



**SIGIS – Special Interest Group
for IAS Standards**

2400 Camino Ramon, Suite 375,
San Ramon, CA 94583, USA

Phone: 925.275.6605

Fax: 925.886.3611

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July 12, 2010

Re: SIGIS Letter to Treasury Secretary Timothy Geithner dated June 23, 2010

Attached to this cover page is a letter sent on behalf of the SIGIS Association regarding implementation of the changes required by the Affordable Care Act pertaining to Over-the-Counter Drugs and Medicines effective January 1, 2011.

It's important to note that:

1. There is a lot of uncertainty about how the change for over the counter drugs and medicines will be applied.
2. We have asked the department of Treasury to provide us with some clarification and to adopt procedures to make the transition easier.
3. We do not know how Treasury will respond.
4. Recipients of a copy of this letter should consult with their own counsel to determine what impact the changes will have on their business.
5. SIGIS does not have the answers at this time, but we are working to get them.

Sincerely,

Jody L. Dietel, CFCI
President

ALSTON & BIRD LLP

One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309-3424

404-881-7000
Fax: 404-881-7777
www.alston.com

John R. Hickman

Direct Dial: 404-881-7885

E-mail: john.hickman@alston.com

June 23, 2010

The Honorable Timothy Geithner
Secretary of Treasury
1500 Pennsylvania Avenue Northwest
Washington, D.C. 20220

Re: Implementation Issues for New Over-the-Counter Drug Rules

Dear Mr. Secretary,

The Special Interest Group for IAS Standard (“SIGIS”) assists thousands of its retail and merchant members with IRS compliance issues that will be affected by the upcoming change for over-the-counter (OTC) drugs and medicines brought about by the Patient Protection and Affordable Care Act (PPACA) (referred to herein as the “New OTC Rule”).¹ Complying with these changes will have an enormous impact on taxpayers who use an electronic debit card to access funds in their health flexible spending account (FSA) or health reimbursement arrangement (HRA). SIGIS believes that much of the unnecessary cost, confusion, and compliance problems that may arise can be avoided, or at least mitigated, if the IRS addresses these issues in advance. SIGIS has identified several issues that will make it difficult for retailers to have the proper systems and processes up and running on January 1, 2011 to comply with these changing rules. Accordingly, for the reasons set forth herein, SIGIS requests that IRS/Treasury:

- Apply a one-month transitional “good faith” compliance period for the New OTC Rule until January 31, 2011 under which retailers, processors, third party administrators (TPAs) and FSA and HRA plans can rely on a plan participant to obtain (and retain) the necessary prescription. At the very least, provide a transition period of at least fifteen (15) days to allow for the implementation of the New OTC Rule, during which time the New OTC Rule will be in effect, but reliance can be placed on plan participants obtaining and retaining prescriptions.
- Provide guidance on the meaning of a “prescribed” drug—to confirm that a medical practitioner’s letter of recommendation will suffice.

¹ New Internal Revenue Code § 106(f).

- Provide guidance on how the New OTC Rule affects the 90% Rule—specifically, state whether the analysis of the prior year’s receipts should still be based on items which qualify as expenses for medical care in 2010 (which does not take the New OTC Rule into account), or whether the analysis of the prior year’s receipts should take the New OTC Rule into account and be based only on items which will be reimbursable from an FSA or HRA in 2011.

Background

The SIGIS Standards

SIGIS creates a standard, voluntary industry solution to meet IRS requirements² for operating an inventory information approval system (an “IIAS”) for purposes of facilitating access to funds in a health flexible spending account (FSA) or health reimbursement arrangement (HRA) with the use of an electronic debit card. The SIGIS Standards enable a broad range of participants in health benefit payment card transactions to implement consistent systems and processes for transaction processing and data retention that comply with IRS rules. These companies include retailers, acquirer processors, payment card networks, issuer processors, and third party administrators. As part of its services to its members, SIGIS has created an “Eligible Product List” (or “EPL”) of eligible healthcare/medical products that currently qualify for purchase with an FSA or HRA electronic payment card. The list is reviewed and modified by the SIGIS List Working Group, a group of benefit plan administrators, and an updated list is released on the 15th of each month. Merchants who wish to use the SIGIS Standard and process IIAS transactions must use the EPL to identify their inventory so that eligible products can be identified and processed at the point of sale in accordance with the SIGIS specification. Most of these merchants have incorporated this mid-month update into their own systems, processes and policies.

As a general practice, most retail merchants and processors invoke a technical “freeze” period related to card processing changes from mid-November through the first week of January. This period represents the busiest time of year for most retail businesses, and they are particularly risk averse to technical changes to systems that could increase the likelihood of system problems and cause revenue loss during this time.

The 90% Rule

Under current law, purchases of qualified medical expenses at stores with the “Drug Stores” and “Pharmacies” merchant category code do not need to be substantiated at the point of sale in order to be eligible for electronic card benefit processing under an

² The SIGIS IIAS standards (the “SIGIS Standards”) are designed to comply with Proposed Treasury Regulations §§ 1.125-6(c) through (f), Revenue Ruling 2003-43, 2003-21 I.R.B. 935, and IRS Notice 2006-69, 2006-31 I.R.B. 107.

FSA or HRA “if, on a store location-by-location basis, 90 percent of the store’s gross receipts during the prior taxable year consisted of items which qualify as expenses for medical care described in section 213(d)”.³ This is commonly referred to as the “90% Rule” and it includes nonprescription medication.⁴

SIGIS has implemented a 90% Rule Program that identifies qualifying merchants. Merchants who want to be included on SIGIS’ list of 90% Rule Merchants must submit an application and attest to their location’s qualification under the 90% Rule. Approximately 3,600 merchants are certified with SIGIS as 90% Rule Merchants. These merchants are faced with the issue of determining the timeframe for their annual renewal certification process with regard to the New OTC Rule. SIGIS’s current annual certification process is based on the merchant’s fiscal tax year because the IRS defines 90% qualification based on the “prior taxable year”. Many merchants do not have a calendar year fiscal year.

Issues and Requests

1. Transition Problem for Compliance with the New OTC Rule

The impact of the New OTC Rule on affected retailers will be huge. SIGIS has approximately 7,300 members who are IIAS merchants that rely on the accuracy of the EPL (about 6,600 small merchants and 700 large retailers). SIGIS estimates that about 35 million Americans have coverage under an FSA or HRA account, and that the New OTC Rule will result in a 35% reduction in approved OTC items by eliminating OTC drugs from the EPL for this population through FSAs and HRAs.

Most SIGIS members have structured their updates of eligible products for IIAS transactions around SIGIS’s mid-month update of the EPL. However, as described above, this practice is often suspended for business reasons during the “freeze” period from mid-November through the first week of January in order to avoid disruption during this busy retail period, and then resumes again in mid-January. Given this freeze period and the January 1, 2011 compliance deadline for the New OTC Rule, SIGIS has identified the following problems with each of the possible approaches for implementing the New OTC Rule:

- Loading the updated EPL in mid-November, prior to the freeze period
 - This will cause OTC items to be declined prior to the January 1, 2011 effective date.

³ Prop. Treas. Reg. § 1.125-6(e)(2).

⁴ See 72 Fed. Reg. 43938, 43944 (Aug. 6, 2007).

- Taxpayers/customers will be confused as allowable OTC items are declined.
- Third party administrators and employers will see an increase in customer calls and complaints, increasing their costs.
- The increased volume of declined POS transactions is likely to result in increased manual processing of claim reimbursements, increasing processing costs.
- Loading the updated EPL after the freeze in the absence of the transitional relief requested herein
 - In the absence of the requested transitional relief, this could allow ineligible OTC items to be accepted from January 1, 2011 through implementation, causing potential compliance problems for the taxpayer/participant and employer.
 - Third party administrators and employers will see an increase in customer calls and complaints, increasing their costs.
- Loading the updated EPL during the standard freeze period, such as in mid-December at the time of the December 15th EPL update
 - This will require significant additional resources to mitigate issues that may arise during this traditionally busy period for retailers. Risk mitigation efforts may result in undue cost and hardship for merchants, vendors, and processors.
 - This would still result in premature declines of OTC drugs just as participants may be trying to meet the December 31st cut-off.

SIGIS's Request for Addressing the Transition Problem

Given the issues set forth above, SIGIS requests that a “good faith” compliance period apply until January 31, 2011. Under such an approach, the New OTC Rule would apply to taxpayers who are FSA/HRA plan participants; but merchants, processors, TPAs, and FSA/HRA plans can continue to process claims as under current procedures in reliance on participants’ agreement to obtain (and retain) the requisite physician’s recommendation.

In the event this one-month good faith compliance period is not provided, SIGIS believes that merchants may choose for business and practical reasons unrelated to the New OTC Rule to simply wait until January 15th to upload the new EPL rather than invest resources in a January 1, 2011 implementation date, which would be a one-time

event. Given the reality of this situation, SIGIS requests that the IRS at least apply the requested good faith compliance period for the New OTC Rule until January 15, 2011. This would:

- Eliminate the need for new IT processes.
- Minimize potential IT risk to merchants during what is traditionally the busiest time of the year.
- Minimize negative impact to taxpayers/consumers by allowing them to continue to use their cards to access FSA/HRA funds via a payment card during 2010 before the law comes into effect.
- Remove the likelihood of undue hardship on merchants, consumers, and administrators.

While we believe that a good faith compliance period until January 15, 2011 is a minimum, providing a good faith compliance period through January 31, 2011 will provide a cushion to allow for adequate edit checks and administrative corrections in the event of errors or unavoidable delays, while still ensuring prompt compliance.

2. “Prescribed” versus “Prescription”

Effective January 1, 2011, OTC drugs and medicines will no longer be reimbursable from a health FSA or HRA unless “prescribed”.⁵ This raises the important issue for SIGIS members as to how to determine whether a drug that may be legally purchased without a prescription has been “prescribed”.

Prescription drugs require greater regulation and control than OTC drugs and medicines, necessitating strict laws governing the components of an acceptable prescription. Imposing the same prescription requirements for OTC drugs is unnecessary from a health care policy standpoint, and would result in the following problems:

- Prescription laws can vary by state, making it very difficult for administrators to adjudicate claims properly and consistently.
- OTC drugs do not have to be obtained directly from the pharmacy window of a retailer—they can be obtained off the shelf and presented for purchase to a non-pharmacist who may not be familiar with the state prescription laws.

⁵ New paragraph (f) of Internal Revenue Code Section 106.

- Pharmacies do not have much incentive to ensure that a proper prescription is provided for OTC drugs because it is not illegal for them to sell an OTC drug without a proper prescription. Further, it is often unknown to the cashier whether the payment card is a health care card until the transaction is processed, and the eligibility of items for purchase using the card is automated currently.

SIGIS's Request for Defining "Prescribed"

SIGIS requests that a drug recommended by a medical practitioner in a "letter of medical necessity" constitute a "prescribed" drug for purposes of the New OTC Rule. By having a single standard—a letter of medical necessity from a medical practitioner that states the name of the drug and their recommendation—compliance burdens are greatly reduced without any harm to taxpayers/participants or health plans. Also, there does not appear to be any advantage to subjecting prescriptions for OTC drugs to the same standard as prescriptions for prescription-only drugs.

3. Attestation Problem for 90% Rule Merchants

All of SIGIS's 3,600 90% Rule Merchants base their 90% qualification on the merchant's fiscal tax year. Indeed, this is all the 90% Rule requires. However, this literally means that a merchant can still qualify under the 90% rule in 2011 based on expenses that qualify in 2010, which includes unprescribed OTC drugs. Even a merchant with a calendar year fiscal year would still be a 90% Rule Merchant for all of 2011. This approach does not seem to be consistent with the New OTC Rule and the purposes of the 90% Rule. We believe that the better approach would be to read the 90% Rule in the context of the New OTC Rule.

SIGIS's Requested Approach to the 90% Rule

SIGIS requests that the IRS prohibit any merchant from relying on the 90% Rule beginning on January 1, 2011 if the merchant will not be able to meet the 90% qualification when taking the New OTC Rule into account, regardless of the merchant's fiscal year. SIGIS has developed the following approach for 90% Rule Merchants who will be renewing their attestations as the January 1, 2011 deadline approaches:

- Merchants attesting prior to September 3, 2010 may still base their attestation on the then-current EPL, which does not take the New OTC Rule into account.
 - These merchants would be required to re-attest by December 31, 2010 using the EPL updated for the New OTC Rule (the "2011 EPL") Note: Because these merchants have not employed an IIAS system, they are not participating in the IIAS EPL re-programming activity described above.

- Merchants attesting or re-attesting on or after September 3, 2010 would use the 2011 EPL.
 - Merchants would then follow their standard fiscal date attestation timeline for future certification.
 - A merchant that cannot meet the 90% attestation using the 2011 EPL will no longer be a SIGIS 90% Rule Merchant after December 31, 2010.
- Merchants who have not attested or re-attested as meeting the 90% definition as of December 31, 2010 will no longer be a SIGIS 90% Rule Merchant after December 31, 2010.

Summary

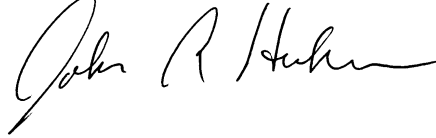
Complying with the upcoming changes for the New OTC Rule will have an enormous impact on taxpayers who use an electronic debit card to access their FSA or HRA funds. SIGIS believes that much of the unnecessary cost, confusion, and compliance problems that may arise can be avoided, or at least mitigated, if the IRS addresses these issues in advance. SIGIS kindly requests the following:

- Apply a transitional “good faith” compliance period for the New OTC Rule until January 31, 2011 under which retailers, processors, third party administrators (TPAs) and FSA and HRA plans can rely on a plan participant to obtain (and retain) the necessary prescription. At the very least, provide a transition period of at least fifteen (15) days to allow for the implementation of the New OTC Rule, during which time the New OTC Rule will be in effect, but reliance can be placed on plan participants obtaining and retaining prescriptions.
- Provide guidance on the meaning of a “prescribed” drug—to confirm that a medical practitioner’s letter of recommendation will suffice.
- Provide guidance on how the New OTC Rules affect the 90% Rule—specifically, state whether the analysis of the prior year’s receipts should still be based on items which qualify as expenses for medical care in 2010 (which does not take the New OTC Rule into account), or whether the analysis of the prior year’s receipts should take the New OTC Rule into account and be based only on items which will be reimbursable from an FSA or HRA in 2011.
- Confirm that SIGIS’s approach to attestation of 90% Rule Merchants complies with IRS requirements.

The Honorable Timothy Geithner
Secretary of Treasury
June 23, 2010
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If further information, or a meeting, would be helpful with regard to the issues discussed herein, please do not hesitate to contact the undersigned.

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Hickman". The signature is fluid and cursive, with the first name "John" being the most prominent.

John R. Hickman

JRH:lk
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J. Mark Iwry
Senior Advisor to the Secretary and Deputy Assistant Secretary for Retirement and
Health Policy
United States Department of Treasury

George H. Bostick
Benefits Tax Counsel
Office of Tax Policy
United States Department of Treasury

Helen H. Morrison
Deputy Benefits Tax Counsel
Office of the Benefits Tax Counsel
Office of Tax Policy
United States Department of Treasury