

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION WASHINGTON, D.C. 20580

Bureau of Competition Health Care Division

April 9, 2010

Kathleen A. Reed Dykema Gossett PLLC 400 Renaissance Center Detroit, MI 48243

Re: University of Michigan Advisory Opinion

Dear Ms. Reed:

This letter responds to your request on behalf of the University of Michigan (the "University") for an advisory opinion on whether a prescription-drug benefit program proposed by the University would fall within the Non-Profit Institutions Act ("NPIA"). The NPIA exempts from the Robinson-Patman Act "purchases of . . . supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit."¹ Based on the information that you have provided, we have concluded that, subject to certain caveats set forth below, the NPIA exemption would apply to the University's proposed use of NPIA-discounted pharmaceuticals through a GPO replenishment-based drug benefit program.

Program Description

We understand from your letter that the University is a public university chartered under the Constitution of the State of Michigan.² It is also a 501(c)(3) tax-exempt entity.³ It provides a prescription drug benefit to its employees and retirees, and their dependents. The University currently does not utilize NPIA-discounted drugs as part of its health program. To reduce the cost of continuing to provide this benefit, the University proposes to establish and operate a GPO replenishment-based drug benefit program (the "proposed program").⁴ In short, the proposed program would allow the University to use NPIA-discounted drugs purchased through a GPO when the NPIA pricing is lower than the standard pricing available to the University through its pharmacy benefits manager. This use of the NPIA-discounted

¹ 15 U.S.C. § 13c.

² See October 26, 2009 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 1.

³ See http://www.umich.edu (last viewed March 1, 2010).

⁴ See October 26, 2009 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 1.

pharmaceuticals, where they are the least expensive option, would reduce the cost to the University of its health benefits program.

The University will engage the services of a number of entities to operate the proposed program. These entities are: (1) informedRx, a for-profit pharmacy benefits manager; (2) Wellpartner, Inc., a for-profit replenishment administrator and mail-order pharmacy, and (3) a number of for-profit retail, mail-order, and University-owned pharmacies (each a "participating pharmacy"). Only University employees and retirees, and their dependents, will be eligible to participate in the program (the "members").⁵

Under the proposed program, members will submit prescriptions to a participating pharmacy, which will contact informedRx to verify the members' eligibility to participate. The participating pharmacy will fill the prescription, collect the copayment, and submit a claim to informedRx for processing and payment. Upon receipt of the claim, and on behalf of the University, informedRx will reimburse the participating pharmacy for pharmaceuticals dispensed to members under the standard rates established in contracts with the University, the participating pharmacy, and informedRx. The University will reimburse informedRx for all claims paid on its behalf and will pay informedRx an administrative fee for its services. The administrative fee paid to informedRx will be a flat fee and will not depend on the type of claim (NPIA or non-NPIA) paid.

On an approximately biweekly basis, informedRx will transfer the data for the claims it has handled for the University to Wellpartner. Wellpartner will use its proprietary algorithms to compare the standard rate already paid by the University for the pharmaceuticals with the NPIA-discounted rate available through the GPO to which the University belongs. If the NPIA-discounted rate available through the GPO is determined to be lower than the standard rate, Wellpartner will process the claim using the NPIA rate. As part of its claims processing, it will: (1) recoup from the participating pharmacy that filled the prescription all monies associated with the claim, less the participating pharmacy's fee; (2) subtract its own administrative fee (a flat fee not tied to the type of claim) from the recouped monies and submit the remainder to the University; and (3) place an order with the GPO for NPIAdiscounted pharmaceuticals to replace (or "replenish") the pharmaceuticals that were dispensed by the participating pharmacy. Upon receiving the order, the GPO's wholesaler will ship the NPIA-discounted pharmaceuticals directly to the participating pharmacy that dispensed the pharmaceuticals, and will send an invoice for the replacement pharmaceuticals to the University for payment. The University will retain all savings associated with the replacement of the standard-rate pharmaceuticals with the NPIA-discounted pharmaceuticals.⁶

To summarize, informedRx will process claims for the University. Wellpartner, using claims data obtained form informedRx, will determine those cases in which NPIA-discounted pharmaceuticals are the least expensive option and, in those instances, will replenish the

⁵ See id.

⁶ See id at 2-3.

participating pharmacy's standard-rate pharmaceuticals with the NPIA-discounted pharmaceuticals.

Though, as explained above, the fees paid to informedRx and Wellpartner will be flat fees that will not vary with the type of claim processed (NPIA or non-NPIA), the participating pharmacy fee is not a flat fee. Rather, for standard-rate claims the participating pharmacy nets the difference between the amount paid for the pharmaceuticals by the pharmacy benefit manager (plus the member copay) and the amount paid by the pharmacy for the pharmaceutical (its wholesale acquisition cost or "WAC"). Thus, the amount the pharmacy earns on each claim varies.

In the case of NPIA claims, the University must attempt to replicate this amount to enable Wellpartner to recoup the correct amount as part of its claims processing and to ensure that the for-profit participating pharmacies do not financially benefit from filling NPIA claims. To replicate the amount, the University would need to know each participating pharmacy's WAC for the pharmaceuticals involved in each NPIA claim. But pharmacies do not generally share this information; they consider their WACs to be proprietary information. For this reason, the University proposes to use Wellpartner's WAC for each pharmaceutical as a substitute for the participating pharmacies' WACs on NPIA claims and to calculate the fee retained by the participating pharmacies on those claims on a "per claim, per drug" basis using the Wellpartner WAC.⁷ Further, the University will use up-to-date WAC data from Wellpartner, and, together with Wellpartner, "will develop and implement an audit process to monitor the GPO Program's compliance with the program parameters."⁸ The University represents that Wellpartner's WAC "is likely to be slightly higher than, or at best, equal to the WAC enjoyed by" the participating pharmacies.⁹ Thus, the University believes that the use of Wellpartner's WAC in the manner described – as a proxy for the participating pharmacies' WACs – is likely to minimize or eliminate the risk that a for-profit participating pharmacy could financially benefit from NPIA claims.

⁸ See id.

⁹ You explain in your January 25, 2010 letter, to Ellen Connelly that Wellpartner "is a large, retail mail order pharmacy with one of the largest drug purchase and sale volumes of pharmacies in its region" and that it purchases its pharmaceuticals in the same market as the participating pharmacies. As a result of its concentration in the Pacific Northwest, however, Wellpartner's "absolute purchasing volume is not as large as the purchasing volume of the national retail pharmacy chains and independent pharmacy group purchasing organizations to which" they belong. This lower purchasing volume is partially offset by the wholesalers' management of their business and pricing by a regional level. These factors, according to your letter, mean that Wellpartner's WAC is likely to be a very close approximation of the participating pharmacies' WACs. *See* January 25, 2010 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 2.

⁷ See January 25, 2010 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 3.

Analysis

Our analysis of whether the proposed program is eligible for the NPIA exemption requires us to answer three questions: (1) is the University – the entity that will be purchasing the NPIA-discounted pharmaceuticals – an eligible entity under the statute; (2) are the NPIA-discounted pharmaceuticals properly considered "supplies" for the University's "own use;"¹⁰ and (3) does the proposed GPO-replenishment structure, ¹¹ which involves for-profit entities at various stages of the program, affect eligibility for the exemption?

1. The University's Eligibility for the NPIA Exemption

Because the NPIA exemption is limited in its availability to certain specified entities, we must first determine if the University is one of those eligible entities. The NPIA exempts from the Robinson-Patman Act "purchases of . . . supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit."¹² The University is a 501(c)(3) public university operated for the advancement of education.¹³ As one of the types of eligible entities specifically listed in the language of the statute, the University is eligible for the NPIA exemption to the Robinson-Patman Act.¹⁴

2. The "Supplies" and "Own Use" Requirements

We next examine whether the proposed program involves the purchase of "supplies" for the University's "own use" as required by the statute. The term "supplies," as used in the NPIA, has been construed broadly to include "anything" required to meet the eligible institution's

¹⁰ 15 U.S.C. § 13c.

¹¹ Under the proposed program, the actual NPIA-discounted pharmaceuticals will not be the pharmaceuticals used to fill members' prescriptions. Rather, the participating pharmacies will fill the prescriptions with the product they have on inventory. If, upon later analysis by Wellpartner and the University, the NPIA-discounted pharmaceuticals are determined to be more cost effective, the University will "replenish" the participating pharmacies' stock with the NPIA-discounted pharmaceuticals.

¹² 15 U.S.C. § 13c.

 13 See http://www.umich.edu (last viewed March 1, 2010). Though the University is chartered under the Constitution of the State of Michigan and is not explicitly incorporated as a non-profit organization, it has all of the indicia of a non-profit entity. It operates for the advancement of education, does not operate for the profit of any individual, and maintains a 501(c)(3) classification under the federal tax code.

¹⁴ 15 U.S.C. § 13c.

needs.¹⁵ Thus, the question becomes whether pharmaceuticals can properly be considered necessary to meet the University's needs and, further, whether the proposed distribution of pharmaceuticals to the members (the University's employees and retirees and their dependents) through the GPO-replenishment system is for the University's "own use." For guidance on these issues, we look to the Supreme Court's decision in *Abbott Laboratories v. Portland Retail Druggists Association.*¹⁶

In *Abbott Laboratories*, retail pharmacies sued pharmaceutical manufacturers under the Robinson-Patman Act, challenging the discounted sale of pharmaceuticals to nonprofit hospitals. The hospitals resold those discounted pharmaceuticals to various types of patients. The Court held that the NPIA exemption is not an open-ended one. Rather, it applies to purchases of supplies by eligible entities only insofar as they are for the entities' "own use;" that is, for use by the entity "in the sense that such use is part of and promotes the [entity's] intended institutional operation."¹⁷ The Court went on to hold that pharmaceuticals purchased for resale to hospital employees and their dependents were covered by the NPIA, because the employees were essential for the hospital to function. In the Court's view, providing them with pharmaceuticals enhanced the hospital's operation.¹⁸

Similar reasoning leads us to conclude that the University's employees enable it to perform its educational mission. As you have explained, the University currently provides health insurance plans with a prescription drug benefit to its employees and their dependents. Continuing to offer this program as an employee benefit contributes to the University's ability to maintain a capable workforce. With the well-documented rise in health-care costs, the availability of an employer-offered health benefit plan has become a critical consideration in an individual's employment decision-making process. The continued availability of the University's health-insurance program is essential to its ability to attract and retain the employees it needs to carry out its institutional purpose. Providing a prescription-drug benefit to its employees also promotes the University's efficient operation by making medicine more affordable and accessible to these employees, thereby improving their health and providing incentives for reduced employee turnover and absences.¹⁹ Thus, consistent with *Abbott Laboratories* and with prior FTC staff advisory opinions, we find that the University's

¹⁶ 425 U.S. 1 (1976).

¹⁷ *Id.* at 14.

¹⁸ *Id.* at 16.

¹⁵ See Logan Lanes v. Brunswick Corp., 378 F.2d 212, 216 (9th Cir. 1967), cert. denied 389 U.S. 893 (1967); see also Abbott Lab. v. Portland Retail Druggists Ass'n, 425 U.S. 1, 5 (1976) (noting that the district court had ruled that purchases of pharmaceuticals by the hospitals were purchases of "supplies" for the hospitals "own use.")

¹⁹ See Valley Baptist Medical Center (Mar. 13, 2003) (FTC staff opinion letter).

provision of discounted pharmaceuticals to its employees and their dependents as part of its program of providing employee benefits would be for its "own use," and thus would be covered by the NPIA exemption.²⁰

Further, we conclude that the University's plan to include retirees in the proposed program does not affect its eligibility for the NPIA exemption. Retiree benefits are an integral part of the package of compensation offered to current and prospective employees and may help the University attract and retain qualified employees through retirement. In this regard, providing a prescription pharmaceutical benefit to retirees furthers the University's education mission just as in the case of current employees. Thus, when the NPIA-discounted pharmaceuticals are provided to retirees as part of an established retirement benefit plan, they are within the University's "own use" in the same way as are those provided to current employees.²¹

3. The Involvement of For-Profit Entities

The proposed program, as described in your letter, will involve a number of for-profit entities. You have represented that only the University – as the eligible entity under the NPIA – will purchase the NPIA-discounted pharmaceuticals. As you explain in your letter, the University will hold the contract with the designated GPO for the purchase of the pharmaceuticals. The University will receive and pay all invoices.²²

To implement its proposed program, however, the University will engage the services of a number of other for-profit entities (i.e. informedRx, Wellpartner, and the participating pharmacies) that are clearly ineligible to benefit from the NPIA exemption. Though the mere involvement of the for-profit entities does not automatically invalidate the proposed program's NPIA eligibility, it does require assurance that none of the for-profit entities will benefit directly or indirectly from the exemption.

In the proposed program, the role of the for-profit entities will be limited. InformedRx will act as a pharmacy benefit manager and will provide mainly administrative support in the form of claims and reimbursement processing. For these services, it will be paid the same flat fee regardless of whether the claim is filled with NPIA-discounted pharmaceuticals or not. Thus, it does not stand to benefit from its participation in the proposed program. Similarly, Wellpartner's roll in the proposed program is limited to performing price comparisons on claims to determine whether the claim would be more economically filled with NPIAdiscounted pharmaceuticals than under the University's standard purchasing mechanism.

²¹ See Connecticut Hospital Association (Dec. 20, 2001) (FTC staff opinion letter).

²² See October 26, 2009 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 5.

²⁰ See *id.; see also* Connecticut Hospital Association (Dec. 20, 2001) (FTC staff opinion letter).

Wellpartner also will help process those claims to be converted into the NPIA claims. For these services, Wellpartner, like informedRx, will receive a flat fee that does not depend on the type of claim (NPIA or non-NPIA).²³ Thus, Wellpartner does not stand to benefit from the NPIA exemption. Both it and informedRx will be paid based on the number of claims processed for the University and not based on the type of claims.

The involvement of the participating pharmacies is more complicated. The use of these pharmacies, in the manner described in your letter, raises two concerns. First, the for-profit pharmacies are retail pharmacies operating in competition with other retail pharmacies in sales to the general public. If these pharmacies were to sell the discounted pharmaceuticals to walk-in customers, such activity would not qualify as being for the University's "own use," and the NPIA exemption for those pharmaceuticals would be lost. We understand from your letter, however, that the structure of the proposed program will prevent this type of inappropriate diversion of NPIA-discounted pharmaceuticals in large part because the replenishment aspect of the program means that no NPIA-discounted pharmaceuticals will be on inventory at the participating pharmacies. Rather, they will only be shipped to the participating pharmacies after Wellpartner conducts its price comparison and once a certain volume is reached. In essence, the participating pharmacies only get the NPIA-discounted drug to replenish sales of a drug to someone who has been determined to have been eligible to receive such a discounted drug and when Wellpartner has determined that the NPIAdiscounted drug was cheaper. As you point out, this structure seems to eliminate the risk that the NPIA-discounted pharmaceuticals will be mishandled by the for-profit pharmacies.²⁴ Additionally, Wellpartner will maintain reports for the University. These reports will create an auditable record by which to confirm that the proposed program is operating within the confines of the NPIA.

The second concern raised by the involvement of the for-profit participating pharmacies involves the fee they will receive from filling prescriptions for the University. If the participating pharmacies potentially were to receive higher fees for filling NPIA claims than from filling standard-rate claims, those ineligible entities would benefit financially from their sale of NPIA-discounted pharmaceuticals under the proposed program, and the exemption would be lost. As we understand it, however, the proposed program effectively eliminates this risk. For NPIA-claims, the University will use a formula for calculating the participating pharmacies' fees that will replicate the amount the participating pharmacies receive for processing standard-rate (or non-NPIA) claims. On standard-rate clams, the participating pharmacies receive the difference between the amount informedRx paid for the pharmacies (plus the member copay) and the participating pharmacies' WACs. Because the participating pharmacies do not share their WACs with the University, the University will

²⁴ See October 26, 2009 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 4.

²³ See October 26, 2009 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 2-3.

attempt to approximate that amount, using Wellpartner's WAC instead of the participating pharmacies' actual WACs, to determine the amount the participating pharmacies should receive for the NPIA claims. The University believes that Wellpartner's WAC will be a very close approximation of the participating pharmacies' WACs because of the way in which pharmaceutical purchasing is carried out in its region. And to the extent there is deviation between Wellpartner's WAC and the participating pharmacies' actual WAC, the University represents that the deviation is likely to result in the participating pharmacies receiving a lower fee on NPIA claims.²⁵ To improve the accuracy of its calculation of the participating pharmacies' fees on a per-claim, per-drug basis.²⁶ Further, the University, together with Wellpartner, "will develop and implement an audit process to monitor the GPO Program's compliance with the program parameters."²⁷

Based on your representations about Wellpartner's WAC and about the University's commitment to make calculations on a per-drug, per-claim basis with up-to-date information, it appears highly unlikely that the participating pharmacies could obtain any benefit through the University's use of the NPIA exemption. Further, the audit system will help the University ensure that the system operates in compliance with the guidance in this letter. If, over the course of the proposed program, it turns out that the ineligible for-profit participating pharmacies are benefitting from the NPIA exemption (because Wellpartner's WAC is not a good approximation of their WACs or for some other reason), this reasoning would not apply.

Conclusion

As discussed above, and with the noted caveats, it is our opinion that the GPO replenishmentbased drug benefit program proposed by the University would fall within the NPIA exemption to the Robinson-Patman Act.

This letter sets out the views of the staff of the Bureau of Competition, as authorized by the Federal Trade Commission's Rules of Practice, and based on the facts as presented by the requesting entity. Under Rule § 1.3(c), 16 C.F.R. § 1.3(c), the Commission is not bound by

²⁵ See January 25, 2010 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 2.

²⁶ See January 25, 2010 letter from Kathy Reed, Dykema Gossett PLLC, to Ellen Connelly, FTC, at 3.

this staff opinion and reserves the right to rescind it at a later time. In addition, this office retains the right to reconsider the questions involved and, with notice to the requesting party, to rescind or revoke the opinion if implementation of the proposed program results in substantial anticompetitive effects, if the program is used for improper purposes, if facts change significantly, or if it would be in the public interest to do so.

Sincerely,

Mark Mins

Markus H. Meier Assistant Director