

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

Do Not Mark In this Box

RECEIVED
96 AUG 29 PM 3:58
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Insurance Commissioner TITLE NUMBER: 114

CITE AUTHORITY W.Va. Code §33-2-10, 33-15C-1, 33-16-16

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: Series 52

TITLE OF RULE BEING PROPOSED: Diabetes Regulation

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

B. Keith Huffman, General Counsel

660



STATE OF WEST VIRGINIA
Offices of the Insurance Commissioner

Legal Division

GASTON CAPERTON
Governor

August 29, 1996

HANLEY C. CLARK
Insurance Commissioner

HAND DELIVERED

Ms. Judy Cooper, Director
Administrative Law Division
Office of the Secretary of State
State Capitol
Charleston, West Virginia 25305

RECEIVED
96 AUG 29 PM 3:58
OFFICE OF THE INSURANCE COMMISSIONER
STATE OF WEST VIRGINIA

Dear Ms. Cooper:

Enclosed please find for filing one (1) copy of the following:

- (1) Notice of Agency Approval of a Proposed Rule and Filing with the Legislative Rule-Making Review Committee;
- (2) Consent to Proposed Rule;
- (3) Fiscal Note;
- (4) Brief Summary of the Rule;
- (5) Statement of Circumstances;
- (6) Legislative Rule-Making Review Committee Questionnaire; and
- (7) The agency-approved rule entitled "Diabetes Regulations," (Series 52).

Please contact me if further information is required.

Sincerely,

Donna S. Quesenberry
Associate Counsel

DQ/avn
Enclosures



STATE OF WEST VIRGINIA
Offices of the Insurance Commissioner

Legal Division

GASTON CAPERTON
Governor

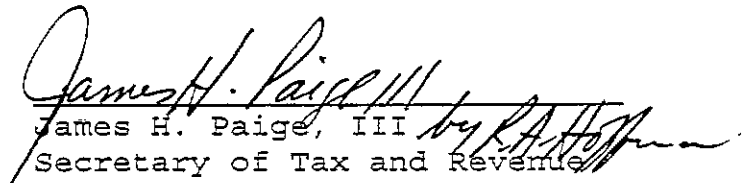
HANLEY C. CLARK
Insurance Commissioner

CONSENT TO FILING OF RULE

To Whom It May Concern:

Pursuant to West Virginia Code § 5F-2-2(a)(12), the undersigned hereby grants consent to the filing of the following rule proposed by the Insurance Commissioner of the State of West Virginia: Title 114, Series 52, relating to "Diabetes Regulations."

Signed this 26th day of July, 1996.


James H. Paige, III
Secretary of Tax and Revenue

APPENDIX B .

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Diabetes Regulations (Series 52)

Type of Rule: Legislative Interpretive Procedural

Agency: Insurance Commissioner

Address: Post Office Box 50540
2019 Washington Street, East
Charleston, West Virginia 25305-0540

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	Increase	Decrease	Current	Next	Thereafter
ESTIMATED TOTAL COST	None				
PERSONAL SERVICES	None				
CURRENT EXPENSE	None				
REPAIRS AND ALTERNATIONS	None				
EQUIPMENT	None				
OTHER	None				

2. Explanation of above estimates:

This rule will have no additional fiscal impact upon state, local or federal government.

Rule Title: Diabetes Regulations (Series 52)

3. Objectives of these rules:

The objective of this proposed rule is to set forth the equipment and supplies for the treatment and/or management of diabetes for both insulin dependent and non-insulin dependent persons with diabetes and those with gestational diabetes which shall be covered by major medical or similar comprehensive-type medical coverage if medically necessary and either prescribed by a licensed physician or upon written order by a licensed physician.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

May produce additional cost to insurance companies providing major medical coverage if equipment and supplies set forth in the rule are not currently covered.

C. Economic Impact on Citizens/Public at Large.

Insurance companies may pass along any additional cost, if any, to consumers in the form of increased premiums. Benefits to consumers with diabetes should outweigh the cost of any increase in premiums.

Date: 26 July 96

Signature of Agency Head or Authorized Representative

Stanley O. Clark

Insurance Commissioner
Legislative Rule
Title 114, Series 52

DIABETES REGULATION

Title 114, Series 52

BRIEF SUMMARY OF RULE

This proposed rule sets forth the equipment and supplies for the treatment and/or management of diabetes for both insulin dependent and non-insulin dependent persons with diabetes and those with gestational diabetes which shall be covered by major medical or similar comprehensive-type medical coverage if medically necessary and either prescribed by a licensed physician or upon written order by a licensed physician.

Insurance Commissioner
Legislative Rule
Title 114, Series 52

DIABETES REGULATION

Title 114, Series 52

STATEMENT OF CIRCUMSTANCES

On March 9, 1996, the West Virginia Legislature passed Senate Bill 312 which added Article 15C to Chapter 33 of the West Virginia Code and Section 16 to Article 16, Chapter 33 of the West Virginia Code, both relating to insurance for diabetics. The purpose of the proposed rule is to set forth the equipment and supplies for the treatment and/or management of diabetes for both insulin dependent and non-insulin dependent persons with diabetes and those with gestational diabetes which shall be covered by major medical or similar comprehensive-type medical coverage if medically necessary and either prescribed by a licensed physician or upon written order by a licensed physician.

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: OFFICE OF THE INSURANCE COMMISSIONER

DATE: August 29, 1996

LEGISLATIVE RULE TITLE: Diabetes Regulation (Series 52)

1. Authorizing statute(s) citation W.Va. Code §§ 33-2-10,
33-15C-1, and 33-16-16

2. a. Date filed in State Register with Notice of Hearing:

July 26, 1996

b. What other notice, including advertising, did you give of the hearing?

None

c. Date of hearing(s): Comment period ended on

August 26, 1996

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached XX No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

August 29, 1996

f. Name and phone number of agency person to contact for additional information:

Donna Ouesenberry

Associate Counsel

(304) 558-0401

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

Not applicable

b. Date of hearing: Not applicable

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

Not applicable

d. Attach findings and determinations and reasons:

Attached Not applicable

Attachment to Question 2(d)

The West Virginia Diabetes Advisory Committee submitted a comment expressing concern for "the lack of definition of who provides the [self-management] education [as provided for in Senate Bill 312] and under what circumstances" self-management education is provided. The Diabetes Advisory Committee contends that "the bill as written could be interpreted to allow registered dietitians and pharmacists who are not certified diabetes educators to provide complete diabetes education" and recommends "a requirement for prescription for education . . . or perhaps a requirement for referral by a health care provider with a personal identification number." Jeffrey T. Hamrick, writing of behalf of the West Virginia Association of Diabetes Educators and the West Virginia Society of Health-System Pharmacists, expresses similar concerns and proposes mandatory continuing education in diabetes education for non-certified individuals.

After a careful review of Senate Bill 312, it has been determined that an amendment to the proposed legislative rule is unnecessary. The concerns of the West Virginia Diabetes Advisory Committee, the West Virginia Association of Diabetes Educators and the West Virginia Society of Health-System Pharmacists are addressed in the bill which specifically requires a physician's prescription for self-management education. West Virginia Code §§ 33-15C-1(b) and 33-16-6(b), as amended by Senate Bill 312, provide in pertinent part:

[c]overage for self-management education and education relating to diet and **prescribed by a licensed physician** shall be limited to; (1) Visits medically necessary upon the diagnosis of diabetes; (2) visits under circumstances whereby a physician identifies or diagnoses a significant change in the patient's symptoms or conditions that necessitates changes in a patient's self-management; and (3) where a new medication or therapeutic process relating to the person's treatment and/or management of diabetes has been identified as medically necessary by a licensed physician (emphasis added)

With regard to the provision of educational services, the bill further provides that the education may be provided by a

physician as part of an office visit for diabetes diagnosis or treatment or

by a licensed pharmacist for instructing and monitoring a patient regarding the proper use of covered equipment, supplies and medications prescribed by a licensed physician, or by a certified diabetes educator certified by a national diabetes educator certification program, or a registered dietitian registered by a nationally recognized professional association of dietitians upon the referral of a physician. . . .
(emphasis added)

The bill clearly states that a licensed pharmacist is limited in his "education" efforts to instructing the patient in the proper use of covered equipment, supplies and medications, rather than providing "complete diabetes education." It is therefore unnecessary for the licensed pharmacist to become a certified diabetes instructor to perform this limited educational service. Additionally, a registered dietitian providing educational services relating to diet, rather than complete diabetes education, is required to be registered by a nationally recognized professional association of dietitians certified to the Commissioner of Insurance by the Commissioner of the Bureau of Public Health. Such qualifications should be sufficient to provide educational services relating to the management of diabetes through diet. Finally, it is outside the scope of Senate Bill 312 to require non-certified individuals to obtain mandatory continuing education relative to diabetes education. In addition to coverage for the equipment and supplies specified in Senate Bill 312, the Insurance Commissioner is granted the specific authority to require by rule coverage for additional equipment and supplies deemed necessary for the treatment and/or management of diabetes. The Commissioner has been granted no specific rule-making authority relative to the educational provisions set forth in the rule. However, to avoid any misinterpretation of the provisions of Senate Bill 312, the Commissioner, charged with enforcement of Chapter 33 of the West Virginia Code, will issue an informational letter setting forth the enforcement position of his office with regard to diabetes self-management and diet education.

In a comment received from PrimeOne, John M. Collins requests that blood pressure monitoring devices be removed as a covered item since these devices are least likely to be warranted as medically necessary. It is the Commissioner's intent with this rule to provide coverage for monitoring equipment and supplies medically necessary as a result of diabetes. Under the proposed rule, coverage will not be provided unless the equipment and supplies are medically necessary because of the diabetic condition and either prescribed by a licensed physician or upon written order by a licensed physician. This language should eliminate those concerns expressed by PrimeOne. The blood pressure monitoring equipment would not be covered if not "medically necessary." Furthermore, if the physician feels that the "monitoring of blood pressure should more appropriately be taken at a physician's office or in other settings by trained medical professionals," then he or she would not prescribe or order such monitoring equipment. Therefore, it is the Commissioner's position that coverage for blood pressure monitoring devices should not be removed from the list of covered equipment and supplies.

Thomas H. Sams, Jr., commenting on behalf of Golden Rule Insurance Company, suggests that subsection 2.1, subdivision e, be amended by deleting the language "not limited to," and listing only those items for which the rule intends to mandate coverage. Mr. Sams contends that where the covered benefits are not clearly stated, the financial burden to the insurer is unknown and may cause a premium increase to West Virginia insureds. We are in agreement with Golden Rule and amend subsection 2.1, subdivision e, to read as follows: "Orthopedic appliances, including ~~but not limited to~~ canes, crutches and walkers."

A copy of all comments are attached hereto.

RECEIVED

AUG 26 1996

**LEGAL DIVISION
W. VA. GOV. DEPT.**

August 16, 1996

Donna Quesenberry, Associate Counsel
West Virginia Insurance Commission
PO Box 50540
1124 Smith Street
Charleston, WV 25305-0540

Dear Ms. Quesenberry:

The West Virginia Diabetes Advisory Committee wishes to express commendations and concerns relative to the legislative rule for diabetes regulations. The equipment and supplies listed and are inclusive to meet the needs of persons with diabetes and are broader in scope than most state's. We are grateful for that. It is unfortunate that most of the items are listed in the bill rather than as rules since that list may at some point become obsolete. However, it would appear that in the rules the list has been expanded and probably could be expanded further in the future if needed.

Our concerns rest with the lack of definition of who provides the education and under what circumstances. It was our hope that the language related to identification of provider and type of teaching provided by each would be clarified. For instance, the bill as written *could* be interpreted to allow registered dietitians and pharmacists who are not certified diabetes educators to provide complete diabetes education. There is considerable evidence, based on advertising of services in some institutions, that many health care providers have indeed interpreted the bill in that fashion. Although the wording of the bill cannot be changed at this point, rules could clarify this issue. A requirement for prescription *for education* would clarify the issue, or perhaps a requirement for referral by a health care provider with a personal identification number. It may be possible for this ammendment to be done before August 26.

Insurance companies and health maintenance organizations should be able to refuse payment for educational services conducted at point of sale if those services were not requested by the physician. The referral method used by consultants might also work, when services are requested by a primary care provider from a consultant, the insurance company requires an identification number for that referring physician. Without an appropriate referral the service is denied for reimbursement.

The scenario that is to be avoided is one in which a primary care clinic hires a certified

diabetes educator (CDE) only to learn that with every insulin or meter prescription the educational services are being performed by a non-CDE pharmacist who is billing for that service before the educator sees the patient. If the rules are not clarified, it would appear that the only solution is for every diabetes supply or medication prescription to carry the stipulation, "for purchase only, no education" or "for supplies and education."

Sincerely,

For the West Virginia Diabetes Advisory Committee

Charlotte Nath, RN, EdD, CDE, Chair Charlotte Nath

Nabil Jabbour, MD, Member [Signature]

cc: Henry G. Taylor, M.D., M.P.H.
Commissioner
WV Bureau for Public Health

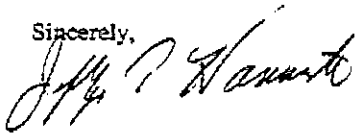
Ms. Donna Quesenberry, Associate Counsel
West Virginia Insurance Commission
PO Box 50540
1124 Smith Street
Charleston, WV 25304-0540

Dear Ms. Quesenberry:

The West Virginia Association of Diabetes Educators wishes to express concerns and commendations relative to legislative rule for diabetes regulations. The equipment and supplies are listed and are inclusive to meet the needs of the persons with diabetes.

Our concerns rest with the lack of definition of who provides the education and under what circumstances. It was our hope that the language related to identification of provider and type of teaching provided by each would be clarified. The bill could be interpreted as to allow non-certified diabetes educators to provide complete diabetes education (i.e. pharmacists, dietitians, nurses, etc.). This is a definite possibility and is a real concern to our organization. I believe complete education of the diabetic should be reserved for individuals who have extensive education in the field. I suggest a mandatory annual number of contact hours in diabetes education for these non-certified individuals and allow them to provide services in their scope of practice, not *complete* diabetes education. Insurance companies and health maintenance organizations should be able to refuse payment for educational services conducted by these individuals if they do not satisfy the mandatory continuing education hours required. I suggest the continuing education hours equate to 25-33% of the required continuing education for that particular profession by law. I do not believe that individual professions should be "singled out" for reimbursement denial without consulting the governing organization for that profession in West Virginia and obtaining recommendations from that governing body.

Sincerely,



Jeffrey T. Hamrick, R.Ph., C.D.E.
President, West Virginia Association of Diabetes Educators
President, West Virginia Society of Health-System Pharmacists

PRIMEONE
An Anthem Health Plan

P.O. Box 1109
Charleston, West Virginia 25324
1-800-607-7461

August 26, 1996

Direct Dial (304) 353-8707

Donna S. Quesenberry, Associate Counsel
West Virginia Insurance Commissioner
1124 Smith St.
P.O. Box 50540
Charleston, WV 25305-0540

Re: Proposed Rule Series 51 Utilization Management
Proposed Rule Series 52 Diabetes Regulation

Dear Ms. Quesenberry:

I have reviewed the above captioned proposed rules and would like to submit two minor comments for your consideration.

The Utilization Management rule defines qualified medical professional as a person licensed or certified pursuant to the laws of the State of West Virginia to provide health care services to persons. Section 4.7(b) of the rule states that qualified medical professionals shall review decisions for pre-authorization of medical services and concurrent review of admissions. This would therefore seem to limit this activity to individuals only licensed or certified by the State of West Virginia. There are currently HMOs licensed in West Virginia with offices based outside the state. The professionals performing the utilization management functions for these entities may only be licensed in the state in which their offices are located. Many of the newly licensed HMOs as well as future companies that may seek Licensure may wish to perform certain utilization management functions at central facilities based at locations outside of West Virginia. This could include the input of specialist or Medical Directors that serve several companies that are interrelated. I would suggest that you amend this section of the regulation to allow for some type of reciprocity for professionals licensed in other jurisdictions.

The diabetes rule at section 2.1 identifies equipment and supplies that must be covered if determined to be medically necessary by the prescribing physician. These items would appear to be in addition to the items specifically mentioned at

██████████
██████████
██████████

§ 33-15c-1 and § 33-16-16 of the West Virginia Code. One of these items, specifically item c. at section 2.1 is a blood pressure monitoring device. This device is the least likely item to be warranted as medically necessary. HMOs generally do not even cover blood pressure monitoring devices for hypertensive patients or patients with heart disease. The monitoring of blood pressure should more appropriately be taken at a physicians office or in other settings by trained medical professionals. These professionals are trained to recognize the need for additional treatment when high readings occur that the patient may not necessarily recognize. Physicians, primary care physicians in particular, allow patients with high blood pressure to routinely visit their office for blood pressure checks free of charge. Identifying this item as covered in the regulation tends to raise the standard of care. Even though HMOs would not consider it medically necessary for a diabetic patient to monitor their blood pressure at home, the fact that it is identified in the regulation implies that the member is entitled to the coverage. We would suggest that this item be removed from the list.

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,


John M. Collins

GOLDEN RULE INSURANCE COMPANY
7440 WOODLAND DRIVE
INDIANAPOLIS, IN 46278-1719

TELE (317) 297-4123
FAX (317) 297-0908

FACSIMILE COVER SHEET

TO: Donna S. Quesenberry

FAX #: 304-558-0412 PHONE #: _____

FROM: Tom Sams

RE: Letter re: Diabetes Regulations

DATE: 8-26-96 TIME: 10:20

This transmission consists of 3 pages, including this cover sheet. If all pages are not received or there are any questions, please contact (317) 297-4123, extension 7615.

This cover sheet and the materials enclosed with this transmission are the private, confidential property of the sender, and the materials are privileged communications intended solely for the receipt, use, benefit, and information of the intended recipient indicated above. If you are not the intended recipient, you are hereby notified that any review, disclosure, copying, distribution, or the taking of any other action in reliance on the contents of this transmission is strictly prohibited and may result in legal liability on your part. This communication may be the subject of a legal privilege. Receipt by anyone other than the intended recipient shall not be a waiver of any privilege. If you have received this transmission in error, please notify us immediately at the above telephone number and arrange for return of this transaction to us.

The original will be sent to you by overnight mail. You will receive it tomorrow, Aug. 27, 1996.

OPERATOR'S NAME: J.

Golden Rule®

August 26, 1996

Ms. Donna S. Quesenberry
Associate Counsel
West Virginia Department of Insurance
P.O. Box 50540
1124 Smith Street
Charleston, West Virginia 25305-0540

Dear Ms. Quesenberry:

I am commenting on behalf of Golden Rule Insurance Company with respect to the proposed rule by the Insurance Commissioner relating to "Diabetes Regulations" -- title 114, Series 52.

Golden Rule is concerned with the proposed rule as it applies to "orthopedic appliances." Section 114-52-2 states, "Any policy which provides major medical or similar comprehensive-type medical coverage shall include coverage for...orthopedic appliances, including but not limited to canes, crutches and walkers." (Emphasis added.)

Covering canes, crutches, and walkers does not pose a problem. However, the language, "but not limited to" leaves insurance companies wide-open to any apparatus which may be considered an "orthopedic appliance."

It is difficult for us to estimate the potential financial impact on our company and more importantly, our insureds with this type of unknown factor involved. For example, some types of durable medical equipment which may be considered orthopedic appliances can cost thousands of dollars.

Golden Rule would suggest the proposed rule be amended by omitting the "but not limited to" language and listing only those items for which the rule intends to mandate coverage.

When mandating coverage and benefits, it is essential to bear in mind the possible financial consequences insureds may face. In a rule such as this, where the covered benefits, or in this case appliances, are not clearly stated, the financial burden is

Golden Rule Insurance Company
Home Office
712 Eleventh Street
Lawrenceville, Illinois 62439
☎ (618) 943-8000

Golden Rule Insurance Company
Golden Rule Building
7440 Woodland Drive
Indianapolis, Indiana 46278-1719
☎ (317) 297-4123

Ms. Donna S. Quesenberry
Page 2
August 26, 1996

unknown. This unknown variable is likely to cause a premium increase for other West Virginia insureds.

By specifically listing the covered benefits, companies can better predict the costs involved in covering these appliances, and can eliminate possible premium increases associated with the additional benefits.

If you have any questions or would like any further information, please feel free to contact me or our local lobbyist Tom Susman.

Sincerely,



Thomas H. Sams, Jr.
Public Policy Specialist
Government Relations

THS/am
Enclosure

cc: Cheryl Lieske
Anita Schrader
Tom Susman

114CSR52
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 52
DIABETES REGULATIONS

Section			
§114-52-1.	General.		
§114-52-2.	Insurance Coverage for Diabetics.		
§114-52-3.	Severability.		

114CSR52
WEST VIRGINIA LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 52
DIABETES REGULATIONS

§114-52-1. General.

1.1. Scope. -- The purpose of this rule is to set forth the equipment and supplies for the treatment and/or management of diabetes which shall be covered by major medical or similar comprehensive-type medical coverage if medically necessary and either prescribed by a licensed physician or upon written order by a licensed physician.

1.2. Authority. -- W. Va. Code §§ 33-2-10, 33-15C-1 and 33-16-16.

1.3. Filing Date. --

1.4. Effective Date. --

§114-52-2. Insurance Coverage for Diabetics.

2.1. Except as provided in W. Va. Code § 33-15-6, any policy which provides major medical or similar comprehensive-type medical coverage shall include coverage for the following equipment and supplies for the treatment and/or management of diabetes for both insulin dependent and noninsulin dependent persons with diabetes and those with gestational diabetes, if medically necessary because of the diabetic condition and either prescribed by a licensed physician or upon written order by a licensed physician:

- a. Urine ketone testing strips;
- b. Urine microalbumin test;
- c. Blood pressure monitoring device;
- d. Podiatric appliances and therapeutic footwear; and

Insurance Commissioner
Legislative Rule
Title 114, Series 52

e. Orthopedic appliances including canes, crutches and walkers.

§114-52-3. Severability.

3.1. If any provision of this rule or the application of this rule to any person or circumstances is for any reason held to be invalid, the remainder of the rule and the application of the provisions to other persons or circumstances shall not be affected by the holding.