

# DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

**SUBJECT:** Vagus Nerve Stimulation Therapy; SPA 2022-0004

# **DESCRIPTION:**

# Statement of Necessity

The purpose of this Rule is to implement the requirements of Act 830 of 2021. Act 830 requires that all Arkansas hospitals shall be paid based on 100% of the Medicare average comprehensive payment rate as of June 1, 2022 for the vagus nerve stimulation therapy, device, and procedure. A Prior Authorization (PA) will be requested.

# Summary of Changes

DHS is updating the physician and hospital provider manuals and amending the Medicaid State Plan coverage pages to comply with Act 830.

The Medicaid State Plan will be updated to include the rate methodology and coverage criteria.

<u>PUBLIC COMMENT</u>: A public hearing was held on this rule on February 3, 2022. The public comment period expired on February 21, 2022. The agency indicated that it received no public comments.

The proposed effective date is June 1, 2022.

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

Per the agency, the additional cost of this rule is \$54,167 for the current fiscal year (\$15,373 in general revenue and \$38,794 in federal funds) and \$650,000 for the next fiscal year (\$184,470 in general revenue and \$465,530 in federal funds). The total estimated cost by fiscal year to state, county, and municipal government to implement this rule is \$15,373 for the current fiscal year and \$184,470 for the next fiscal year.

The agency indicated that there is a new or increased cost or obligation of at least \$100,000 per year to a private individual, private entity, private business, state government, county government, municipal government, or to two or more of those entities combined. Accordingly, the agency provided the following written findings:

(1) a statement of the rule's basis and purpose;

The purpose of this rule is to implement the requirements of Arkansas Act 830 of 2021.

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

Act 830 of 2021 requires that Vagus Nerve Stimulation, therapy, device, and procedure be covered by Arkansas Medicaid and defines how each component is to be covered.

- (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;

Vagus Nerve Stimulation provides safe and effective therapy for those who require use of the device for their condition and will help qualifying clients to control their diagnosis in a manner that will assist them in managing their symptoms.

(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;

No less costly alternatives were identified.

(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;

No alternatives are proposed at this time.

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

# N/A

- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
- (a) the rule is achieving the statutory objectives;
- (b) the benefits of the rule continue to justify its costs; and
- (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

The agency monitors State and Federal rules and regulations for opportunities to reduce and control cost.

**LEGAL AUTHORIZATION:** This rule implements Act 830 of 2021. The Act, sponsored by Representative Howard Beaty, Jr., required certain reimbursement rates in the Arkansas Medicaid program for vagus nerve stimulation therapy system devices. Per the Act, "[t]he Department of Human Services shall establish separate vagus nerve

stimulation therapy system device reimbursement rates for all acute care hospitals who are Medicaid providers." Act 830, § 1(a), *codified at* Ark. Code Ann. § 20-77-145(a).



# **Division of Medical Services**

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

P: 501.682.8292 F: 501.682.1197

# **MEMORANDUM**

TO: Interested Persons and Providers

FROM: Elizabeth Pitman, Director, Division of Medical Services

DATE: January 21, 2022

SUBJ: Vagus Nerve Stimulation Therapy

As a part of the Arkansas Administrative Procedure Act process, attached for your review and comment are proposed rule revisions.

Public comments must be submitted in writing at the above address or at the following email address: <a href="Mailto:ORP@dhs.arkansas.gov">ORP@dhs.arkansas.gov</a> 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.

If you have any comments, please submit those comments in writing, no later than February 21, 2022.

#### 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: §§ 25-10-129, 20-76-201, and 20-77-107.

# Effective June 1, 2022:

The Director of the Division of Medical Services (DMS) updates the physician and hospital provider manuals and amends the Medicaid State Plan to comply with Act 830 of 2021. Act 830 requires that all Arkansas hospitals be paid one hundred percent of the Medicare average comprehensive payment rate as of June 1, 2022 for vagus nerve stimulation therapy, devices, and procedures, if a prior authorization is granted. Vagus Nerve Stimulation provides safe and effective therapy for those who require use of the device for their condition and will help qualifying clients to control their diagnosis in a manner that will assist them in managing their symptoms.

The division updates the state plan rate methodology and coverage criteria as well. All rates are published on the agency's <u>website</u>. Except as otherwise noted in the plan, state developed fee schedules are the same for both governmental and private providers. The projected annual cost of this change for state fiscal year (SFY) 2022 is \$54,167.00 (\$15,373.00 state portion with a federal match of \$38,794.00), and for SFY 2023 is \$650,000.00 (\$184,470.00 state portion with a federal match of \$465,530.00).

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 <a href="https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/">https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/</a>. Public comments must be submitted in writing at the above address or at the following email address: <a href="https://organization.org/ORP@dhs.arkansas.gov">ORP@dhs.arkansas.gov</a>. All public comments must be received by DHS no later than February 21, 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. 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.

A public hearing by remote access only through a Zoom webinar will be held on February 3, 2022 at 10:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at <a href="https://us02web.zoom.us/j/87463688929">https://us02web.zoom.us/j/87463688929</a>. The webinar ID is 874 6368 8929. 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 <a href="https://orentable.com/ORP@dhs.arkansas.gov">ORP@dhs.arkansas.gov</a>.

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.

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Elizabeth Pitman, Director Division of Medical Services

#### **TOC** required

# 217.150 Vagus Nerve Stimulation

6-1-22

The Arkansas Medicaid Program covers vagus nerve stimulation therapy, device, and procedure. Vagus nerve stimulation therapy, device, and procedure require prior authorization for medical necessity.

View or print the procedure codes for Hospital/Critical Access Hospitals/ESRD services.

<u>View or print contact information to obtain the DHS or designated vendor step-by-step process for requesting prior authorization.</u>

# 245.040 Prior Authorization of Vagus Nerve Stimulation Therapy, Device, and Procedure 6-1-22

The Arkansas Medicaid Program requires prior authorization for vagus nerve stimulation therapy, device, and procedure for medical necessity.

<u>View or print contact information to obtain the DHS or designated vendor step-by-step process for requesting prior authorization.</u>

# 272.520 Vagus Nerve Stimulation Therapy, Device and Procedure Billing Protocol 6-1-22

The Arkansas Medicaid Program covers vagus nerve stimulation therapy, device, and procedure. When filing a claim, providers will bill the cost for both the device and procedure under the single billing code.

View or print the procedure codes for Hospital/Critical Access Hospitals/ESRD services.

# **TOC** required

# **251.250 Vagus Nerve Stimulation**

6-1-22

The Arkansas Medicaid Program covers vagus nerve stimulation therapy, device, and procedure under the Hospital Outpatient program. Vagus nerve stimulation therapy device and procedure require prior authorization for medical necessity. Refer to the Hospital manual for further information regarding prior authorization and outpatient hospital billing instruction.

<u>View or print the procedure codes for Physician/Independent Lab/CRNA/Radiation</u> Therapy Center services.

<u>View or print contact information to obtain the DHS or designated vendor step-by-step process for requesting prior authorization.</u>

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

ATTACHMENT 4.19-B Page 1aa(1)

# METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE

**August**June 1, 201822

- 2.a. Outpatient Hospital Services (continued)
  - (6) Border City University-Affiliated Pediatric Teaching Hospitals

Special consideration is given to border city university-affiliated pediatric teaching hospitals due to the higher costs typically associated with such hospitals. Effective for claims with dates of service on or after January 1, 2018, outpatient hospital facility services provided to patients under the age of 21 at border city university-affiliated pediatric teaching hospitals will be reimbursed based on reasonable costs with interim payments and a year-end cost settlement. The State will utilize cost data in a manner approved by CMS consistent with the method used for identifying cost for the private hospital access payments as outlined in this Attachment 4.19-B, Page 1a.

Arkansas Medicaid will use the lesser of the reasonable costs or customary charges to establish cost settlements. The cost settlements will be calculated using the methods and standards used by the Medicare Program.

A border city university-affiliated pediatric teaching hospital is defined as a hospital located within a bordering city (see Attachment 4.19-A page 3b) that submits to the Arkansas Medicaid Program a copy of a current and effective affiliation agreement with an accredited university, and documentation establishing that the hospital is university-affiliated, is licensed and designated as a pediatric hospital or pediatric primary hospital within its home state, maintains at least five different intern pediatric specialty training programs, and maintains at least one-hundred (100) operated beds dedicated exclusively for the treatment of patients under the age of 21.

(7) Effective for claims with dates of service on or after June 1, 2022, all Arkansas hospitals shall be paid based on 100% of the Medicare average comprehensive payment rate as of June 1, 2022 for the vagus nerve stimulation therapy, device and procedure. All rates are published on the agency's website. Except as otherwise noted in the plan, state developed fee schedules are the same for both governmental and private providers.

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