

ARKANSAS REGISTER

Proposed Rule Cover Sheet



Secretary of State
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Name of Department _____

Agency or Division Name _____

Other Subdivision or Department, If Applicable _____

Previous Agency Name, If Applicable _____

Contact Person _____

Contact E-mail _____

Contact Phone _____

Name of Rule _____

Newspaper Name _____

Date of Publishing _____

Final Date for Public Comment _____

Location and Time of Public Meeting _____

TOC required**272.502 Drug Treatment for Pediatric PANS and PANDAS****6-1-22**

- A. Effective for dates of service on and after 6/1/2022 drug treatment will be available to all qualifying Arkansas Medicaid beneficiaries when specified conditions are met for one (1) or both of the following conditions:
1. Pediatric acute-onset neuropsychiatric syndrome (PANS).
 2. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).
- B. The drug treatments include off-label drug treatments, including without limitation intravenous immunoglobulin (IVIG).
- C. Medicaid will cover drug treatment for PANS or PANDAS under the following conditions:
1. The drug treatment must be authorized under a Treatment Plan; and
 2. The Treatment Plan must be established by the **approved PANS/PANDAS provider.**
- D. A Prior Authorization (PA) must be obtained for each treatment. Providers must submit the current Treatment Plan to the Quality Improvement Organization (QIO) along with the request for Prior Authorization. (Add link to AFMC.)
- E. The authorized procedure codes and required modifiers are found in the following link:

View or print the procedure codes for Hospital/Critical Access Hospitals/ESRD services, including PANS and PANDAS procedure codes.

*TOC required***252.483 Drug Treatment for Pediatric PANS and PANDAS****6-1-22**

- A. Effective for dates of service on and after 6/1/2022 drug treatment will be available to all qualifying Arkansas Medicaid beneficiaries when specified conditions are met for one (1) or both of the following conditions:
1. Pediatric acute-onset neuropsychiatric syndrome (PANS).
 2. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).
- B. The drug treatments include off-label treatments, including without limitation intravenous immunoglobulin (IVIG).
- C. Medicaid will cover drug treatment for PANS or PANDAS under the following conditions:
1. The drug treatment must be authorized under a Treatment; and
 2. The Treatment Plan must be established by the **approved PANS/PANDAS provider.**
- D. A Prior Authorization (PA) must be obtained for each treatment. Providers must submit the current Treatment Plan to the Quality Improvement Organization (QIO) along with the request for Prior Authorization. (Add link to AFMC.)
- E. The authorized procedure codes and required modifiers are found in the following link:
- View or print the procedure codes for Nurse Practitioner services, including PANS and PANDAS procedure codes.**

TOC required**292.930****Drug Treatment for Pediatric PANS and PANDAS****2-15-156-1-22**

- A. Effective for dates of service on and after 6/1/2022 drug treatment will be available to all qualifying Arkansas Medicaid beneficiaries when specified conditions are met for one (1) or both of the following conditions:
1. Pediatric acute-onset neuropsychiatric syndrome (PANS).
 2. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS).
- B. The drug treatments include off-label drug treatments, including without limitation intravenous immunoglobulin (IVIG).
- C. Medicaid will cover drug treatment for PANS or PANDAS under the following conditions:
1. The drug treatment must be authorized under a Treatment Plan; and
 2. The Treatment Plan must be established by the **approved PANS/PANDAS provider**.
- D. A Prior Authorization (PA) must be obtained for each treatment. Providers must submit the current Treatment Plan to the Quality Improvement Organization (QIO) along with the request for Prior Authorization. (Add link to AFMC.)
- E. The authorized procedure codes and required modifiers are found in the following link:
- View or print the procedure codes for Physician/Independent Lab/CRNA/Radiation Therapy Center services, including PANS and PANDAS procedure codes.**

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-A
Page 5a

AMOUNT, DURATION, AND SCOPE OF
SERVICES PROVIDED

Revised: **January-June 1, 2022**

CATEGORICALLY NEEDY

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

a. Prescribed Drugs

- (1) Each recipient age twenty-one (21) or older may have up to six (6) prescriptions each month under the program. Family Planning, tobacco cessation, oral prescription drugs for opioid use disorder prescribed by an X-DEA waived provider as part of a Medication Assisted Treatment plan, EPSDT, high blood pressure, ~~hypercholesterolemia~~hypercholesterolemia, blood modifiers, diabetes and respiratory illness inhaler prescriptions do not count against the prescription limit.
- (2) Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
- (3) The Medicaid agency provides coverage, to the same extent that it provides coverage for all Medicaid recipients, for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses – with the exception of those covered by Part D plans as supplemental benefits through enhanced alternative coverage as provided in 42 C.F.R. §423.104 (f) (1) (ii) (A) – to full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D.

The following excluded drugs, set forth on the [Arkansas Medicaid Pharmacy Vendor's Website](#), are covered:

- a. select agents when used for weight gain:
Androgenic Agents;
- b. select agents when used for the symptomatic relief of cough and colds:
Antitussives; Antitussive-Decongestants; and Antitussive-Expectorants;
- c. select prescription vitamins and mineral products, except prenatal vitamins and fluoride:
B 12; Folic Acid; and Vitamin K;
- d. select nonprescription drugs:
Antiarthritics; Antibacterials and Antiseptics; Antitussives; Antitussives-Expectorants; Analgesics; Antipyretics; Antacids; Antihistamines; Antihistamine-Decongestants; Antiemetic/Vertigo Agents; Gastrointestinal Agents; Hematinics; Laxatives; Ophthalmic Agents; Sympathomimetics; Topical Antibiotics; Topical Antifungals; Topical Antiparasitics; and Vaginal Antifungals; and
- ~~e.~~ non-prescription products for smoking cessation and
- ~~f.~~ off-label use of drug treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS), including without limitation, intravenous immunoglobulin, also known as "IVIG".
- ~~e.~~

- (4) The State will reimburse only for the drugs of pharmaceutical manufacturers who have entered into and have in effect a rebate agreement in compliance with Section 1927 of the Social Security Act, unless the exceptions in Section 1902(a)(54), 1927(a)(3), or 1927(d) apply. The State permits coverage of participating manufacturers' drugs, even though it may be using a formulary or other restrictions. Utilization controls will include prior authorization and may include drug utilization reviews. Any prior authorization program instituted after July 1, 1991 will provide for a 24-hour

turnaround from receipt of the request for prior authorization. The prior authorization program also provides for at least a seventy-two (72) hour supply of drugs in emergency situations.

UNRECORDED

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-A
Page 5aaa

AMOUNT, DURATION AND SCOPE OF
SERVICES PROVIDED
June 1, 2022

Revised: ~~September 30, 2011~~

CATEGORICALLY NEEDY

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

a. Prescribed Drugs (continued)

Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

When a pharmacist receives a prescription for a brand or trade name drug, and dispenses an innovator multisource drug that is subject to the Federal Upper Limits (FULs), the innovator multisource drug must be priced at or below the FUL or the prescription hand annotated by the prescriber "Brand Medically Necessary". Only innovator multisource drugs that are subject to the Federal Upper Limit at 42 CFR 447.332(a) and dispensed on or after July 1, 1991, are subject to the provisions of Section 1903(i)(10)(B) of the Social Security Act.

For drugs listed on the Arkansas Medicaid Generic Upper Limit List, the upper limit price will not apply if the prescribing physician certifies in writing that a brand name drug is medically necessary.

The Arkansas Medicaid Generic Upper Limit List is comprised of State generic upper limits on specific multisource drug products and CMS identified generic upper limits on multisource drug products.

The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence – 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

(6) Off-Label Drug Treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The Medicaid agency will provide coverage of off-label use of drug treatments, including without limitation, intravenous immunoglobulin, also known as "IVIG", to treat Medicaid beneficiaries who are diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, or both. Treatment must be under a treatment plan established by an approved PANS/PANDAS provider.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-B
Page 4g

AMOUNT, DURATION, AND SCOPE OF
SERVICES PROVIDED

Revised: **January-June 1, 2022**

MEDICALLY NEEDY

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

a. Prescribed Drugs

- (1) Each recipient age twenty-one (21) or older may have up to six (6) prescriptions each month under the program. Family Planning, tobacco cessation, oral prescription drugs for opioid use disorder when prescribed by an X-DEA waived provider as part of a Medication Assisted Treatment plan, EPSDT, high blood pressure, ~~hypercholesterolemia~~**hypercholesterolemia**, blood modifiers, diabetes and respiratory illness inhaler prescriptions do not count against the prescription limit.
- (2) Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
- (3) The Medicaid agency provides coverage, to the same extent that it provides coverage for all Medicaid recipients, for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses – with the exception of those covered by Part D plans as supplemental benefits through enhanced alternative coverage as provided in 42 C.F.R. §423.104 (f) (1) (ii) (A) – to full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D.

The following excluded drugs, set forth on the [Arkansas Medicaid Pharmacy Vendor's Website](#), are covered:

a. select agents when used for weight gain:

Androgenic Agents;

b. select agents when used for the symptomatic relief of cough and colds:

Antitussives; Antitussive-Decongestants; **and** Antitussive-Expectorants;

c. select prescription vitamins and mineral products, except prenatal vitamins and fluoride:

B 12; Folic Acid; and Vitamin K;

d. select nonprescription drugs:

Antiarthritics; Antibacterials and Antiseptics; Antitussives; Antitussives-Expectorants; Analgesics; Antipyretics; Antacids; Antihistamines; Antihistamine-Decongestants; Antiemetic/Vertigo Agents; Gastrointestinal Agents; Hematinics; Laxatives; Ophthalmic Agents; Sympathomimetics; Topical Antibiotics; Topical Antifungals; Topical Antiparasitics; and Vaginal Antifungals; and

e. non-prescription products for smoking cessation and

e.f. off-label use of drug treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS), including without limitation, intravenous immunoglobulin, also known as "IVIG".

- (4) The State will reimburse only for the drugs of pharmaceutical manufacturers who have entered into and have in effect a rebate agreement in compliance with Section 1927 of the Social Security Act, unless the exceptions in Section 1902(a)(54), 1927(a)(3), or 1927(d) apply. The State permits coverage of participating manufacturers' drugs, even though it may be using a formulary or other restrictions. Utilization controls will include prior authorization and may include drug utilization reviews. Any prior authorization program instituted after July 1, 1991, will provide for a 24-hour turnaround from receipt of the request for prior authorization. The prior authorization program also provides for at least a 72-hour supply of drugs in emergency situations.

TN: 22-0005

Approved:

Effective: 06/01/22

Supersedes TN: 21-0009

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE ARKANSAS

ATTACHMENT 3.1-B
Page 4i

AMOUNT, DURATION AND SCOPE OF
SERVICES PROVIDED
1, 2022

Revised: September 30, 2011, June

MEDICALLY NEEDY

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

a. Prescribed Drugs (continued)

Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

When a pharmacist receives a prescription for a brand or trade name drug, and dispenses an innovator multisource drug that is subject to the Federal Upper Limits (FULs), the innovator multisource drug must be priced at or below the FUL or the prescription hand annotated by the prescriber "Brand Medically Necessary". Only innovator multisource drugs that are subject to the Federal Upper Limit at 42 CFR 447.332(a) and dispensed on or after July 1, 1991, are subject to the provisions of Section 1903(i)(10)(B) of the Social Security Act.

For drugs listed on the Arkansas Medicaid Generic Upper Limit List, the upper limit price will not apply if the prescribing physician certifies in writing that a brand name drug is medically necessary.

The Arkansas Medicaid Generic Upper Limit List is comprised of State generic upper limits on specific multisource drug products and CMS identified generic upper limits on multisource drug products.

The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence – 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

(6) Off-Label Treatment for Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The Medicaid agency will provide coverage of off-label use of drug treatments, including without limitation, intravenous immunoglobulin, also known as "IVIG", to treat Medicaid beneficiaries who are diagnosed with pediatric acute-onset neuropsychiatric syndrome or pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, or both. Treatment must be under a treatment plan established by an approved PANS/PANDAS provider.

b. Dentures

Refer to Attachment 3.1-B Item 4.b(7) for coverage of dentures for Child Health Services (EPSDT) recipients.

Dentures are available for eligible Medicaid beneficiaries age 21 and over, but are benefit limited. Specific benefit limits and prior authorization requirements for beneficiaries age 21 and over are detailed in the Dental Provider Manual.

Dentures are excluded from the annual limit but are limited to one set per lifetime.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services

DIVISION Division of Medical Services

PERSON COMPLETING THIS STATEMENT Jason Callan

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

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

SHORT TITLE OF THIS RULE Act 637- Hospital, Physician and Nurse Practitioner Provider Manuals and SPA to add PANS/PANDAS treatment

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☒ No ☐
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

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

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

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

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

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

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

- (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

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

Next Fiscal Year

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

Other (Identify) _____
 Total \$ _____

Other (Identify) _____
 Total \$ _____

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

Current Fiscal Year

General Revenue \$255,420
 Federal Funds \$644,580
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total \$ 900,000

Next Fiscal Year

General Revenue \$1,021,680
 Federal Funds \$2,578,320
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total \$ 3,600,000

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

Current Fiscal Year

\$ _____

Next Fiscal Year

\$ _____

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

Current Fiscal Year

\$ 255,420

Next Fiscal Year

\$ 1,021,680

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; - *To authorize off-label use of drug treatments to treat Medicaid beneficiaries with pediatric acute-onset neuropsychiatric syndrome (PANS) and pediatric autoimmune neuropsychiatric disorders (PANDAS) associated with streptococcal infection.*
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute; - *To comply with ACT 637 which authorizes off-label use of drug treatments to treat Medicaid beneficiaries with pediatric acute-onset neuropsychiatric syndrome*

(PANS) and pediatric autoimmune neuropsychiatric disorders (PANDAS) associated with streptococcal infection.

- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and - *New Legislation*
 - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs; - *This advances treatment options for beneficiaries diagnosed with PANS/PANDAS.*
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule; - *None at this time.*
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule; - *None*
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and - *N/A*
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives. - *DMS reviews all rules periodically.*

Statement of Necessity and Rule Summary
Act 637 - Hospital, Physician and Nurse Practitioner Provider Manuals and SPA
(PANS/PANDAS)

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

The purpose of this Rule is to enact the requirements of Act 637 of 2021. Act 637 authorizes the use of off-label drug treatments to treat Medicaid beneficiaries with Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The Act further states that the off-label treatments include, but are not limited to, use of intravenous immunoglobulin (also known as "IVIG") and they must be included in a Treatment Plan. The sole provider for creating the Treatment Plans, and providing the treatments, will be the Postinfectious Autoimmune Encephalopathy Center of Excellence (as required in the Act).

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

The Division of Medical Services (DMS) implements updates to rules to comply with Act 637, and additionally, is requiring a Prior Authorization (PA) to these treatments so that the Treatment Plan can be submitted to the Quality Improvement Organization (QIO) along with the PA request. The Division of Medical Services is updating the Hospital, Physician, and Nurse Practitioner provider manuals and amending the Medicaid State Plan as follows:

Summary of Changes

Hospital Provider Manual– New section added

- Section 272.502 – Provides coverage for the use of off-label drug treatments, including intravenous immunoglobulin (IVIG), to treat Medicaid beneficiaries diagnosed with PANS or PANDAS. A treatment plan and a prior authorization are required. The treatment plan must be submitted by the approved PANS/PANDAS provider.

Physician Provider Manual – New section added

- Section 292.930 - Provides coverage for the use of off-label drug treatments, including intravenous immunoglobulin (IVIG), to treat Medicaid beneficiaries diagnosed with PANS or PANDAS. A treatment plan and a prior authorization are required. The treatment plan must be submitted by the approved PANS/PANDAS provider.

Nurse Practitioner Provider Manual -New section added

- Section 252.483 - Provides coverage for the use of off-label drug treatments, including intravenous immunoglobulin (IVIG), to treat Medicaid beneficiaries diagnosed with PANS or PANDAS. A treatment plan and a prior authorization are required. The treatment plan must be submitted by the approved PANS/PANDAS provider.

State Plan Amendment (SPA)

- Attachment 3.1-A, Page 5a – Added (f), updated to include the use of intravenous immunoglobulin as a covered drug to treat PANS or PANDAS.
- Attachment 3.1-A, Page 5aaa – Added (6), updated to include the use of intravenous immunoglobulin as a covered drug to treat PANS or PANDAS.
- Attachment 3.1-B, Page 4g – Added (f), updated to include the use of intravenous immunoglobulin as a covered drug to treat PANS or PANDAS.
- Attachment 3.1-B, Page 4i – Added (6), updated to include the use of intravenous immunoglobulin as a covered drug to treat PANS or PANDAS.

Please attach additional documents if necessary

NOTICE OF RULE MAKING

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

Effective June 1, 2022:

The Director of the Division of Medical Services amends Section II of the following provider manuals to comply with Act 637 of the 93rd General Assembly: Hospital, Physician, and Nurse Practitioner; as well as corresponding changes to the Medicaid State Plan Amendment (SPA). The amendments authorize the use of off-label drug treatments to treat Medicaid beneficiaries with Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS). The off-label treatments include, but are not limited to, use of intravenous immunoglobulin (also known as "IVIG") and they must be included in a Treatment Plan. The sole provider for creating the Treatment Plans and providing the treatments will be the Postinfectious Autoimmune Encephalopathy Center of Excellence, as required by Act 637 (the approved provider). A Prior Authorization (PA) will be required for these treatments so that the Treatment Plan can be submitted to the Quality Improvement Organization (QIO) with the PA request. The proposed rule estimates a financial impact of \$900,000 (\$644,580 of which is federal funds) for state fiscal year (SFY) 2022 and \$3,600,000 (\$2,578,320 of which is federal funds) for SFY 2023.

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 <https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/>. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than April 9, 2022. 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 March 24, 2022, at 11:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at <https://us02web.zoom.us/j/83367620116>. The webinar ID is 833 6762 0116. If you would like the electronic link, "one-tap" mobile information, listening only dial-in phone numbers, or international phone numbers, please contact ORP at ORP@dhs.arkansas.gov.

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

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin. 4502035775



Elizabeth Pitman, Director
Division of Medical Services