OPINION OF TRUSTEES

In Re

Complainant: Employees
Respondent: Employer
ROD Case No: 93-079 – March 17, 2000

Trustees: A. Frank Dunham, Michael H. Holland, Donald E. Pierce, Jr., and Elliot A. Segal.

The Trustees have reviewed the facts and circumstances of this dispute concerning the provision of health benefits coverage for generic and brand name prescription drugs under the terms of the Employer Benefit Plan.

Background Facts

The Employer has implemented a prescription drug program that requires the use of generic drugs in lieu of brand name drugs unless the prescribing physician submits written justification of the medical necessity for the brand name drug(s) to the Employer's Plan Administrator; checking the "Brand Name Only" box on the prescription form or writing "Do Not Substitute" on the prescription is insufficient. In those instances where approval has not been requested or received, the Employee must pay the difference between the generic and brand name drug. The Employer's drug program provides for payment of generic drugs that are approved by the federal Food and Drug Administration (FDA) and rated AB or better.

The Employer's drug program was communicated to Employees and Pensioners at the time it was implemented through general meetings, letters to retirees and memoranda to Employees.

The Employees' representative maintains that the requirement to submit written medical necessity documentation for brand name drugs does not conform to the terms of the 1993 Coal Wage Agreement, and that the drug plan may create a financial hardship for Beneficiaries because it requires them to pay the difference between generic and brand name drugs.

Dispute

Are the Employer's requirements that a Beneficiary provide medical documentation to support the use of brand name drugs, and pay the difference between generic and brand name, consistent with the provisions of the 1993 Employer Benefit Plan?

Positions of the Parties

Position of the Employee: The Employer's prescription drug program does not conform to the terms of the Employer Benefit Plan because only the allowance for a generic equivalent is provided when brand name drugs are prescribed but not approved by the Plan Administrator. Written justification then must be submitted before the brand name allowance will be provided. This may create a hardship for Beneficiaries.

Position of the Employer: The Employer's prescription drug program is consistent with the cost containment provisions of the 1993 Coal Wage Agreement and the 1993 Employer Benefit Plan because it effectively reduces costs without reducing the quality of health care. Only drugs approved by the FDA and rated AB or better are allowed. The requirement that the prescribing physician submit written justification is reasonable and is working well for the great majority of the Beneficiaries.

Pertinent Provisions

Article XX (10) b. of the 1993 Coal Wage Agreement states:

> Enhanced Cost Containment Program
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> b. Generic Drug Substitution
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> If a Beneficiary uses a brand name drug when a generic equivalent is available, the Beneficiary is responsible for the difference in cost between the generic drug and the brand name drug, in addition to the normal copayment. . . In addition, if the prescribing physician determines that use of a brand name drug is medically necessary, the generic drug will not be considered "available," and there will be no additional payment by the Beneficiary for the use of the brand name drug.

The Introduction to Article III of the 1993 Employer Benefit Plan states in pertinent part:

> . . . Covered services shall be limited to those services which are reasonable and necessary for the diagnosis or treatment of an illness or injury and which are given at the appropriate level of care, or are otherwise provided for in the Plan. The fact that a procedure or level of care is prescribed by a physician does not mean that it is medically reasonable or necessary or that it is covered under this Plan. . . .

Article III A. (4) (a) of the 1993 Employer Benefit Plan states:

(4) Prescription Drugs

(a) Benefits Provided

Reasonable charges for prescription drugs or insulin are covered benefits. Reasonable charges will consist of the lesser of:

(1) The amount actually billed per prescription or refill,

(2) The price of the applicable generic substitution drug, if AB or better-rated, approved by the federal Food and Drug Administration; or, in the event the prescribing physician determines that the use of a brand name drug is medically necessary, the price of such brand name drug; or

(3) The current price paid to participating pharmacies in any prescription drug program established by the Employer.

However, in no event will a Beneficiary be responsible to pay more for a single prescription than the appropriate co-payment set forth in this Plan, plus any difference between the price of the generic and the brand name drug, where applicable.

Article III A. (10) (b) and (h) 2. of the 1993 Employer Benefit Plan state, in pertinent part:

(10) General Provisions

(b) Administration

The Plan Administrator is authorized to promulgate rules and regulations to implement and administer the Plan, and such rules and regulations shall be binding upon all persons dealing with the Beneficiaries claiming benefits under this Plan. . . .

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(h) Explanation of Benefits (EOB) and Hold Harmless

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> 2. The Employer and the UMWA agree that excessive charges and escalating health costs are a joint problem requiring a mutual effort for solution. In any case in which a provider attempts to collect excessive charges or charges for services not medically necessary, as defined in the Plan, from a Beneficiary, the Plan Administrator or his agent shall, with the written consent of the Beneficiary, attempt to resolve the matter, either by negotiating a resolution or defending any legal action commenced by the provider. . . .

Article IV. A. (2) and C. 16. of the 1993 Employer Benefit Plan state, in pertinent part:

> Article IV. Managed Care, Cost Containment
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> A. (2) In addition, the Employer may implement certain other managed care and cost containment rules, which may apply to benefits provided both by PPL providers and by non-PPL sources, but which (except for the deductibles and co-payments specifically provided for in the Plan) will not result in a reduction of benefits or additional costs for covered services provided under the Plan.
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> C. The following requirements apply to a PPL implemented under this Plan:
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> 16. Percertification -- Precertification for services (including hospitalization) performed by PPL providers is the responsibility of the provider, and not the covered individual. In addition, precertification in the event a covered individual is referred to a provider outside the PPL is the responsibility of the PPL provider making the referral.

Discussion

Article XX (10) b. of the 1993 Wage Agreement requires that a Beneficiary pay the difference in cost for the use of a brand name drug when a generic drug is available. If, however, the prescribing physician determines that the brand name drug is medically necessary, then the generic drug will not be considered "available," and there will be no additional payment by the Beneficiary. This is further developed in Article III. A. (4) (a) of the 1993 Employer Benefit Plan, which states that the Beneficiary is responsible for the additional cost of a brand name drug over the generic substitute where a generic equivalent that has been approved by the FDA and is

rated AB or better is available. Article III. A. (10) (b) authorizes an Employer to promulgate rules and regulations to implement and administer the Plan. The Trustees have determined in prior RODs (see RODs 81-697 and 84-042) that such rules and regulations are binding if they are reasonable and have been effectively communicated to the Beneficiaries. Additionally, Article IV A. (2) states that an Employer may implement other managed care and cost containment rules but, except for the deductibles and co-payments provided for in the Plan, such rules cannot result in a reduction of benefits or additional costs for covered services provided under the Plan.

The Employer in this case has established a generic drug substitution program to assist in containing drug costs. Only drugs approved by the FDA and rated AB or better qualify. Under the program, if a prescription is filled with a brand name drug when a generic is available, the plan will pay only the generic price less the applicable co-pays and deductibles and the Beneficiary will be charged the difference. A letter to retirees further states, "If your doctor can provide documented evidence . . . that the [brand name] drug is medically necessary the plan will pay the increased cost. We strongly urge you to use generic drugs whenever possible." The mailing also included a pamphlet on generic drugs that states, "If a generic is available, the plan will reimburse at the generic rate. If you purchase a brand name when a generic is available, you pay the difference between the generic and brand name prices and submit medical documentation from the treating physician to the plan administrator for review."

Under the 1993 Employer Benefit Plan, when a generic drug is "available" but the Beneficiary chooses to use a brand name drug, the Beneficiary is responsible for the cost difference between the generic and brand name drug. From the information submitted, the Employer's drug program was effectively communicated.

Is the Employer's requirement for written justification consistent with the 1993 Wage Agreement and the 1993 Employer Benefit Plan? Or, should a physician's indication, as by checking a "Brand Name Only" box, or by written note, "Do Not Substitute," be sufficient? The Employer requires that the physician submit written justification for the Plan Administrator's review at the time the prescription is written. If medical necessity for the brand name is shown, the brand name drug is dispensed with the usual co-payment. If medical necessity for the brand name is not shown at the time the brand name drug is dispensed, the Beneficiary must pay the difference between the generic and brand name drug as well as the co-payment, and submit the physician's medical necessity letter to the Plan Administrator later.

In several instances, the 1993 Employer Benefit Plan allows review of a physician's decisions. The Introduction to Article III, allows general review in light of "[t]he fact that a procedure or level of care is prescribed by a physician does not mean that it is medically reasonable or necessary or that it is covered under this Plan." Article III. A. (10) (h) 2. the "Hold Harmless" section, allows review to determine excessive charges or charges for services that are not medically necessary. Article IV C. 16. allows pre certification review of hospitalization and other medical services. Thus, the Employer's requirement that physicians provide a statement to

the Plan Administrator justifying the use of a brand name over a generic drug is reasonable and consistent with the provisions of the 1993 Coal Wage Agreement and the 1993 Employer Benefit Plan; provided, however, the Employer does not impose rules that arbitrarily hinder or deny a Beneficiary reasonable and timely access to required medications. In the point-of-sale environment where drugs are secured by the Beneficiary, the rules should not be unnecessarily cumbersome or restrictive.

Opinion of the Trustees

The Employer's generic drug program is consistent with the prescription drug coverage and cost containment provisions of the 1993 Wage Agreement and the 1993 Employer Benefit Plan, provided the Employer does not impose rules that arbitrarily hinder or deny a Beneficiary reasonable and timely access to required medications.