I. PURPOSE

This Notice provides guidance on § 9003 of the Patient Protection and Affordable Care Act (Affordable Care Act), Pub. L. No. 111-148, enacted March 23, 2010, which revises the definition of medical expenses as it relates to over-the-counter drugs. Section 9003 generally applies after December 31, 2010.

II. BACKGROUND

Section 9003 of the Affordable Care Act adds new § 106(f) of the Internal Revenue Code, which revises the definition of medical expenses for employer-provided accident and health plans, including health flexible spending arrangements (health FSAs) and health reimbursement arrangements (HRAs). Section 9003 also revises the definition of qualified medical expenses for Health Savings Accounts (HSAs) and Archer Medical Savings Accounts (Archer MSAs).
III. PAYMENT OR REIMBURSEMENT OF MEDICINES OR DRUGS RESTRICTED TO PRESCRIBED DRUGS, INSULIN, AND OVER-THE-COUNTER DRUGS THAT ARE PRESCRIBED

Section 106 provides that the gross income of an employee does not include employer-provided coverage under an accident or health plan. Section 105(b) generally provides that the gross income of an employee does not include amounts paid as reimbursements for medical care under an employer-provided accident or health plan. New § 106(f), as added by the Affordable Care Act, provides that, for purposes of §§ 106 and 105, beginning after December 31, 2010, expenses incurred for a medicine or a drug shall be treated as a reimbursement for medical expenses only if such medicine or drug is a prescribed drug (determined without regard to whether such drug is available without a prescription) or is insulin. Thus, under new § 106(f), expenses incurred for medicines or drugs may be paid or reimbursed by an employer-provided plan, including a health FSA or HRA, only if (1) the medicine or drug requires a prescription, (2) is available without a prescription (an over-the-counter medicine or drug) and the individual obtains a prescription, or (3) is insulin. Expenses incurred for over-the-counter medicines or drugs purchased without a prescription before January 1, 2011 may be reimbursed tax-free at any time, pursuant to the terms of the employer’s plan.

The Affordable Care Act also amends § 223(d)(2)(A) with respect to HSAs and § 220(d)(2)(A) with respect to Archer MSAs, to provide that for amounts paid after December 31, 2010, a distribution from an HSA or Archer MSA for a medicine or drug is a tax-free qualified medical expense only if the medicine or drug is a prescribed drug (determined without regard to whether such drug is available without a prescription) or is insulin. Thus, under new § 223(d)(2)(A) and new § 220(d)(2)(A), a distribution from an HSA or an Archer MSA for a medicine or drug is a tax-free qualified medical expense only if (1) the medicine or drug requires a prescription, (2) is an over-the-counter medicine or drug and the individual obtains a prescription, or (3) is insulin. If amounts are distributed from an HSA or Archer MSA for any medicine or drug which does not satisfy this requirement, the amounts will be distributions for nonqualified medical expenses, which are includable in gross income and generally subject to a 20% additional tax. This change does not affect HSA or Archer MSA distributions for medicines or drugs made before January 1, 2011, nor does it affect distributions made after December 31, 2010, for medicines or drugs purchased on or before that date. See Revenue Ruling 2003-102, 2003-2 C.B. 559.
Section 213(d)(3) defines a prescribed drug as a drug or biological that requires a prescription of a physician for its use by an individual. In contrast, under §§106(f), 223(d)(2)(A) and 220(d)(2)(A), an individual may be reimbursed for over-the-counter medicines or drugs, so long as the individual obtains a prescription for the medicines or drugs. For purposes of §§ 106(f), 223(d)(2)(A) and 220(d)(2)(A) only, a “prescription” means 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.

The rules in §§ 106(f), 223(d)(2)(A), and 220(d)(2)(A) do not apply to items that are not medicines or drugs, including equipment such as crutches, supplies such as bandages, and diagnostic devices such as blood sugar test kits. Such items may qualify as medical care if they otherwise meet the definition of medical care in § 213(d)(1), which includes expenses for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body. However, expenses for items that are merely beneficial to the general health of an individual, such as an expenditure for a vacation, are not expenses for medical care. Treas. Reg. § 1.213-1(e)(1)(ii).

IV. HEALTH FSA AND HRA DEBIT CARDS AND OVER-THE-COUNTER DRUG EXPENSES

The current rules for use of health FSA or HRA debit cards are set forth in Prop. Treas. Reg. § 1.125-6 and in Rev. Rul. 2003-43, 2003-1 C.B. 935; Notice 2006-69, 2006-2 C.B. 107; Notice 2007-2, 2007-1 C.B. 254; and Notice 2008-104, 2008-2 C.B. 1298. Current debit card systems are not capable of substantiating compliance with new § 106(f), which is effective for expenses incurred after December 31, 2010, with respect to over-the-counter medicines or drugs because the systems are incapable of recognizing and substantiating that the medicines or drugs were prescribed. Therefore, except as provided below, for expenses incurred on and after January 1, 2011, health FSA and HRA debit cards may not be used to purchase over-the-counter medicines or drugs. Notwithstanding the preceding sentence, in order to facilitate the significant changes to existing systems necessary to reflect the statutory change, the IRS will not challenge the use of health FSA and HRA debit cards for expenses incurred through January 15, 2011 if the use of the debit cards complies with the guidance specified in
the first sentence of this paragraph. However, on and after January 16, 2011, over-the-counter medicine or drug purchases at all providers and merchants (whether or not they have an inventory information approval system (IIAS)) must be substantiated before reimbursement may be made. Substantiation is accomplished by submitting the prescription (or a copy of the prescription or other documentation that a prescription has been issued) for the over-the-counter medicine or drug, and other information from an independent third party that satisfies the requirements under Prop. Treas. Reg. § 1.125-6(b)(3)(i). Thus, for example, a customer receipt issued by a pharmacy which identifies the name of the purchaser (or the name of the person for whom the prescription applies), the date and amount of the purchase and an Rx number satisfies the substantiation requirements for over-the-counter medicines or drugs, as does a receipt without an Rx number accompanied by a copy of the related prescription. Debit cards may continue to be used for medical expenses other than over-the-counter medicines or drugs.

Notice 2007-2 provides that health FSA and HRA debit cards may be used at a pharmacy that does not have an IIAS if 90 percent of the store’s gross receipts during the prior taxable year consists of items which qualify as expenses for medical care under § 213(d). Until further guidance is issued, debit cards may be used at a pharmacy that satisfies the 90-percent test to purchase over-the-counter medicines or drugs that have been prescribed, provided that substantiation is properly submitted, in accordance with the terms of the plan, including the prescription (or a copy of the prescription or other documentation that a prescription has been issued) and other information from an independent third party that satisfies the requirements under Prop. Treas. Reg. § 1.125-6(b)(3)(i). Solely for the purpose of determining whether a pharmacy meets this 90-percent test, sales of over-the-counter medicines and drugs at the pharmacy may continue to be taken into account after December 31, 2010.

V. EFFECTIVE DATES

For expenses incurred after December 31, 2010, payments or reimbursements for medicines or drugs from an employer-provided accident and health plan, including a health FSA or an HRA, are restricted to prescribed drugs, insulin, and over-the-counter drugs that are prescribed. This effective date applies regardless of whether the plan year for the employer’s plan is a fiscal or calendar year or
whether there is no plan year (or other coverage period in the case of an HRA), and regardless of any applicable grace period for a health FSA (as provided in Prop. Treas. Reg. § 1.125-1(e)).

Tax-free distributions for qualified medical expenses from an HSA or Archer MSA for medicines or drugs purchased after December 31, 2010, are restricted to prescribed drugs, insulin, and over-the-counter medicines or drugs that are prescribed.

VI. TRANSITION RULE FOR CAFETERIA PLAN AMENDMENTS

Cafeteria plans may need to be amended to conform to the new over-the-counter drug requirements. Pursuant to Prop. Treas. Reg. § 1.125-1(c), cafeteria plan amendments may be effective only prospectively. Notwithstanding the rule against retroactive amendments, an amendment to conform a cafeteria plan to the requirements set forth in this Notice that is adopted no later than June 30, 2011, may be made effective retroactively for expenses incurred after December 31, 2010 (or after January 15, 2011 for health FSA and HRA debit card purchases).

VII. EFFECT ON OTHER DOCUMENTS

The IRS intends to amend the regulations under §§ 1.105-1, 1.105-2, 1.106-1, 1.125-1 and 1.125-5 to provide for the new definition of medical expenses. Taxpayers may rely on this Notice pending the issuance of the amended regulations. See also Revenue Ruling 2010-23 in this issue of the Internal Revenue Bulletin, which states that Revenue Ruling 2003-102, 2003-2 C.B. 559, is obsoleted. Also, the following guidance concerning the definition of qualified medical expenses under § 220(d)(2) (Archer MSAs) and § 223(d)(2) (HSAs) is modified: Notice 96-53, Q&A 22, 1996-2 C.B. 219; Notice 2004-2, Q&A 26, 2004-1 C.B. 269; Notice 2004-50, Q&A 38, Notice 2008-51, 2008-1 C.B. 1163; and Notice 2008-52, 2008-1 C.B. 1166. Notice 2006-69, 2006-2 C.B. 107, is amplified.

REQUEST FOR COMMENTS

The IRS and Treasury invite comments on further guidance that may be needed on § 9003 of the Affordable Care Act (for example, on new designs for debit card systems that could provide substantiation
that an over-the-counter medicine or drug was prescribed). Comments should be submitted on or before December 27, 2010, and should include a reference to Notice 2010-59. Send submissions to CC:PA:LPD:PR (Notice 2010-59), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered **Monday through Friday** between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2010-59), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC 20044, or sent electronically, via the following e-mail address: *Notice.comments@irs counsel.treas.gov*. Please include “Notice 2010-59” in the subject line of any electronic communication. All material submitted will be available for public inspection and copying.

**DRAFTING INFORMATION**

The principal author of this notice is Robin Ehrenberg of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). For further information regarding this Notice, contact Ms. Ehrenberg at (202) 622-6080 (not a toll-free call).