

CHALLENGES REGARDING FSAs AND OTC MEDICATIONS ... AND AN UPDATE ON HIPAA

By Jeanine Freeman, JD

The Patient Protection and Affordability Care Act of 2010 (PPACA or ACA) affects employee flexible spending accounts (FSAs) and health reimbursement accounts (HRAs). In particular, beginning in January 2011, over-the-counter (OTC) medicines or drugs are no longer considered qualifying medical expenses subject to preferred tax treatment unless the OTC medicine or drug is prescribed. This change does not apply to insulin nor does it apply to medical equipment and supplies purchased without a prescription.

The IRS has issued frequently asked questions (FAQs) to assist in understanding the ramifications of this change at www.irs.gov/newsroom/article/0,,id=227308,00.html. IRS Notice 2010-59 probably explains the law's new provisions the best. (www.irs.gov/pub/irs-drop/n-10-59.pdf.) "[E]xpenses 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. Notice 2010-59 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."

Why the change? It appears to be a policy decision to focus tax credits on medical expenses necessary to support a patient's ongoing treatment or preventative care. This PPACA change also affects health savings accounts (HSAs) and Archer medical savings accounts (MSAs).

Many patients, faced in 2011 with a noticeably

reduced listing of items on which they can spend their set-aside flex dollars, are unhappy. Some patients have relatively high OTC drug expenses associated with their medical conditions. Could a physician issue a prescription for an OTC drug or medicine in such situations?

IMS contacted the Iowa Board of Pharmacy and was told that a prescriber may issue a prescription for an OTC medication or device. It is not illegal to do so. The Board noted that in the past, physicians have issued prescriptions in limited situations to assure that the patient's commercial insurance would pay for the medication. Prescriptions also are issued to authorize the administration of OTC products in care facilities.

Patients with prescriptions from their physician for OTC medicines and drugs in support of their treatment regimen will see changes at the pharmacy counter which no longer can accept FSA or HRA debit cards for OTC purchases because those cards cannot substantiate compliance with the prescription requirement.

Physicians worry, come the end of the year, whether they will be bombarded by patient requests for prescriptions for OTCs to spend down their flex dollars. Risk managers remind physicians: writing a prescription is the practice of medicine. Prescriptions issued for OTCs need to be medically necessary, not otherwise contraindicated, and documented in the medical record. Physicians should not issue blanket scripts to patients to allow them to purchase whatever they elect at the pharmacy counter.

HIPAA Enforcement Update

Iowa physicians have taken HIPAA's Privacy and Security Rules seriously and have implemented policies, procedures and practices consistent



Jeanine Freeman, JD, is Deputy Executive Vice President of Legal Affairs and Policy Development for the Iowa Medical Society.

with them. Nonetheless, physicians and their privacy officers should note: federal enforcers, who adopted an early enforcement position that fostered education and good faith compliance, now are more aggressive and want HIPAA covered entities to take note.

The Office of Civil Rights (OCR), the federal enforcement agency for the Privacy Rule, has encouraged health care providers to pay particular attention to its “resolution agreement” with Massachusetts General Hospital (MGH). MGH agreed to pay a \$1 million “resolution amount” and to develop policies and procedures, train employees, and designate an internal monitor for compliance to settle alleged HIPAA violations.

The facts behind the Agreement relate to the loss of medical records by an MGH employee while riding a subway train. The employee had removed the records to work on them at home. The records consisted of billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis, and the name of the provider of 66 of the patients as well as the practice’s daily office schedules for three days containing the names and medical record numbers of 192 patients. While on the train, the employee placed the records on the seat beside her; they were not in an envelope and were bound by a rubber band. The employee, upon leaving the train, simply forgot the records and they were never recovered.

In settling, MGH did not admit to a HIPAA violation. The Agreement further specifies that it does not constitute an adjudication of fact or law nor does it constitute an admission or finding of liability of any kind. The \$1 million resolution amount is not a penalty. The Corrective Action Plan (CAP), effective for three years, is the heart

of the Agreement.

Under the CAP, MGH agrees to develop, maintain, and revise, as necessary, written policies and procedures governing physical removal and transport of PHI and laptop and USB drive encryption consistent with HIPAA’s Privacy and Security rules. Those policies and procedures must be submitted to the OCR for review and approval and then must be distributed to members of MGH’s workforce who access and use PHI. Employees must read and agree to abide by the policies and procedures. Employee training also shall be provided and employees must certify to receipt of the training. Employee violations of policies and procedures shall be reported to the “monitor” named under the Agreement. Duties for the monitor (i.e., unannounced site inspections, interviews with employees, inspection of documents, reports to the OCR) are specified in the Agreement. MGH also must file implementation reports.

OCR enforcement in the MGH case is more focused on assuring good HIPAA policies and procedures and, importantly, MGH cooperated toward that end. Clearly, though, the OCR is ready to impose monetary terms as further evidenced in its settlement with Cignet Health Center in Maryland imposing a \$4.3 million civil monetary penalty (CMP), \$1.3 million for denying patients access to their medical records (patients, some of whom wanted the records to transfer their care, complained to the OCR) and \$3 million for repeatedly failing to respond to OCR investigation demands. OCR Director Georgina Verdugo warned: “The U.S. Department of Health and Human Services will continue to investigate and take action against those organizations that knowingly disregard their obligations under these rules.”