More Guidance Under The Affordable Care Act:

External Review of Denied Appeals — and — New Rules for FSA, HRA and HSA Reimbursement of OTC Drugs

For more information regarding this or any other employment-related issue, please contact your Vorys attorney or a member of the Vorys Labor and Employment Group by calling 614.464.6400.

External Review of Denied Appeals

One of the mandates under the Patient Protection and Affordable Care Act (ACA) is that non-grandfathered health plans must adopt new standards for claims and appeals and provide external review of denied appeals. Regulations issued July 23, 2010 (and summarized in a Vorys Client Alert available at http://www.vorys.com/healthcarereform) spelled out stringent new requirements for claims and appeals, but included only a general framework for external review of denied appeals under self-insured health plans. The Department of Labor (DOL) has now issued Technical Release 2010-01 (available at http://www.dol.gov/ebsa/healthreform/) creating a safe harbor interim external review process. The timeline for external review is as follows:

1. Request for external review: 4 months. A participant has 4 months after the denial of an appeal to request external review.

2. Preliminary review of request:

   - 5 business days: The plan has 5 business days after the receipt of a request to conduct a preliminary review to determine whether the issue in question is subject to external review. (Expedited timeline for urgent care: The plan must conduct the preliminary review immediately.) Generally, issues related to eligibility for coverage are not subject to external review.

   - 1 business day: If the plan concludes the request is not subject to external review or is incomplete, the plan must notify the claimant within 1 business day after conclusion of the preliminary review. (Expedited timeline for urgent care: The plan must immediately notify the claimant.) If the request is incomplete, the plan must describe the missing information and give 48 hours (or the balance of the 4 month period) to file a complete request. If the request is subject to external review, see #3.

3. Referral to independent review organization (IRO):

   A plan must contract with at least 3 IROs. As an alternative to direct contractual relationships between a plan and 3 IROs, the DOL has informally indicated that a plan may refer external reviews to IROs contracted with its third-party administrator.

   - Deadline not specified: If, in the preliminary review, the plan concludes the claim is eligible for external review, the claim must be assigned to an IRO.

   - 5 business days: Within 5 business days after assignment to the IRO, the plan must provide to the assigned IRO the documents and any information considered in denying the appeal. (Expedited timeline for urgent care: The plan must send documents and information electronically or by telephone, fax or other expeditious manner.)

- 45 days: Within 45 days after assignment to the IRO, the IRO must provide written notice of its decision. (Expedited timeline for urgent care: The IRO must provide notice of its decision as expeditiously as circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review.

4. Implementation of reversal: Immediate. "Immediately" upon receiving a notice of an external review decision reversing the denial of an internal appeal, the plan must provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim.

   A different external review process applies to non-grandfathered insured plans; insured and self-insured governmental plans; and insured and self-insured church plans.

   The DOL published sample notices for decisions on claims, appeals and external reviews. Third-party administrators and insurers will want to consider the models as they update their explanations of benefits (EOBs). The government also expects to publish model language on claims, appeals and external review for use in summary plan descriptions.

   Compliance with the new standards for claims and appeals and the interim external review process will be challenging. If your self-insured plan is losing grandfathered status, you will want to touch base with your third-party administrator as to its preparations for compliance.

New Rules for FSA, HRA and HSA Reimbursement of OTC Drugs

Health flexible spending accounts (FSAs) and health reimbursement accounts (HRAs) have been permitted to reimburse participants for over-the-counter (OTC) drugs and supplies since 2003. The ACA changes the rules for OTC drugs purchased on and after January 1, 2011, regardless of grandfathered status or plan year. OTC drugs purchased on and after January 1, 2011 cannot be reimbursed from FSAs or HRAs except for: (a) insulin; and (b) OTC drugs for which a participant has a prescription. IRS guidance on the new rules (Notice 2010-59 and Q&As) is available at http://www.irs.gov/newsroom/article/0,,id=220809,00.html?portlet=6.

The new rules apply to OTC drugs purchased on and after January 1, 2011 even if an FSA has a grace period allowing expenses incurred in the first 2 ½ months of 2011 to be paid from a 2010 FSA balance. However, OTC drugs purchased before January 1, 2011 may be reimbursed on and after January 1, 2011.

The IRS addressed the question of what constitutes a prescription for an OTC drug. According to the IRS, a prescription is "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."

Because FSAs and HRAs must now collect documentation of prescriptions before reimbursing for OTC drugs, debit cards cannot be used for the purchase of OTC drugs. Instead, a plan must require submission of the OTC drug prescription with a claim for reimbursement. Although a prescription is not required for OTC medical supplies, the purchase of OTC supplies with a debit card will be problematic because the debit card systems do not currently distinguish between OTC drugs and supplies.

The IRS provided a limited transition rule for debit cards: A participant need not supply a copy of the prescription for OTC drugs purchased with a debit card on or before January 15, 2011. Starting January 16, 2011, all debit card purchases of OTC drugs must be substantiated with a copy of a prescription.

Because the purchase of OTC drugs without a prescription is no longer a permissible medical expense, a health savings account (HSA) distribution for an OTC drug purchased without a prescription on or after January 1, 2011 is taxable to the accountholder and subject to an additional tax of 20%.

You will want to work with your FSA or HRA administrator on new processes to substantiate claims. Open enrollment materials will need to explain the new rule so that employees make accurate estimates of reimbursable medical expenses for purposes of deciding how much to contribute to their FSAs in 2011.