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Docket #: 054.00.97-002

October 29, 1997

TO: ALL LICENSED DISABILITY INSURERS, ALL LICENSED HEALTH MAINTENANCE ORGANIZATIONS ("HMO'S"), ALL LICENSED HOSPITAL & MEDICAL SERVICE CORPORATIONS, ALL LICENSED FRATERNAL BENEFIT SOCIETIES, ALL REGISTERED MET'S, MEWA'S, AND SELF-INSURED HEALTH CARE PLANS, ALL REGISTERED THIRD PARTY ADMINISTRATORS ("TPA'S"), AND OTHER INTERESTED PARTIES

TO: ARKANSAS DEPARTMENT OF HEALTH, ARKANSAS DEPARTMENT OF HUMAN SERVICES, STATE MEDICAL BOARD, STATE PODIATRY EXAMINING BOARD, STATE BOARD OF OPTOMETRY, STATE BOARD OF PHARMACY, STATE BOARD OF NURSING, STATE BOARD OF PHYSICAL THERAPY, STATE DIETETICS LICENSING BOARD

FROM: ARKANSAS INSURANCE DEPARTMENT

SUBJECT: PROPOSED RULE AND REGULATION, "DIABETES SELF-MANAGEMENT ACT OF 1997"

### NOTICE OF PUBLIC HEARING

Pursuant to Arkansas Code Annotated §§25-15-203(2), 23-61-108 and 23-75-125, and other applicable laws, NOTICE is hereby given that a Public Hearing will be held on December 3, 1997, at 9:00 a.m. in the First Floor Hearing Room, Arkansas Insurance Department, at 1200 West Third Street (Third & Cross Streets), Little Rock, Arkansas.

1. The Public Hearing will be held to determine whether the Insurance Commissioner should adopt the new Proposed Rule on Act 1249 of 1997, "The Diabetes Self-Management Act of 1997". A copy of the proposed new Rule is attached for review.

2. All interested persons are encouraged to attend the Public Hearing and may appear and present (orally or in writing) statements, arguments or opinions on the Proposed Rule.

3. Persons wishing to testify should notify the undersigned as soon as possible; and are requested to submit intended statements in writing. All comments at the Public Hearing on the Proposed Rule, as well as written comments without testimony, are allowed and encouraged.

Please direct your inquiries to the undersigned at (501) 371-2820 or Fax: (501) 371-2629, or to Director John Shields, Life and Health Division at (501) 371-2800.

Sincerely,

*Jean Langford*  
Jean Langford  
Chief Counsel, Legal Division

Enclosure: Proposed Diabetes Rule

FILED  
97 NOV -3 PM 2:07  
SECRETARY OF STATE  
STATE OF ARKANSAS

**PROPOSED  
NEW  
RULE AND REGULATION  
DIABETES SELF-MANAGEMENT ACT OF 1997**

**FILED**  
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SHARON PRIEST  
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STATE OF ARKANSAS  
BY \_\_\_\_\_

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**Section 1. Purpose**

The purpose of this Regulation is to implement and coordinate compliance with the Arkansas diabetes self-management benefits mandated for inclusion in insurance and HMO policies and contracts under the provisions of Arkansas Act 1249 of 1997, effective August 1, 1997.

**Section 2. Authority**

This Rule is issued pursuant to the authority vested in the Commissioner under Ark. Code Ann. §§23-61-108 and 25-15-203, Act 1249 of 1997, and other applicable provisions of Arkansas law.

**Section 3. Applicability and Scope**

A. APPLICATION. (1) This Rule shall apply to every disability (health) insurer, hospital or medical service corporation, health maintenance organization ("HMO"), and fraternal benefit society licensed by the Arkansas Insurance Commissioner ("Commissioner"). This Rule applies to group and individual policies or contracts issued on an expense-incurred, service, or pre-paid risk-sharing basis by authorized licensees of the Insurance Commissioner. This Rule shall be applicable to any health insurance policy which is delivered, issued, issued for delivery, renewed, extended, or modified in this State on and after the effective date of this Rule as adopted by the Commissioner.

(2) This Rule shall be applicable to a health insurance policy providing coverage or benefits to an Arkansas resident in accordance with Act 1249 of 1997, whether the health care insurer or other entity which provides the coverage is located within or outside the State of Arkansas or not; and the policy shall be deemed to be delivered in this State within the meaning of Act 1249 of 1997.

B. EXCLUSIONS. This Regulation shall not apply to disability income, specified disease, Medicare Supplement, hospital indemnity, or accident-only policies. This Rule shall not apply to long term care plans, disability income plans, short-term renewable individual health insurance (disability) policies which expire after six (6) months, medical payments under homeowner or

1 automobile insurance policies, or to workers' compensation or employers' liability insurance  
2 policies or contracts.

#### 3 4 **Section 4. Effective Date**

5  
6 The effective date of this Rule is \_\_\_\_\_, upon signature of the Commissioner  
7 and statutory filing.

#### 8 9 **Section 5. Definitions**

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11 As used in this Rule:

12  
13 A. COMMISSIONER means the Arkansas Insurance Commissioner.

14  
15 B. DEPARTMENT means the Arkansas Insurance Department.

16  
17 C. DIABETES means and shall include Type 1, Type 2, or Gestational Diabetes and means  
18 diabetes mellitus, a common chronic, serious systemic disorder of energy metabolism which  
19 includes a heterogeneous group of metabolic disorders which can be characterized by an  
20 elevated blood glucose level. The terms diabetes and diabetes mellitus are considered  
21 synonymous and defined to include persons using insulin, persons not using insulin, individuals  
22 with elevated blood glucose levels induced by pregnancy, or persons with other medical  
23 conditions or medical therapies which wholly or partially consist of elevated blood glucose  
24 levels.

25  
26 D. DIABETES EDUCATOR or HEALTH CARE PROVIDER or CERTIFIED DIABETES  
27 EDUCATOR (CDE) means an individual licensed by one of the following Arkansas State Boards  
28 and duly certified to instruct in diabetes self-management:

- 29 1. The State Medical Board;  
30 2. The State Podiatry Examining Board;  
31 3. the State Board of Optometry;  
32 4. The State Board of Pharmacy;  
33 5. The State Board of Nursing;  
34 6. The State Board of Physical Therapy; and  
35 7. The Dietetics Licensing Board.

36  
37 E. DIABETES SELF-MANAGEMENT TRAINING means instruction in an inpatient or  
38 outpatient setting, including medical nutrition therapy relating to diet, caloric intake and diabetes  
39 management but excluding programs the primary purposes of which are weight reduction, which  
40 enable diabetic patients to understand the diabetic management process and daily  
41 management of diabetic therapy as a method of avoiding frequent hospitalizations and  
42 complications when the instruction is provided in accordance with a program in compliance with  
43 the National Standards for Diabetes Self-Management Education Program developed by the  
44 American Diabetes Association.

45  
46 F. HEALTH CARE INSURER means any insurance company, fraternal benefit society,  
47 hospital and/or medical services corporation, or health maintenance organization issuing or  
48 delivering a health (disability) insurance policy subject to the Arkansas Insurance Code, codified  
49 as Ark. Code Ann. §§23-60-101, et seq., or its successor laws; and in particular, the provisions  
50 of Ark. Code Ann. §§23-74-101, et seq., as to fraternal benefit societies; and provisions of Ark.

Code Ann. §§23-75-101, et seq., as to hospital or medical service corporations; and the provisions of Ark. Code Ann. §23-76-101, et seq. as to health maintenance organizations.

G. HEALTH INSURANCE POLICY means a group or individual disability insurance policy, contract or plan which provides medical coverage on an expense-incurred, service, or prepaid risk-sharing basis issued by authorized stock and mutual insurers, authorized fraternal benefit societies, authorized hospital or medical service corporations, and authorized health maintenance organizations.

## Section 6. Coverage Mandated; Limitations

A. Pursuant to Section 2 of Act 1249 of 1997, every individual and group health insurance policy as defined in this Rule shall include coverage for one (1) lifetime training program per insured for diabetes self-management training, when medically necessary. Training which is compensable under the policy may include one (1) or more than one (1) visit from the physician or diabetes educator. The training which is compensable under the policy shall include additional training sessions offered by the health care provider, upon an order to the patient by a physician, on grounds of medical necessity and when the diabetic patient's condition changes or worsens upon a determination by that physician that it is a significant change in the diabetic patient's condition.

B. Any training for diabetes self-management shall only be covered in the health care policy when medically necessary as determined by a physician, and only if it is provided by an appropriately licensed health care provider or certified diabetes educator (CDE) credentialed as required by Act 1249 of 1997 and defined in Subsection (D) of Section 5 above. As to additional requirements, the physician for the diabetic patient must be licensed under Ark. Code Ann. §§17-95-201, et seq. The diabetes educator shall only provide diabetes self-management training within his or her scope of practice after having demonstrated expertise in diabetes care and treatment. The physician or diabetes educator shall only provide such training after having completed an education training program required by his or her medical licensing board when such program is in compliance with the most recent edition of the National Standards for Diabetes Self-Management Education Program, developed by the American Diabetes Association. For the patient's training to be compensable under the health care policy, the physician must issue a written prescription ordering the training for the patient or the patient's parent, spouse or legal guardian. For compensable coverage, the training must be successfully completed by the diabetic patient; the diabetes educator or CDE must certify such successful completion; and either shall provide such written certification to the health care insurer providing the coverage.

C. The coverage required under this Rule and Act 1249 of 1997 shall be consistent with other benefits provided in the health insurance policy with regard to deductibles; coinsurance; other patient cost-sharing amounts or out-of-pocket limits; and prior authorization or other utilization review requirements or processes.

D. The provisions of Act 1249 of 1997 and this Rule do not prohibit health care insurers from selectively negotiating contracts with qualified providers of diabetes self-management training programs, so long as the provisions of this Rule are followed.

E. The health care insurers may legitimately exclude from coverage diabetes self-management training, diabetes equipment, supplies and related services which are not medically necessary for the treatment of Type 1, Type 2 or gestational diabetes; provided that

such determinations are made by licensed physicians; and provided that such determinations are consistent with Act 1249 of 1997 and this Rule, as well as other applicable laws and rules and regulations; and provided that such determinations are not at variance with generally accepted standards of the medical profession.

## **Section 7. Standards for Diabetes Self-Management Training**

The diabetes education process for self-management training shall include the following standards:

(1) **Needs Assessment.** The health care provider or certified diabetes educator shall conduct an individualized educational needs assessment with the participation of the patient, family, legal guardian, or support systems to be used in the development of the educational plan and interventions. The educational needs assessment shall include, but not be limited to, the following:

- (A) Health history;
- (B) Medical history;
- (C) Previous use of medication;
- (D) Diet history;
- (E) Current mental health status;
- (F) Use of health care delivery systems;
- (G) Life-style practices such as occupation, education, financial status, social and cultural and religious practices, or preventive behaviors;
- (H) Physical and psychological factors including age, mobility, visual acuity, manual dexterity, alertness, attention span, and ability to concentrate;
- (I) Barriers to learning such as education, literacy level, perceived learning needs, motivation to learn, and attitude;
- (J) Family and social support; and
- (K) Previous diabetes education, including actual knowledge and skills.

(2) **Education Plan.** The health care provider or certified diabetes educator shall develop a written education plan from information obtained in the needs assessment, including the following:

- (A) Desired patient outcomes;
- (B) Measurable, behaviorally-stated learner objectives; and
- (C) Instructional methods.

(3) **Education Intervention.** The health care provider or diabetes educator shall create an educational setting conducive to learning with adequate resources for space, teaching and audio-visual aids to facilitate the educational process. The CDE shall use a planned content outline. The content outline shall be provided based on the needs assessment, and shall include:

- (A) Diabetes pathophysiology;
- (B) Stress and psychological adjustment;
- (C) Family involvement in disease management;
- (D) Medical nutrition therapy;
- (E) Exercise and physical activity;
- (F) Medications;
- (G) Blood glucose monitoring and use of results;
- (H) Diabetes management which is the relationship between nutrition, exercise, medication, and blood glucose levels;

- (I) Prevention, detection, and treatment of acute complications;
- (J) Prevention, detection and treatment of chronic complications;
- (K) Foot, skin and dental care;
- (L) Behavior change strategies, goal setting risk factor reduction, and problem solving;
- (M) Benefits, risks, and management options for improving glucose control;
- (N) Uses of health care systems and community resources; and
- (O) Preconception care, pregnancy and gestational diabetes.

(4) **Evaluation of Learner Outcomes.** The certified diabetes educator shall review and evaluate the degree to which the person with diabetes is able to demonstrate diabetes self-management skills as identified by behavioral objectives.

(5) **Plan for Follow-up for Continuing Learning Needs.** The certified diabetes educator shall review the educational plan and recommend any additional educational interventions to meet continuing learning needs.

(6) **Documentation.** The certified diabetes educator shall maintain written files and shall thereby completely and accurately document the educational experiences provided.

## **Section 8. Equipment, Supplies and Appliances**

When deemed medically necessary for Type 1, Type 2, or gestational diabetes, and after prescription or diagnosis by a licensed physician or health care provider with prescribing authority, all individual or group health insurance policies as defined in Section 5 of this Rule must reimburse or cover the equipment, appliances, insulin, prescriptions, drugs, and services described in this Section:

- (1) Blood glucose monitors, which include all commercially available blood glucose monitors designed for patient use and for persons who have been diagnosed with diabetes;
- (2) Blood glucose monitors for the legally blind, which include all commercially available blood glucose monitors designed for patient use with adaptive devices and for persons who are legally blind and have been diagnosed with diabetes;
- (3) Test strips for glucose monitors, which include test strips whose performance shall achieve the standards of the American College of Pathology, glucose control solutions, lancet devices, and lancets for monitoring glucemic control;
- (4) Visual reading and urine testing strips, which include visual reading strips for glucose, urine testing strips for ketones, or urine test strips for both glucose and ketones. Urine test strips for glucose only are not acceptable as the sole method of monitoring;
- (5) Insulin, which includes all commercially available insulin preparations including insulin analog preparations available in either vial or cartridge;
- (6) Injection aids, which include devices used to assist with insulin injection;
- (7) Syringes, which include insulin syringes, pen-like insulin injection devices, pen needles for pen-like insulin injection devices, and other disposable parts required for insulin injection aids;

(8) Insulin pumps as prescribed by the physician and appurtenances thereto, which include insulin infusion pumps and supplies such as skin preparations, adhesive supplies, infusion sets, cartridges, batteries and other disposable supplies needed to maintain insulin pump therapy. These include durable and disposable devices used to assist in the injection of insulin;

(9) Oral agents for controlling the blood sugar level, which are prescription drugs;

(10) Podiatric appliances for prevention of complications associated with diabetes; which include therapeutic molded or depth-inlay shoes, replacement inserts, preventive devices, and shoe modifications for prevention and treatment subject to an annual maximum limit of \$2,000; and

(11) Glucagon Emergency Kits and injectable glucagon.

#### Section 9. Penalties

Health care insurers who fail to comply with the provisions of this Rule shall be subject to investigations and administrative proceedings and penalties for trade practice violations enumerated in Ark. Code Ann. §§23-66-201, and following, and other applicable laws and rules.

#### Section 10. Severability

Any section or provision of this Rule held by a court to be invalid or unconstitutional will not affect the validity of any other section or provision of this Rule.

(Signature upon approval)

MIKE PICKENS  
INSURANCE COMMISSIONER  
STATE OF ARKANSAS

DATE