, two (2) signed SS-81's (Consent for Release of Information) must also be secured and forwarded, along with the original SS-800, to the Crippled Children's Services Section. The worker must sign as witness on the SS-800 and SS-81's.

If the child is a Medicaid recipient at the time a CCS Application is made, the child's Medicaid ID number must be entered on the application. If the applicant is not certified for Medicaid at the time the CCS Application is taken, they must be screened for potential Medicaid eligibility.

The Social Service Worker in the county office must forward the CCS Application to CCS Central Office for CCS' eligibility determination and notify CCS of the disposition of the Medicaid Application, including the amount of unmet liability necessary to qualify for Spend-Down on applicants who are not Medicaid eligible.

FAILURE TO PROVIDE REQUESTED INFORMATION/DOCUMENTATION

An applicant who refuses to complete a Medicaid Application when so instructed, or provide necessary information and/or documentation to determine Medicaid eligibility will not be accepted for CCS coverage. The applicant will be given thirty (30) days to supply requested information before the application is denied.

ELIGIBILITY FOR CRIPPLED CHILDREN'S SERVICES

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* AGE. A child must be under 18 years of age. All expenditures made by the Crippled Children's Services on behalf of a child, must be for services received prior to his/her 18th birthday (Unless CF). The single exception for this age limit is made for individuals with Cystic Fibrosis (CF). Individuals with a diagnosis of CF who are financially eligible for services, will be accepted for limited care after their 18th birthday. Inpatient and outpatient treatment at Arkansas Children's Hospital (ACH), and up until their 21st birthday, medication and equipment. After their 21st birthday, neither medication or equipment will be purchased unless special funds are provided for this purpose.

RESIDENCE. All children on the Crippled Children's Program must be residents of Arkansas. Patients moving into the state from out-of-state, where they have been on a Crippled Children's Program, will be required to complete an application for the Arkansas Program.

FINANCIAL. A child is considered financially eligible for CCS if his parent, spouse, legal guardian, or the family unit* meets the financial criteria under CCS' sliding income eligibility scale. Consideration is given to available income in connection with recognized standards of need and the extent to which available resources can be used to meet the current cost of medical care. The probable cost of the child's treatment will be a significant factor in determining financial eligibility.

A sliding scale established by CCS and updated periodically as budget permits will be the basis for financial eligibility. This sliding scale will also determine the level of CCS participation. In some situations, CCS will require the family to pay for specific portions of the child's treatment or care.

ELIGIBILITY FOR CRIPPLED CHILDREN'S SERVICES

FINANCIAL (continued)

The Central Office will review each case on it's own merits. Neither the local Social Services Office, or the hospital staff who take applications, will pre-screen these applicants. Each person is eligible to make an application.

MEDICAL ELIGIBILITY. To qualify medically for services under the auspices of the Crippled Children's Program, a patient must meet the definition of a crippled child. In addition, his medical need, must be such as to require the services of a physician or surgeon with specialized skills beyond the level of care provided by the family physician. If the available information indicates that the applicant may be eligible for medical services within the scope of the Program, an invitation will be sent for the child to secure a diagnostic examination at an appointed time and place in the geographic area in which he/she lives, or an invitation will be issued to a specialized clinic. Medical eligibility is determined following the report of such examination. Final determination of eligibility for treatment through CCS is made after a final diagnosis has been established. Acceptance of a patient for diagnostic coverage or treatment coverage will be considered separately. Scaled financial criteria considering projected treatment cost and criteria for the degree of medical severity must be satisfied to establish treatment coverage after the diagnostic requirements are met.

The medically crippled patient will be treated by CCS only for his/her eligible condition. Directly related medical or surgical services may be approved when necessary to prepare the patient to receive the authorized CCS treatment or when such services may enhance or preserve the recommended treatment.

An unrelated medical condition not classified as "eligible" in it's own right does not become eligible because the patient is accepted for treatment of another condition that is eligible.

*Definition of family unit for eligibility purposes: Those to be counted in the family unit will be any person(s) under age 18, living in the same household and depending upon the casehead for his/her livelihood.

OTHER FACTORS IN DETERMINING ELIGIBILITY

The acceptance of any case for treatment is dependent upon additional factors relating more particularly to the individual child. These factors include:

- Reasonable expectation of cure or restoration of useful function or facilitation of dependent care for handicapped child.
- Availability of accepted form of treatment.
- Priority of need for medical care as compared with other children potentially eligible for the program within the limitation of funds available.

LEGEND

A	Minor correctable conditions requiring services of a physician specialist.
B	Conditions requiring bracing, surgery, long-term medications, possibly PT, OT, ST.
C	Conditions requiring long-term outpatient treatment, bracing, shoes, surgery, urology supplies, medications, special diets, appliances, PT, OT, ST.
D	Conditions are the same as C, but the administration makes a decision once the CCS financial resources and the estimated cost of the illness in ratio to a family's total yearly income & their capability to pay have been reviewed.
E	Conditions are the same as C, but the child is accepted for services which do not constitute any financial outlay from CCS, such as case management, CCS clinics and loan of equipment.

FINANCIAL ELIGIBILITY

(FROM CCS STATE PLAN REVISED FEBRUARY 1981)

A child is considered needy for CCS if his parent, spouse, legal guardian, or family unit* is unable financially to provide essential medical care in whole or in part. Consideration is given to available income in connection with recognized standards of need and the extent to which available resources can be used to meet the current cost of medical care. The probable cost of the child's treatment will be a significant factor in determining financial eligibility.

The Central Office will review each case on its own merits. The local Social Services Office will not pre-screen these applications. Each person is eligible to make an application.

A sliding scale established by CCS and updated periodically, as budget permits, will be the basis for financial eligibility. This sliding scale will also determine the level of CCS' participation. In some situations, CCS will require the family to pay for specific portions of the child's treatment or care.

*Definition of family unit for eligibility purposes: Those to be counted in the family unit will be any person(s) under age 18, living in the same household and depending upon the casehead for his/her livelihood.

ARKANSAS DEPARTMENT
OF HUMAN SERVICES
NOTICE OF PRIVACY
PRACTICES

Updated: December 08, 2016

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Department of Human Services (DHS) provides many types of services, such as health and social services. DHS staff must collect information about you to provide these services. DHS knows that information collected about you and your health is private. DHS and all associates at all locations are required by law to maintain the privacy of patients' Protected Health Information (PHI) and to provide individuals with the Notice of the legal duties and privacy practices with respect to PHI.

DHS is required to give you a notice of our privacy practices for the information we collect and keep about you. We are required to abide by the terms of this Notice. We reserve the right to change the terms of this Notice and these new term will affect all PHI that we maintain at the

Revised notices may be picked up at any office or online at:
[http://humanservices.arkansas.gov/publicationDocs/PUB-407.p](http://humanservices.arkansas.gov/publicationDocs/PUB-407.pdf)

In certain circumstances, DHS may use and disclose PHI without written consent.

For Treatment: We will use your health information to provide you with medical treatment or services. We will disclose PHI to doctors, nurses, technicians, students in health care training programs, or other personnel who are involved in taking care of you. For example, a doctor treating you for a broken leg may need to know if you have diabetes because that might slow the healing process. In addition, he/she may need to tell the dietitian to arrange for appropriate meals. Different departments of DHS may share health information about you in order to coordinate the services you need, such as prescriptions, lab work and x-rays. We may disclose health information to people outside DHS who provide your medical care like nursing homes or other doctors. We may tell your health insurer about treatment your doctor has recommended to obtain prior approval to determine whether your plan will cover the cost of the treatment. We may contact you to provide reminders of appointments.

For Payment: DHS will use and disclose PHI to other health care providers to assist in payment of your bills. For example, we will use it to send bills and collect payment from you, your insurance company, or other payers, such as Medicare, for the care, treatment, and other related services you receive.

For Health Care Operations: DHS may use or disclose your PHI for the purpose of our business operations. These uses and disclosures are necessary to insure our patients receive quality care. For example, we may use PHI to review the quality of our treatment and services, and to evaluate the performance of staff, contracted employees and students in caring for you.

Business Associates: We may use or disclose your PHI to an outside company that assists us in operating our health system and performs various services for us. This includes, but is not limited to, auditing, accreditation, legal services, data processing, and consulting services. These outside companies are called "business associates" and contract with us to keep PHI received confidential in the same way we do. These companies may create or receive PHI for us.

For Public Health Activities: DHS may use or disclose your PHI for public health activities that are permitted or required by law. For example, we may disclose PHI in certain circumstances to control or prevent a communicable disease; injury; disability; to report births and deaths; and for public health oversight activities or interventions. We may disclose PHI to the Food and Drug Administration (FDA) to report adverse events or product defects, to track products, to enable product recalls, or to conduct post-market surveillance as required by law or to state or federal government agencies. We may disclose PHI, if directed by a public health authority, to a foreign government agency that is collaborating with the public health authority.

For Health Oversight Activities: DHS may disclose PHI to a health oversight agency for activities authorized by law. For example, these oversight activities include audits; investigations; inspections; licensure; disciplinary actions; or civil, administrative, criminal, or other proceedings or actions. Agencies seeking this information include government agencies that regulate the health care system, such as accreditation programs, other regulatory programs, and government agencies that ensure compliance with civil rights laws.

As Required by Law and For Law Enforcement: DHS will use and disclose PHI when required or permitted by federal, state, and local laws, or by court order. Under certain conditions, we may disclose PHI to law enforcement officials for law enforcement purposes. For example, these may include (1) responding to a court order or similar process; (2) as necessary to locate or identify a suspect, fugitive, material witness, or missing person; (3) reporting suspicious wounds, burns or other physical injuries; or (4) as relating to the victim of a crime.

Lawsuits and Other Legal Proceedings: DHS may disclose PHI in the course of any judicial or administrative proceeding or in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized.) If certain conditions are met, we may disclose your PHI in response to a subpoena, a discovery request, or other lawful process.

Abuse or Neglect: We may disclose your PHI to a government authority that is authorized by law to receive reports of abuse, neglect, or domestic violence. Additionally, as required by law, if we believe you have been a victim of

abuse, neglect, or domestic violence, we may disclose your PHI to a governmental entity authorized to receive it.

For Government Programs: DHS may use and disclose PHI for public benefits under other government programs. For example, DHS may disclose PHI for the determination of Supplemental Security Income (SSI) benefits.

To Avoid Harm: DHS may disclose PHI to law enforcement in order to avoid a serious threat to the health and safety of a person or the public.

For Research: DHS may use and share your health information for certain kinds of research. For example, a research project may involve comparing the health and recovery of patients who received one medication to those who received another for the same condition. All research projects, however, are subject to a special approval process. In some instances, the law allows us to do some research using your PHI without your approval.

Family Members and Friends: If you agree, do not object, or we reasonably infer that there is no objection, DHS may disclose PHI to a family member, relative, or other person(s) whom you have identified to be involved in your health care or the payment of your health care. If you are not present, or are incapacitated, or it is an emergency or disaster relief situation, we will use our professional judgment to determine whether disclosing limited PHI is in your best interest. We may disclose PHI to a family member, relative, or other person(s) who was involved in the health care or the payment for health care of a deceased individual if not inconsistent with prior expressed preferences of the individual known to DHS. You also have the right to request a restriction on our disclosure of your PHI to someone who is involved in your care.

Coroners, Medical Examiners, and Funeral Directors: DHS may release your PHI to a coroner or medical examiner. For example, this may be necessary to identify a deceased person or to determine cause of death. We may also release your PHI to a funeral director, as necessary, to carry out his/her duties.

Organ Donations: We will disclose PHI to organizations that obtain, bank, or transplant organs or tissues.

National Security and Protection of the President: DHS may release your PHI to an authorized federal official or other authorized persons for purposes of national security, for providing protection to the President, or to conduct special investigations, as authorized by law.

Correctional Institution: If you are an inmate of a correctional institution or under the custody of a law enforcement officer, DHS may release your PHI to them. The PHI released must be necessary for the institution to provide you with health care, protect your or other's health and safety, or for the safety and security of the correctional institution.

Military: If you are a veteran or a current member of the armed forces, DHS

REPEALED

may release your PHI as required by military command or veteran administration authorities.

Workers' Compensation: DHS will disclose your health information that is reasonably related to a worker's compensation illness or injury following written request by your employer, worker's compensation insurer, or their representative.

Employer Sponsored Health and Wellness Services: We maintain PHI about employer sponsored health and wellness services we provide our patients, including services provided at their employment site. We will use the PHI to provide you medical treatment or services and will disclose the information about you to others who provide you medical care.

Shared Medical Record/Health Information Exchanges: We maintain PHI about our patients in shared electronic medical records that allow the DHS associates to share PHI. We may also participate in various electronic health information exchanges that facilitate access to PHI by other health care providers who provide you care. For example, if you are admitted on an emergency basis to another hospital that participates in the health information exchange, the exchange will allow us to make your PHI available electronically to those who need it to treat you.

Sponsor of the Plan: DHS may disclose PHI to the sponsor of a group health plan or a health insurance issuer.

Other Uses and Disclosures of PHI

Other uses and disclosures of your PHI that are not described above will be made only with your written authorization. If you provide DHS with an authorization you may revoke it in writing, and this revocation will be effective for future uses and disclosures of PHI. The revocation will not be effective for information that we have used or disclosed in reliance on the authorization.

For example, most uses and disclosures of psychotherapy notes, uses and disclosures of PHI for marketing purposes, and disclosures that constitute the sale of PHI require your written authorization.

Your PHI Privacy Rights

Right to Revoke Permission: If you are asked to sign an authorization to use or disclose PHI, you can cancel that authorization at any time. You must make the request in writing. This will not affect PHI that has already been shared.

The Right to Access to Your Own Health Information: You have the right to inspect and copy most of your protected health information for as long as we maintain it as required by law. We may require that you make this request in writing. We may charge you a nominal fee for each page copied and postage if applicable. You also have the right to ask for a summary of this information. If you request a summary, we may charge you a nominal fee.

Right to Request Restrictions: You have the right to request certain restrictions of our use or disclosure of your PHI. We are not required to agree to your request in most cases. But if DHS agrees to the restriction, we will comply with your request unless the information is needed to provide you emergency treatment. DHS will agree to restrict disclosure of PHI about an individual to a health plan if the purpose of the disclosure is to carry out payment or health care operations and the PHI pertains solely to a service for which the individual, or a person other than the health plan, has paid DHS for in full. For example, if a patient pays for a service completely out of pocket and asks DHS not to tell his/her insurance company about it, we will abide by this request. A request for restriction should be made in writing. To request a restriction you must contact the DHS Privacy Officer. We reserve the right to terminate any previously agreed-to restrictions (other than a restriction we are required to agree to by law). We will inform you of the termination of the agreed-to restriction and such termination will only be effective with respect to PHI created after we inform you of the termination.

Right to Request Confidential Communications: You may request in writing that we communicate with you in an alternative manner or at an alternative location. For example, you may ask that all communications be sent to your work address. Your request must specify the alternative means or location for communication with you. It also must state that the disclosure of all or part of the PHI in a manner inconsistent with your instructions would put you in danger. We will accommodate a request for confidential communications that is reasonable and that states that the disclosure of all or part of your protected health information could endanger you.

Right to Inspect and Copy: You have the right to inspect and receive a copy of your PHI about you that may be used to make decisions about your health. A request to inspect your records may be made to your nurse or doctor while you are an inpatient or to the DHS Privacy Officer while an outpatient. For copies of your PHI, requests must go to the DHS Privacy Officer. For PHI in a designated record set that is maintained in an electronic format, you can request an electronic copy of such information. There may be a charge for these copies.

Right to Amend: You may ask us to amend the information, for as long as DHS maintains the information. Requests for amending your PHI should be made to the DHS Privacy Officer. The DHS personnel who maintain the information will respond to your request within 60 days after you submit the written amendment request form. If we deny your request, we will provide you a written explanation. You may respond with a statement of disagreement to be appended to the information you wanted amended. If we accept your request to amend the information, we will make reasonable efforts to inform others, including people you name, of the amendment and to include the changes in any future disclosures of that information.

Right to Get a List of Disclosures: You have the right to ask DHS for a list of disclosures made after April 14, 2003. You must make the request in writing. With some exceptions, you have the right to receive an accounting of certain disclosures of your PHI. A nominal fee will be charged for the record search.

Right to Get a Paper Copy of this Notice: You have the right to ask for a paper copy of this notice at any time

Right to File a Complaint: You have the right to file a complaint if you feel DHS has violated your rights. To do so, contact the Privacy Officer by using the information below. You can file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights by using the contact information below. We will not retaliate against you for filing a complaint.

Right to be notified of a Breach: You have the right to be notified in the event that we (or one of our Business Associates) discover a breach of unsecured protected health information involving your medical information.

See the contact information below:
To View, Inspect, Copy, or Amend your PHI,
To Request Confidential Communications,
To Request an accounting (list) of disclosures, To Request Restrictions,
To Revise Authorizations, or
To File a Complaint.

This privacy notice is also available at:
<http://humanservices.arkansas.gov/publicationDocs/PUB-407.pdf>

You may contact your local DHS office or the DHS Privacy Officer at the address listed below.

DHS Privacy Officer
Arkansas Department of Human Services
P.O. Box 1437, Suite S260
Little Rock, Arkansas 72203-1437 Telephone: 1-855-283-0835
TDD: (501) 682-8911
Email: DHSPrivacyOfficer@dhs.arkansas.gov

Office for Civil Rights
U.S. Department of Health & Human Services
1301 Young Street-Suite 1169
Dallas, TX 75202
(800) 368-1019; (800) 537-7697(TDD)
(202) 619-3818 Fax
www.hhs.gov/ocr/privacy/hipaa/complaints/

ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES

I, _____ (print name of client or legal representative) have been given a copy of DHS's Notice of Privacy Practices and have had a chance to ask questions about how my PHI will be used.

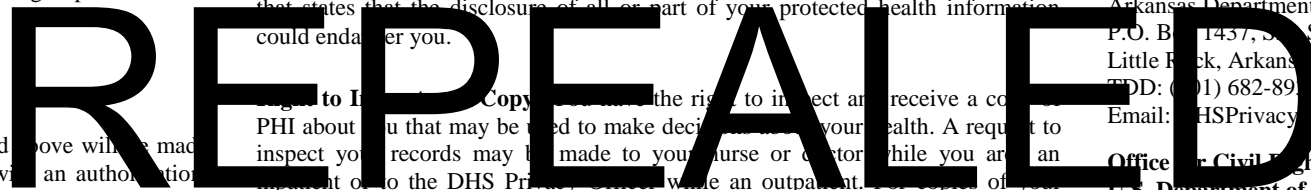
Client's Signature

Date

Legal or Personal Representative of Client (if applicable)

Date

File the original signed copy in the case record; give the recipient of this notice a copy of this document.



DEPARTAMENTO DE
SERVICIOS HUMANOS DE
ARKANSAS
AVISO DE PRACTICAS DE
PRIVACIDAD

Actualizado: Diciembre 08, 2016

ESTE AVISO DESCRIBE COMO LA INFORMACION MEDICA ACERCA DE USTED PUEDE SER USADA Y REVELADA Y COMO PUEDE USTED TOMAR ACCESO A ESTA INFORMACION. FAVOR DE REVISAR CUIDADOSAMENTE.

El Departamento de Servicios Humanos (DHS) provee muchos tipos de servicios, tal como servicios de salud y sociales. El personal de DHS sabe que la información acumulada acerca de usted y su salud es privada. DHS y todos sus asociados en todos locales requieren que por ley mantengan la privacidad de pacientes Información de Salud Protegida (PHI) y proveer a individuos con el Aviso de obligaciones legales y prácticas de privacidad con respecto a PHI.

Se requiere de DHS darle aviso de nuestras prácticas de privacidad por la información que acumulamos y guardamos acerca de usted. Se nos requiere cumplir con los plazos de este Aviso. Reservamos el derecho de cambiar los plazos de este Aviso y este nuevo plazo afectara todo PHI que mantenemos por ese tiempo.

Avisos modificados pueden ser obtenidos en cualquier oficina o línea en:
<http://humanservices.arkansas.gov/publicationDocs/PUB-407.pdf>

En ciertas circunstancias, DHS podría usar y revelar PHI sin consentimiento por escrito.

Para Tratamiento: Usaremos su información de salud para proveerle con tratamiento médico o servicios. Le revelaremos PHI a doctores, enfermeras, técnicos, estudiantes en programas de entrenamiento de cuidado, o otro personal que este involucrado en su cuidado. Por ejemplo, un doctor que le da trato por una pierna quebrada quizá necesite saber si usted tiene diabetes porque quizá el proceso de alivio se demorará. Adicionalmente, el/ella deben decirle al dietista que prepare comidas apropiadas. Diferentes departamentos de DHS tal vez compartan su información médica para poder coordinar los servicios que necesite, tal como recetas, laboratorio y rayos x. Tal vez revelemos información de Salud a personas fuera de DHS que proveen atención médica tal como casa de asilo u otros doctores. Tal vez le diremos a su seguro de salud acerca del tratamiento que su doctor a recomendado para obtener aprobación previa para determinar si al cabo su plan le cubre el costo del tratamiento. Tal vez nos pongamos en contacto con usted para proveerle recordatorios de citas.

Para Pago: DHS usará y revelará PHI a otros proveedores de cuidado de salud para asistir en pagos de sus cuentas. Por ejemplo, lo usaremos para mandar cuentas y reclamar pagos para usted, su seguro de salud, u otros deudores, tal como Medicare, por el cuidado, tratamiento, y otros servicios relacionados que recibe.

Para Operaciones de Cuidado de Salud: DHS tal vez use o revele su PHI para el propósito de nuestras operaciones. Estos usos y revelaciones son necesarios para asegurar que nuestros pacientes reciban el mejor cuidado. Por ejemplo, tal vez usemos PHI para revisar la calidad de nuestro tratamiento y servicios, y para evaluar la ejecución del personal, empleados contratados y estudiantes que le prestan cuidado.

Asociados de Negocios: Tal vez usemos o revelemos su PHI a una compañía que nos asiste en operar nuestro sistema de salud y desempeña varios servicios para nosotros. Esto incluye, pero no está limitado a, auditoria, acreditación, servicios legales, procesamiento de datos, y servicios de consulta. Estas compañías de afuera se llaman "asociados de negocios" y se contratan con nosotros para mantener confidencial PHI recibida en la misma forma que lo hacemos nosotros. Estas compañías pueden crear o recibir PHI por nosotros.

Para Actividades de Salud Pública: DHS tal vez use o revele su PHI para actividades de salud pública que son permitidas o exigidas por ley. Por ejemplo, tal vez revelemos PHI en ciertas circunstancias para controlar o prevenir una enfermedad contagiosa; daño; discapacidad; para reportar nacimientos y defunciones; y para la vigilancia e intervenciones de salud pública. Tal vez revelemos PHI a la Administración de Alimentos y Drogas (FDA) para reportar eventos desfavorables o productos defectivos, para seguir el rastro de productos, para facilitar el retiro de productos, o para conducir vigilancia después de salir al mercado como es exigido por ley o por agencias del gobierno del estado o federal. Tal vez revelemos PHI, si una autoridad de salud pública lo dicta, y agencia de gobierno extranjera que está colaborando con la autoridad de salud pública.

Para Vigilancia de Actividades de Salud: DHS tal vez revele PHI a una agencia de vigilancia de salud para actividades autorizadas por ley. Por ejemplo, estas

agencias de salud pública tal como auditoria, investigaciones; inspección, requisitos de licenciamiento, acciones disciplinarias; civiles, administrativas, y de procedimiento criminal, o acciones. Agencias que solicitan esta información incluyen agencias del gobierno federal, como el sistema de salud, programas de beneficios, y programas regulatorios, y agencias gubernamentales que regulan conformidad con las leyes de derechos civiles.

Exigido Por Ley o Por Autoridades De La Ley: DHS usara y revelara PHI cuando exijan o permitan las leyes federales, estatales, y locales, o por orden de la corte. Bajo ciertas condiciones, tal vez revelemos PHI a oficiales de la ley para el propósito de ejecución. Por ejemplo, tal vez esto incluye (1) respondiendo a una orden de corte o proceso similar; (2) como sería necesario para localizar o identificar a un sospechoso, fugitivo, testigo, o persona ausente; (3) reportando heridas sospechosas, quemaduras o otras lastimaduras físicas; o (4) si es relacionado a la víctima de un crimen.

Demandas u Otros Procedimientos Legales: DHS tal vez revele PHI en el transcurso de cualquier procedimiento judicial o administrativo o en respuesta a una orden de la corte o tribunal administrativo (al grado que tal revelación es expresamente autorizada.) Si ciertas condiciones son adheridas, tal vez revelemos su PHI en respuesta a una citación, a un pedido de descubrimiento, u otro proceso legal.

Abuso o Negligencia: Tal vez revelemos su PHI a una autoridad del gobierno que está autorizada por ley para recibir reportes de abuso, negligencia, o violencia doméstica. Adicionalmente, como la ley lo exige, si creemos que usted ha sido víctima de abuso, negligencia, o violencia doméstica, tal vez revelemos su PHI a una entidad autorizada para recibirlo.

Para Programas Del Gobierno: DHS tal vez use y revele PHI para beneficios públicos bajo otros programas gubernamentales. Por ejemplo, DHS tal vez revele PHI para la determinación de beneficios de Ingreso de Seguridad Suplemental (SSI).

Para Evitar Daño: DHS tal vez revele PHI a autoridades de la ley con el fin de evitar una seria amenaza contra la salud y bienestar de una persona o del público.

Para Investigación: DHS tal vez use o comparta su información de salud para ciertas clases de investigación. Por ejemplo, un proyecto de investigación tal vez involucre comparar la salud y recuperación de pacientes que reciben un medicamento a otros que reciben otro por la misma condición. Todos los proyectos, sin embargo, son sujetos a un proceso especial de aprobación. En algunos instantes, la ley nos permite hacer algo de investigación usando su PHI sin su consentimiento.

Miembros De La Familia Y Amistades: Si usted acede, no tiene inconveniente, o nosotros razonablemente entendemos que no hay protesta, DHS tal vez revele PHI a un miembro de la familia, pariente, u otra persona(s) que usted ha identificado para que estén involucrados en su cuidado de salud o el pago de su cuidado de salud. Si usted no está presente, o está incapacitado, o es una emergencia o situación de auxilio por desastre, usaremos nuestro juicio profesional para determinar si el revelar PHI limitada es en su mejor interés. Tal vez revelemos PHI a un miembro de la familia, pariente, u otra persona(s) quien estuvo involucrado en el cuidado de salud o el pago por cuidado de salud de un individuo fallecido si no son contrarios con preferencias expresadas anteriormente de los individuos conocidos por DHS. Usted también tiene al derecho de pedir una restricción en nuestra revelación de su PHI a alguien que esté involucrado en su cuidado.

Examinadores Médicos, y Directores de Funerarias: DHS tal vez revele su PHI a un investigador o examinador médico. Por ejemplo, esto quizá sería necesario para identificar a una persona fallecida o para determinar la causa de muerte. Tal vez también revelemos su PHI a un director de funeraria, en lo necesario, para cumplir con sus obligaciones.

Organos: Nosotros revelaremos PHI a organizaciones que obtengan, banco, o trasplante de órganos o tejidos.

Seguridad Nacional y Protección del Presidente: DHS tal vez revele su PHI a un oficial federal autorizado u otras personas autorizadas con el propósito de seguridad, para proveer protección al Presidente, o para conducir investigaciones especiales, autorizadas por ley.

Institución Correccional: Si usted es un preso de una institución correccional o bajo la custodia de un oficial de ley, DHS tal vez revele a ellos su PHI. El PHI divulgado tendrá que ser necesario para que la institución le provea su cuidado de salud, proteja su salud y evitar peligro para usted y a otros, o que la institución correccional tenga seguridad y esté libre de peligro.

Militar: Si usted es veterano o un miembro actual de las fuerzas armadas, DHS tal vez divulgue su PHI como es el requisito del comando militar o autoridades de la administración de veteranos.

Compensación de Trabajadores: DHS revelara su información de salud que es razonablemente se relaciona a la compensación del trabajador por enfermedad o lastimadura seguida del pedido por escrito de parte de su empleador, el seguro de compensación del trabajador, o su representante.

Servicios de Salud y Bienestar Patrocinados por el Empleador: Mantenemos PHI acerca de servicios de salud y bienestar patrocinados por el empleador que proveemos a nuestros pacientes, incluyendo servicios provistos en su sitio de empleo. Usaremos el PHI para proveer su tratamiento médico o servicios y revelaremos información acerca de usted a otros que proveen su cuidado médico.

Intercambios de Información Compartida de Registro Medico/Salud: Mantenemos PHI acerca de nuestros pacientes en registros médicos electrónicos compartidos que permite a asociados de DHS a compartir PHI. También quizá participemos en varios intercambios de información electrónica acerca de salud que facilita el acceso a PHI por otros proveedores de cuidado de salud que proveen su cuidado. Por ejemplo, si usted es admitido de emergencia a otro hospital que participa en el intercambio de información de salud, el intercambio nos permitirá hacer su PHI electrónicamente disponible para aquellos que necesiten darle tratamiento.

Patrocinador del Plan: DHS tal vez revele PHI al patrocinador del plan del grupo de salud o al que publica su seguro de salud.

Otros Usos y Revelaciones de PHI

Otros usos y revelaciones de su PHI que arriba no se describió sería hecho solo con su consentimiento por escrito. Si usted provee DHS con una autorización, usted puede revocarla por escrito, y esta revocación será efectiva para usos futuros y revelaciones de PHI. La revocación no será efectiva para información que hemos usado y revelado de acuerdo con la autorización. Por ejemplo, la mayoría de los usuarios y revelaciones de notas de terapia psicológica, usuarios y revelaciones de PHI para propósito del mercado, y revelaciones que constituye la venta de PHI requiere su autorización por escrito.

Sus Derechos Privados PHI

Derecho de Revocar el Permiso: Si le han pedido que firme una autorización para el uso o revelación PHI, usted puede cancelar esa autorización en cualquier momento. Tendrá que hacer el pedido por escrito. Esto no afectará PHI que ya ha sido compartido.

El Derecho al Acceso a su Propia Información de Salud: Usted tiene el derecho de inspeccionar y hacer copias de la mayoría de la información de su salud protegida por todo el tiempo que la conservemos como requiere la ley. Tal vez le pidamos que su requisito lo haga por escrito. Tal vez le cobremos un cargo mínimo por cada copia y el cargo de correo si aplica. Usted tiene el derecho de pedir el resumen de esta información. Si pide resumen, quizá se le cobre cargo mínimo.

Derecho a Pedir Restricciones: Usted tiene el derecho de pedir ciertas restricciones de nuestro uso y revelación de su PHI. En la mayoría de los casos, no estamos obligados a estar de acuerdo en su pedido. Pero si DHS está de acuerdo con la restricción, cumpliremos con su requisito a menos que la información sería necesaria para proveerle tratamiento de emergencia. DHS accederá a poner restricción en revelar PHI acerca de un individuo a un plan de salud si el propósito de la revelación es para conseguir pago u operaciones de cuidado de salud y el PHI solamente pertenece a un servicio por lo que un individuo, o persona aparte del plan de salud, ha pagado en total a DHS. Por ejemplo, si un paciente paga por completo de su bolsa el servicio y le pide a DHS que no le avise a su compañía de seguro, cumpliremos con su pedido. Un pedido de restricción tendrá que ser por escrito. Para pedir una restricción usted tendrá que ponerse en contacto con el oficial de Privacidad de DHS. Reservamos el derecho de terminar cualquier restricción hecha previamente (aparte de la restricción que se nos exige por ley). Le informaremos de la terminación de la

restricción que se tenía de acuerdo y tal terminación solo será efectiva con respecto al PHI creado después que le informemos de su terminación.

Derecho a Pedir Comunicación Confidencial: Usted podrá pedir por escrito que nos comuniquemos con usted de una manera alternativa o en un local alternativo. Por ejemplo, puede pedir que todas sus comunicaciones se le envíen al domicilio de su empleo. Su pedido tendrá que especificar formas alternativas o locales de como comunicarse con usted. También tendrá que declarar que la revelación toda o en parte de PHI en manera inconsistente con sus instrucciones lo pondría poner en peligro. Le acomodaremos un pedido que sea razonable para comunicaciones confidenciales y que aclara que la revelación toda o en parte de su información de salud protegida le podría poner en peligro.

Derecho a Inspeccionar y Hacer Copia: Usted tiene el derecho de inspeccionar y recibir una copia de PHI acerca de usted que tal vez se use para hacer decisiones acerca de su salud. Un pedido para inspeccionar sus registros se le puede hacer a su enfermera o doctor mientras usted está hospitalizado o al Oficial de Privacidad siendo paciente de entrada y salida. Para copias de su PHI, pedidos tendrán que ser enviados al Oficial de Privacidad de DHS. Para PHI en un grupo de registro designado que es conservado en forma electrónica, usted puede pedir una copia electrónica de tal información. Tal vez se haga cargo por estas copias.

Derecho de Notificación: Si usted nos pide que le informemos de la información que tenemos de usted, el tiempo que DHS mantenga la información. Pedir para enmendar su PHI tendrá que hacerlo con el Oficial de Privacidad de DHS. El personal de DHS que conserva la información para a su control de 60 días después de entregar la información de su enmienda por escrito. Si negamos su pedido, le daremos una explicación por escrito. Usted puede responder con una declaración de desacuerdo para que sea adjunta a la información que posee enmendada. Si aceptamos su pedido de enmendar la información, haremos esfuerzos razonables para informar a los demás, incluyendo a personas que usted nombre, de la enmienda y que incluya los cambios en cualquiera revelaciones futuras de esa información.

Derecho de Obtener Una Lista de Revelaciones: Usted tiene el derecho de pedir a DHS una lista de revelaciones hechas después de Abril 14, 2003. Usted tendrá que hacer el pedido por escrito. Con algunas excepciones, usted tiene el derecho de recibir una contabilidad de ciertas revelaciones de su PHI. Se le hará un cargo mínimo por buscar el registro.

Derecho de Obtener Copia de Papel de Este Aviso: En cualquier tiempo usted tiene el derecho de pedir una copia de papel de este aviso.

Derecho de Someter Una Queja: Usted tiene el derecho de someter una queja si siente que DHS ha violado sus derechos. Para hacerlo, póngase en contacto con el Oficial de Privacidad usando la información abajo. Usted puede someter una queja con el departamento, U.S. Department of Health and Human Services, Office for Civil Rights usando la información de contacto abajo. No tomaremos represalia contra usted por someter una queja.

Derecho de Ser Notificado de una Violación: Usted tiene el derecho de ser notificado en el evento que nosotros (o uno de nuestros Asociados de Negocios) descubre una violación de información de salud protegida involucrando su información médica.

**Ve a abajo la información de contacto:
Para Ver, Inspeccionar, Copiar, o Enmendar su PHI, Para Pedir Comunicaciones confidenciales, Para Pedir una contabilidad (lista) de revelaciones, Para Pedir Limitaciones, Para Modificar Autorizaciones, o Para Someter una Queja.**

Este aviso de privacidad también se consigue en:
<http://humanservices.arkansas.gov/publicationDocs/PUB-407.pdf>

Puede ponerse en contacto con su oficina local DHS o con el Oficial de Privacidad de DHS en los siguientes domicilios.

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DHS Privacy Officer
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Little Rock, Arkansas 72203-1437
Tel. 1-855-283-0835/9TDD: 501 682 8933

Office of Privacy Officer@dhs.arkansas.gov.

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U.S. Department of Health & Human Services
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(202) 619-3818 Fax
www.hhs.gov/ocr/privacy/hipaa/complaints/