

OTC Drugs: Six Questions Employers Must Answer

By Rich Glass, J.D.



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When the IRS issued Notice 2010-59 in early September, it clearly answered many questions related to the prohibition of unprescribed over-the-counter (OTC) medicine and drugs that becomes effective in 2011 for health flexible spending accounts (FSAs), health savings accounts (HSAs), Archer medical savings accounts (MSAs) and health reimbursement arrangements (HRAs). (See ¶292, ¶140 and ¶311 of the *Handbook*, respectively, for more on HSAs, MSAs and HRAs.)

Reading between the lines, the guidance clearly challenges employers that offer flexible benefits to answer six key questions. Unfortunately, employers do not have as much time to articulate a response as the IRS took. The effective date for the OTC change is Jan. 1, 2011 (delayed until Jan. 16, 2011 for electronic payment card transactions). This prohibition does not apply to unprescribed insulin. The OTC prohibition is a result of §9003 of the Affordable Care Act (ACA), the health care reform law that was enacted in March 2010.

Here are the six questions that plan sponsors need to answer:

1) How will you administer the prescription requirement?

An OTC drug is reimbursable if the participant obtains a valid prescription for it. The notice defines a prescription as “a written or electronic order for a medicine or drug that meets the legal requirements of a prescription in the state in which the medical expense is incurred and that is issued by an individual who is legally authorized to issue a prescription in that state.” This definition presents several difficulties.

First, each state defines “prescriptions” differently. For example, look at how two neighboring states approach the issue: Michigan and Ohio (see box).

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Michigan and Ohio Definitions Of ‘Prescription’

Michigan

Michigan’s definition is contained in Section 333.17708(3) of the Public Health Code and merely requires that the prescription must be in writing and signed by a licensed prescriber.

Ohio

Ohio’s requirements are contained in Section 3719.06(C) of its Health-Safety-Morals Code. The prescription must contain the name and address of the patient, the date, the signature, name and address of the prescriber and the prescriber’s federal registry number.

To complicate matters, the notice indicates that it is the state where the drug is incurred (or purchased)

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that controls. Thus, you could have a Detroit doctor's prescription, which complies with Michigan law, but for which the drug purchase occurs in Toledo. The prescription would need to comply with the more stringent requirements of Ohio law.

One possible approach is to look at all the states where an employer has employees and apply the requirements of the most stringent state to all prescribed OTC drugs. Another approach is to require a separate medical necessity document that captures all the major pieces of information, including quantity and duration. This would be in addition to the signed prescription, which typically must be on a special form.

The notice does not address how exactly the drug or medicine needs to be described in the prescription. For example, if the prescription specifies a brand name of pain reliever (for example, Tylenol), can a participant substitute another brand of pain reliever (for example, Walmart brand)? Arguably, this should be acceptable, especially if the two drugs have the same active ingredient.

The notice also does not address prescriptions for recurring conditions. If a participant continues to have a cold after the OTC cold medicine has been used up, is the original prescription valid for an additional purchase? Again, arguably, this should be acceptable if the medical condition is of a duration that will exceed the supply initially purchased.

2) When will you amend plan-related documents?

Current rules require ERISA plans and cafeteria plans to provide an adequate description of what expenses will be reimbursed and communication of any changes to all affected participants. The OTC prohibition triggers changes to plan documents and summary plan descriptions (SPDs, see ¶530, ¶821 and ¶915), probably through a summary of material modifications (SMMs, see ¶822). When there is a material reduction in benefits, this may be done no later than 60 days after the plan year starts. A cafeteria plan cannot make retroactive amendments.

The notice gives employers some time to make changes, until June 30, 2011. Certainly, an employer that waits until that date will encounter problems when OTC expenses start to be rejected because

they are not accompanied by a prescription. It is recommended that these documents be amended and communicated well in advance of Jan. 1, 2011.

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3) How will you communicate this change?

A multi-faceted approach is best because this is a radical departure from how flexible benefits have operated over the past several years. Consider conveying this change via various media at least six different times before New Year's Day.

Some ways to communicate the change (in addition to providing updated plan-related documents, as described above) include:

- add information to your standard e-mail signature;
- broadcast a company-wide voicemail;
- distribute an updated list of eligible and ineligible expenses;
- send reminders (electronic and in writing) throughout open enrollment;
- include information with paychecks or pay stubs;
- update your benefits web page;

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- post signs where benefits and employment-related information and notices are located;
- discuss during open enrollment meetings; or
- place a suitable warning on the election form itself.

Flexible benefits featuring electronic payment cards necessitate another round of communications because the IRS pushed back the compliance deadline from Jan. 1, 2011, to Jan. 16, 2011. That is because the cards depend on an Inventory Information Approval System (IIAS) that would be difficult for many vendors to change during the December holidays. Discuss with your electronic payment card vendor how this change will be implemented and communicated to ensure that everyone gets the message.

4) How will you define medicine and drugs?

One interesting oddity about health care reimbursements is that the definition is circular. Sadly, the notice does not do much to clear up any confusion. A medicine or drug is defined in Treas. Reg. §1.213-1(e)(2) as any-

thing “generally accepted as falling within the category of medicine and drugs.” What the notice does clarify is that certain OTC items will continue to be reimbursable without the need of a prescription. These items include:

- Equipment (for example, crutches)
- Supplies (for example, bandages)
- Diagnostic devices (for example, blood sugar test kits)

The Special Interest Group for IIAS Standards (SIGIS) maintains the IIAS. It has defined the term “medicine and drugs” to include 19 different categories that will not be auto-substantiated after Jan. 15, 2011:

http://www.sig-is.org/en/documents/2010_09_22_SIGIS_PressRelease.pdf.

There are some borderline items. How about saline solution? Or a therapeutic bandage? Are these medicines/drugs or medical supplies? These are not easy questions to answer. The answer may vary depending on how the item is to be used.

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Chronology

Tax Status of Over-the-counter Drugs

Year	Law/Guidance	Description	Reference
1954	26 USC §213	Law enacted to allow deduction for medical care expenses; drugs are limited to prescriptions	http://www.law.cornell.edu/uscode/uscode26/usc_sec_26_00000213----000-.html
1960	26 CFR §1.213-1	Regulations issued, further defining medical care expenses	http://edocket.access.gpo.gov/cfr_2003/aprqr/pdf/26cfr1.213-1.pdf
1982	26 USC §105(b)	Law amended for reimbursement accounts to refer to Code Section 213(d) definition of medical care	http://www.law.cornell.edu/uscode/uscode26/usc_sec_26_00000105----000-.html
2003	Revenue Ruling (Rev. Rul.) 2003-58	Clarified that unprescribed medicine and drugs were ineligible for tax deduction	http://www.irs.gov/pub/irs-drop/rr-03-58.pdf
2003	Rev. Rule. 2003-102	Clarified that unprescribed medicine and drugs were eligible for flex plan reimbursement	http://www.irs.gov/pub/irs-drop/rr-03-102.pdf
2010	Affordable Care Act (ACA), Section 9003	Prohibited flex plan reimbursement of unprescribed medicine and drugs, effective Jan. 1, 2011	http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf
2010	Rev. Rul. 2010-23	Rendered Rev. Rul. 2003-102 obsolete	http://www.irs.gov/pub/irs-drop/rr-10-23.pdf
2010	Notice 2010-59	Clarified rules related to OTC prohibition in ACA, §9003	http://www.irs.gov/pub/irs-drop/n-10-59.pdf

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Nondiscrimination Testing

New Nondiscrimination Rules Apply To Group Health Plans

Group health plans have new rules to follow prohibiting discrimination in favor of highly compensated individuals (HCIs). The rules, set by the Patient Protection and Affordable Care Act (PPACA), went into effect on Sept. 23. The guidance came in IRS Notice 2010-63. (For more on nondiscrimination rules, see Tab 700 of the *Handbook*.)

The new rules incorporate the nondiscrimination requirements of Code Section 105 (see below) and apply them to insured group health plans. If a self-insured plan does not comply with Section 105(h), HCIs lose a tax benefit. But if an insured group health plan discriminates in the way it provides benefits through the plan, the plan itself will face penalties.


Generally, this will entail an excise tax of \$100 per day per individual discriminated against for each day the plan is not in compliance. Such plans could also face civil action under ERISA or the Public Health Service Act.

Section 105

Section 105(b) generally excludes from gross income amounts paid through employer-sponsored health coverage. This exclusion does not apply to amounts paid to an HCI, and that constitute an excess reimbursement of the HCI, under a self-insured medical reimbursement plan that does not satisfy the requirements of Section 105(h)(2) for a plan year.

A self-insured medical reimbursement plan will satisfy the requirements of Section 105(h)(2) if (1) the plan does not discriminate in favor of HCIs as to the eligibility to participate; and (2) the benefits provided under the plan do not discriminate in favor of participants who are HCIs.

Finding out More

Additional information on Notice 2010-63 is available from its principal author, Karen Levin of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), by calling (202) 622-6080 (not a toll-free call). 

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5) Will your plan allow mid-year election changes?


This is an issue for noncalendar plan years. The existing rules in Treas. Reg. §1.125-4 articulate the limited reasons a participant can change an FSA election during the middle of a plan year. The notice was silent on this issue. While one could argue that the OTC prohibition constitutes a significant cost or coverage curtailment, the regulations are clear that this exception does not apply to health FSAs.

Under a liberal approach, one could contend that other well-accepted election changes (for example, changes to comply with nondiscrimination testing, mistakes of fact) are not in Treas. Reg. §1.125-4. You should simply be able to add this to the list.

The conservative approach is to prohibit any election changes during the plan year because of the OTC prohibition. Participants either knew or should have known about the new rule when they made their original elections.

6) Will you discontinue reimbursing OTC items all together?

Given the complexity of administering this new mandate, some employers may consider amending their plan's design to make OTC medicine and drugs ineligible, regardless of whether they are prescribed. They could go beyond that step and forbid reimbursement of any OTC items, thus avoiding having to make the distinction between what constitutes a medicine or drug. Consider carefully how such reactions will play among your participant base, especially if they have enjoyed the benefits of OTC reimbursement since the original Notice 2003-102 was issued in 2003.

The bottom line with the new rules on OTC medicine and drugs is simply this: It may be a bitter pill, but taking it probably won't lead to a terminal condition. After all, flexible benefits can be used to reimburse all sorts of out-of-pocket expenses, and in the coming years, market and industry pressure from health care reform may well result in more expenses coming out of your pocket. 

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