PROPOSED RULE 127

AUTHORIZATION OF OFF-LABEL USE OF DRUG TREATMENTS FOR PEDIATRIC ACUTE-ONSET AND AUTOIMMUNE NEUROPSYCHIATRIC SYNDROME

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SECTION 1. AUTHORITY

This Rule is issued pursuant to Act 1054 of 2021 (hereafter, Act 1054), as codified in Ark. Code Ann. § 23-79-1903, which requires the Arkansas Insurance Department ("AID") to issue rules for the implementation and administration of coverage for use of off-label drug treatments to treat patients diagnosed with acute-onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection under Ark. Code Ann. § 23-79-1903.

SECTION 2. DEFINITIONS

Unless otherwise separately defined in this rule and consistent with state law, the terms or phrases as used in this rule shall follow the definitions of such terms or phrases as defined in Ark. Code Ann. § 23-79-1903.

(1) "Healthcare service" means a healthcare procedure, treatment, or service provided by a medical provider.

(2) "Medical Provider" means a person who performs healthcare services for patients with PANS or PANDAS, as defined in Act 1054, and herein.

(3) "PANS" means pediatric acute-onset neuropsychiatric syndrome, a clinically defined disorder characterized by sudden onset of obsessive-compulsive symptom

or eating restrictions, accompanied by two (2) or more symptoms of acute behavioral deterioration or motor and sensory changes, or both.

(4) "PANDAS" means pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, described as a subset of symptoms affecting children and adolescents within the broader PANS classification.

SECTION 3. COVERAGE REQUIREMENT REVIEW

(a) Pursuant to Ark. Code Ann. § 23-79-1903(c), a health benefit plan that is offered, issued, provided, or renewed in this state shall provide coverage for off-label use of intravenous immunoglobin (hereafter "IVIG"), to treat individuals diagnosed with pediatric acute-onset neuropsychiatric syndrome and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection, or both, on or after January 1, 2022, under a patient specific treatment plan established by the Post-infectious Autoimmune Encephalopathy Clinic established by the University of Arkansas for Medical Sciences in collaboration with Arkansas Children's Hospital.

(b) Coverage for off-label use of IVIG and associated drug treatment as set forth in § 3(a) above may be subject to policy deductions or copayment requirements and any standard prior authorization review of a healthcare insurer or health benefit plan, and such coverage for benefits shall not be diminished or limited as otherwise allowable under a health benefit plan.

SECTION 4. CODING FEE FOR EVALUATION

Every health benefit plan shall permit appropriate claims, coding fees, or charges for related healthcare services, including evaluations, performed by medical providers in association or collaboration with the Post-infectious Autoimmune Encephalopathy Clinic established by the University of Arkansas for Medical Sciences in collaboration with Arkansas Children's Hospital, as described in § 3(a) above.

SECTION 5. ENFORCEMENT AND PENALTIES

Pursuant to Ark. Code Ann. § 23-61-103 et seq. the Insurance Commissioner shall have the power and authority expressly conferred or reasonably implied by the Insurance Code. This includes, but is not limited to, the power to fully investigate potential violations of Act 1054 and this Rule, conduct examinations, take injunctive and administrative action as necessary and appropriate, and impose fines and penalties upon a finding that a health benefit plan has failed to comply herewith.

SECTION 6. EFFECTIVE DATE

The effective date of this Rule is January 1, 2022.

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ALAN MCCLAIN
INSURANCE COMMISSIONER

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DATE