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Re: Interpretive Opinion No. 04-15, Applicability of the Tennessee Prescription Drug Discount Plan Regulations to Copay Assistance Programs

Dear Mr. Broemel,

The Division of Insurance of the Tennessee Department of Commerce and Insurance (“Division”) is in receipt of the request for an interpretive opinion submitted on or about April 21, 2015 to Tony Greer, Chief Counsel for Insurance. Your inquiry requested guidance regarding whether copay assistance programs are subject to regulation by the Division.

Specifically, you asked whether a copay assistance program, designed to assist insured individuals to pay costly copay obligations for specific prescribed drugs, is required to obtain a certificate of authority from the Division pursuant to the Volunteer Rx Program found in Tenn. Code Ann. § 56-57-101, *et seq.*

The facts as understood by the Division are as follows: a copay assistance program provides assistance in the payment of costly copay obligations related to specific drugs manufactured by the company providing the copay assistance program. This program does not provide assistance for any and all prescription drugs with copayment requirements. Individuals who qualify for this copay assistance program include individuals with insurance¹ that covers the contemplated drug,

¹ This copay assistance program does not apply to state or federally funded plans. Exempt from this program are individuals enrolled in Medicare, Medicare Part D, Medicare Advantage, Tricare, Veterans Affairs (VA), Department of Defense (DoD), federally funded commercial insurance plans, or other state or federally funded programs.

but who still have prohibitively high copay obligations in excess of their insurance coverage. Uninsured individuals are not qualified to participate in this program.

This copay assistance program does not restrict participating individuals to specific pharmacies. Rather, participating individuals are entitled to utilize this assistance at any entity where the program drug may be purchased. Furthermore, this copay assistance program does not impose fees on participating individuals; the program is free to patients prescribed the contemplated drug. This copay assistance program limits participants to twelve (12) uses of the program and an eight thousand dollar (\$8,000) cap per calendar year. The program does not provide a percentage discount, but rather pays the individual's entire copay less five dollars (\$5). Essentially, participating insured individuals incur a five dollar (\$5) out-of-pocket expense per prescription filled for the plan-contemplated drug.

First and foremost, a contract for insurance is “an agreement by which one party, for a consideration, promises to pay money or its equivalent, or to do some act of value to the assured, upon the destruction or injury, loss or damage of something in which the other party has an insurable interest[.]” Tenn. Code Ann. § 56-7-101(a) (2012). The copay assistance program described above is not insurance as no consideration is paid by the participating individuals. Additionally, as this program is synonymous with a manufacturer rebate, the program does not rise to the level of insurance under the Tennessee Insurance Law. As this program cannot be considered insurance under Tennessee Insurance Law, whether it is a Prescription Drug Discount Plan, and thus subject to regulation, must be determined.

The Division requires any entity² operating a Prescription Drug Discount Plan to obtain a certificate of authority to so operate. Tenn. Code Ann. § 56-57-103 (2005). Prescription Drug Discount Plans include “any card or other purchasing mechanism or device, that is not insurance, that purports to offer discounts or access to discounts to any person for the retail purchase of prescription drugs from licensed pharmacies.” Tenn. Code Ann. § 56-57-101(7) (2005). The typical business structure of a Prescription Drug Discount Plan includes member payment of upfront membership fees, a network of participating licensed pharmacies, and a fixed list of prescription drugs and drug classifications covered under the plan or, alternatively, an open formulary of drugs. *See* Tenn. Code Ann. § 56-57-104 (2005). A member of a Prescription Drug Discount Plan is not obligated to maintain insurance in order to participate in the plan; membership is predicated on enrollment or payment of membership fees alone. § 56-57-101(3).

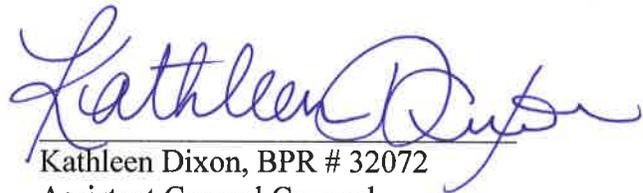
The copay assistance program described above seeks to complementarily benefit a limited number of individuals; specifically, insured individuals with valid prescriptions for a program-contemplated drug. The program does not provide discounts, but instead pays the entirety of a participant's copay in excess of five dollars (\$5). The program further does not dictate where an individual may utilize the benefits provided under this plan. Lastly, this program does not provide comprehensive benefits for any prescription filled, it only covers the program-contemplated drug manufactured by the entity providing the copay assistance program. Such a plan is not a Prescription Drug Discount Plan, and is not subject to regulation under Tenn. Code Ann. § 56-57-101, *et seq.*

² For the purposes of this opinion, an entity includes any individual or business entity. *See* § 56-57-101(5).

Please note that the Division has not made an independent investigation of the facts to determine the accuracy or completeness of the information supplied, but has instead relied solely upon the information you have provided. If such information is incorrect or changes substantially, it would be necessary for the Division to reconsider the matter and the position stated herein would be void. This letter expresses the Division's position on enforcement action only and does not purport to express legal conclusions on the issues presented. This position is furnished solely for the benefit and use of the entities described herein. Please be advised that further publication or use of this position may only be made with the Division's prior written consent.

This response by the Division is to a specific fact situation relating to the interpretation of a specific copay assistance program and the Volunteer Rx Act and should not be construed as a legal position or opinion of the Commissioner of the Tennessee Department of Commerce and Insurance or of any other official in the Department. Please note that the conclusions contained herein are based upon the representations that have been made to the Division, and any different facts or conditions might require a different response. As each inquiry is reviewed on the specific facts presented, this response is based only on such facts and may not be used as precedent by any person or entity. Any variation in the facts presented to the Division by Mr. W. Davidson Broemel could result in a different conclusion than asserted herein.

If you have further questions or concerns regarding this letter, please feel free to contact me.



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