

K. Reimbursement Must Satisfy Code § 105(h) Nondiscrimination Rules

A health FSA must comply with the nondiscrimination rules for self-funded medical reimbursement plans under Code § 105(h). Simply stated:

- a health FSA must not discriminate in favor of highly compensated individuals as to eligibility to participate; and
- health FSA benefits must not discriminate in favor of participants who are highly compensated individuals.²¹¹

Note that a health FSA offered under a simple cafeteria plan will be treated as meeting the health FSA nondiscrimination rules; for more information, see Section XXXIII.

Nondiscrimination issues will largely be a matter of plan design, rather than arising on a case-by-case basis in an administrator's reimbursement decision. However, administrators often have to use some discretion in deciding whether a participant's request meets the Code requirements for reimbursement. It is not unusual for administrators to feel uncomfortable denying a request made by a senior executive. Keep in mind that failing to administer a plan uniformly and consistently on behalf of all participants can trigger discrimination (as well as other) problems when those benefiting from unusually favorable treatment are highly compensated.

Section XXXI discusses how the Code § 105(h) nondiscrimination rules apply to health FSAs. For a full discussion of the nondiscrimination rules for health FSAs, see Sections XXVIII through XXXI.

L. Health FSA Expenses That Are Difficult to Administer

There are several reasons why an expense may be difficult to administer:

- it may be unclear whether the particular type of expense is reimbursable (e.g., there may be no guidance or the guidance is vague);
- the expense may be hard to substantiate (or the participant may have submitted inadequate substantiation);
- the expense may be one that an administrator has not seen before—because health FSAs reimburse medical expenses that have not been reimbursed by other health plans, administrators often must adjudicate unusual items; or
- the expense may have a high potential for participant abuse (e.g., expensive capital items).

Many of these expenses fall within the “potentially qualifying expense” category in the table of common expenses in subsection M, and therefore would require additional substantiation (e.g., a note from a medical practitioner recommending the item to treat a specific medical condition) before the health FSA could provide reimbursement.

Administration Tip: Developing Solutions for Difficult Expenses. Administrators should keep track of how they resolve the expenses that cause them difficulties. Not only will this help them to be uniform and consistent in future adjudications, it will help them resolve similar issues more quickly in the future.* One approach is to exclude the difficult expenses from the plan by amendment. This should be done on a prospective basis at open enrollment, making sure that all plan documents and employee communications are consistent. Also, such exclusions should comply with other applicable laws (e.g., health care reform, ADA, ADEA, and Title VII).†

* ERISA plans are required to maintain reasonable procedures governing benefit claims that ensure consistency in the claims approval process. See Section XXII.

† See Section XXII.

In this subsection L, we address certain expenses that are difficult to administer because of one or more of the above reasons, including the following:

- procedures directed at improving appearance, such as cosmetic surgery;
- prescription and over-the-counter (OTC) medicines and drugs;
- vitamins, natural medicines, and nutritional and herbal supplements;
- special foods;
- weight-loss programs;
- exercise programs and health club membership dues;
- naturopathic, holistic, and alternative treatments;
- travel expenses, meals, and lodging;

²¹¹ See Code § 105(h)(2).

- capital expenditures;
- long-term care expenses;
- plan administration costs;
- local, sales, service, and other taxes;
- infertility expenses;
- special schools;
- telemedicine; and
- expenses that could be for personal as well as medical reasons.

Expenses Often Fall Into More Than One Category. Many expenses can fall into more than one “difficult” category, each of which has its own special rules. For example, one IRS information letter considered the implications of using cayenne pepper to treat a medical condition.* The analysis raised concerns about alternative healers, personal-use items, drugs and medicines, special foods, and vitamins. Administrators should consider all possible categories into which an expense might fall.

* IRS Information Letter 2001-0297 (Dec. 31, 2001).

If you cannot find information on the difficult or unusual expense you are looking for in subsection L or in the table in subsection M, here are some additional places to search:

- Code § 213(d) and Treas. Reg. § 1.213-1;
- IRS revenue rulings, revenue procedures, and notices;²¹²
- U.S. Tax Court decisions;²¹³
- IRS information letters and private letter rulings;²¹⁴
- IRS Publication 502 (Medical and Dental Expenses);²¹⁵
- frequently asked questions on the IRS website;²¹⁶ and
- informal comments by IRS officials (e.g., conferences and telephone calls) (note that these comments are not binding).

1. Procedures Directed at Improving Appearance, Such as Cosmetic Surgery

Code § 213(d)(9)(A) provides that medical care “does not include cosmetic surgery or other similar procedures, unless the surgery or procedure is necessary to ameliorate a deformity arising from, or directly related to, a congenital abnormality, a personal injury resulting from an accident or trauma, or disfiguring disease.” The primary requirement is the existence of a procedure; Code § 213(d)(9)(B) defines “cosmetic surgery” to be “any procedure which is directed at improving the patient’s appearance and does not meaningfully promote the proper function of the body or prevent or treat illness or disease.” At least one IRS official has noted that the IRS generally uses the term “cosmetic procedure,” not “cosmetic surgery.”²¹⁷ If not excluded for other reasons, treatments such as pills or creams to reduce wrinkles would also be considered cosmetic procedures. Consequently, we call Code § 213(d)(9) the “cosmetic-procedure exception” from medical care.

The cosmetic-procedure exception addresses concerns about the overly broad application of the Code § 213(d) definition of medical care. Specifically, Code § 213(d)(1)(A) includes, in the definition of medical care, amounts paid “for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body.”²¹⁸ Legislative history for the cosmetic-procedure exception notes that “the IRS has interpreted ‘medical care’ as including procedures that permanently alter any structure of the body, even if the procedure generally is considered to be an elective, purely cosmetic treatment

²¹² These can be accessed at the IRS website, available at <http://www.irs.gov/> (as visited June 4, 2019).

²¹³ These can be accessed at the United States Tax Court website, available at <http://www.ustaxcourt.gov/> (as visited June 4, 2019).

²¹⁴ These can be accessed at the IRS website, available at <http://www.irs.gov/> (as visited June 4, 2019). Note that these are not binding and cannot be cited as precedent.

²¹⁵ Note that IRS Publication 502 should be used with caution, as it can be misleading in some instances and can be out-of-date—see subsection D.

²¹⁶ These can be accessed at the IRS website, available at <http://www.irs.gov/> (as visited June 4, 2019).

²¹⁷ Informal, nonbinding remarks of John Sapienza, IRS, Office of Chief Counsel, May 2002 ECFC Teleconference. *But see* IRS Publication 502 (Medical and Dental Expenses) (using the term “cosmetic surgery” throughout).

²¹⁸ Emphasis added.

(such as removal of hair by electrolysis and face-lift operations).²¹⁹ Consequently, Congress added the exclusion to ensure that unnecessary cosmetic procedures would not constitute tax-favored medical care under Code § 213.

a. Procedures That Generally Are Cosmetic (and Thus Are Not for Medical Care)

Examples of procedures that generally would fall under the cosmetic-procedure exception (and thus not be for medical care) include face-lifts, electrolysis, hair removal, hair transplants, and teeth whitening (but see the discussion of teeth whitening below). Although such procedures affect a structure or function of the body, they generally are performed for elective, cosmetic purposes.

b. Procedures That Generally Are Considered to Be for Medical Care (Even Though They Have Cosmetic Effects)

In contrast, expenses for orthodontia and radial keratotomy generally do not fall within the cosmetic-procedure exception, so long as they correct a physical defect.²²⁰ In other words, although these procedures have cosmetic effects, they more importantly promote the proper function of the body.²²¹ Surgery to treat severe obesity should be treated similarly. Note, however, that liposuction generally is regarded as a cosmetic procedure.²²²

c. Procedures That Are Necessary to Ameliorate a Deformity (and Thus Are for Medical Care)

Some procedures can be “saved” from the cosmetic-procedure exception (i.e., can still be considered medical care under Code § 213(d)) if they meet certain requirements. Under Code § 213(d)(9)(A), the cosmetic-procedure exception does not apply to surgeries or procedures that are “necessary to ameliorate a deformity arising from, or directly related to, a congenital abnormality, a personal injury arising from an accident or trauma, or disfiguring disease.” Consequently, to qualify for the safe harbor, the procedure must first treat a condition that is a deformity (presumably from the perspective of society in general, not just from the perspective of the individual). Second, the deformity must be caused by one of the three specified types of events (congenital abnormality, personal injury, or disfiguring disease).

How has the cosmetic-procedure exception been applied to specific expenses? As an example, breast reconstruction for an individual who has had a mastectomy as part of treatment for cancer is an expense for medical care because the surgery ameliorates a deformity directly related to a disease.²²³ In another example, the IRS held that a cosmetic-procedure treatment to correct a facial deformity that originated from numerous surgeries designed to correct a congenital abnormality qualified as a medical care expense because the facial deformity arose from or was directly related to congenital abnormalities.²²⁴ (In other words, the relationship between the cosmetic-procedure treatment and the congenital abnormality that was needed to qualify for the safe harbor existed, although there were intervening procedures.)

In contrast, teeth whitening to correct discoloration as a result of age does not treat a disease or promote the proper function of the body but is instead directed at improving appearance.²²⁵ Because the discoloration is not a deformity and is not caused by a disfiguring disease or treatment, the cost of whitening teeth in that circumstance is purely cosmetic and is not an expense for medical care. (One IRS official, however, has indicated that expenses for teeth whitening for blackened teeth that were the result of a disfiguring disease may qualify as medical care.)²²⁶

Subtle variations in the facts underlying submitted claims might lead to different conclusions about whether a procedure falls under the safe harbor (and is thus for medical care despite its cosmetic effects). For example, a health FSA might be able to reimburse a 20-year-old woman who undergoes treatment to restore all her hair after losing it as a result of alopecia areata (a disease that causes sudden hair loss), but it

²¹⁹ H.R. Conf. Rep. No. 964, 101st Cong., 2d Sess., 1030-1041, 1031 (Oct. 27, 1990).

²²⁰ See, e.g., Rev. Rul. 2003-57, 2003-22 I.R.B. 959 (“Eye surgery to correct defective vision, including laser procedures such as LASIK and radial keratotomy, corrects a dysfunction of the body.”).

²²¹ See Priv. Ltr. Rul. 200226003 (Mar. 7, 2002); IRS Publication No. 502; and Priv. Ltr. Rul. 9625049 (June 21, 1996) (radial keratotomy and laser eye surgery qualify as a medical expense under Code § 213). See also Prop. Treas. Reg. § 1.125-5(k)(3) (orthodontia expenses are reimbursable under a health FSA).

²²² IRS Publication 502 (Medical and Dental Expenses).

²²³ Rev. Rul. 2003-57, 2003-22 I.R.B. 959. Furthermore, surgery and reconstruction of the other breast “to produce a symmetrical appearance,” is required under the Women’s Health and Cancer Rights Act (WHCRA—see ERISA § 713).

²²⁴ Priv. Ltr. Rul. 200344010 (Mar. 27, 2003).

²²⁵ Rev. Rul. 2003-57, 2003-22 I.R.B. 959.

²²⁶ Informal, nonbinding remarks of Donna Crisalli, IRS, Office of Chief Counsel, May 2002 ECFC Teleconference.

might reject a claim from a 50-year-old man who has simply experienced male pattern baldness (typically arising from the aging process). In the first situation, there is probably a deformity arising from a disfiguring disease; in the second case, even if there were a deformity (which seems unlikely), aging is not considered a disfiguring disease.²²⁷

Special issues arise with respect to how the cosmetic-procedure exception from medical care applies to medicines and drugs. See subsection L.2.

Sex Reassignment Surgery and Related Expenses. The Tax Court has held that a taxpayer's hormone therapy and sex reassignment surgery treated a disease within the meaning of Code § 213(d); therefore, these procedures were for medical care and were not cosmetic surgery. The court found that the taxpayer suffered from gender identity disorder (GID), a widely recognized and serious medical condition, and that mental health professionals consider hormone therapy and sex reassignment surgery to be appropriate and effective treatment for GID. However, the court concluded that the taxpayer's breast augmentation surgery was cosmetic surgery and not for medical care, because her breasts were "within a normal range of appearance" before the surgery, and surgery was not needed "for comfort in the social gender role."^{*}

- * *O'Donnabhain v. Comm'r*, 134 T.C. No. 4 (2010). The holding in this case differed from the conclusion previously reached by the IRS with respect to the taxpayer in Chief Counsel Advice 200603025 (Oct. 14, 2005). However, the IRS later announced that it would follow the Tax Court's decision and would no longer take the position reflected in its earlier Chief Counsel Advice. See Action on Decision 2011-3, I.R.B. 2011-47. Neither the Chief Counsel Advice nor the Action on Decision can be used or cited as precedent.

2. Medicines and Drugs (Over-the-Counter and Prescription)

What's a Prescription Drug? What's an Over-the-Counter (OTC) Drug? We use the term "prescription drug" to refer to a drug that can be obtained only by means of a physician's prescription.* We use the term "OTC drug" to refer to a drug that is sold lawfully without a prescription (i.e., a drug that can be sold "over the counter"). Some drugs are introduced as prescription drugs and later become available as OTC drugs. For example, Claritin initially was a prescription drug but is now an OTC drug.

- * See Code § 213(d)(3).

Medicines and drugs are reimbursable if they are Code § 213(d) medical care expenses and meet other Code requirements, whether they can be acquired only with a prescription or are available over the counter (i.e., without a prescription). Under Code §§ 213(a) and (b), which allow an itemized deduction for medical expenses, medicines that do not require a prescription (like aspirin) are not deductible.

For many years, the IRS also interpreted this provision to mean that such items were not reimbursable under a health FSA.²²⁸ In Revenue Ruling 2003-102 (the 2003 OTC Ruling), however, the IRS announced that over-the-counter (OTC) drugs purchased to alleviate or treat personal injuries or sickness of the employee or the employee's spouse or dependents could be reimbursed by health FSAs and other employer-provided health plans.²²⁹ This rule was subsequently modified by health care reform, which allowed expenses for medicines and drugs (other than insulin) incurred after 2010 to be reimbursed only if they were prescribed (determined without regard to whether a prescription was necessary to acquire the drug), thereby

²²⁷ Rev. Rul. 2003-57, 2003-22 I.R.B. 959.

²²⁸ See, e.g., IRS Information Letter 2000-0080 (May 23, 2000).

²²⁹ Rev. Rul. 2003-102, 2003-38 I.R.B. 559. The OTC Drug Ruling applied not only to health FSAs, but to any employer-provided health plans that were subject to the income exclusion under Code § 105(b) for medical care expenses, including HRAs, insured medical plans, and self-insured medical reimbursement plans. The same rules also applied to HSAs. For more information on HRAs and HSAs, see *Consumer-Driven Health Care* (Thomson Reuters/Tax & Accounting, 2004-present, updated quarterly).

imposing a prescription requirement on OTC drugs other than insulin.²³⁰ In March 2020, the prescription requirement for OTC drugs was removed for expenses incurred after December 31, 2019.²³¹

Does Our Plan Need to Be Amended to Allow Reimbursement of OTC Drugs

Without a Prescription? Whether an amendment is required will depend on how the plan document is drafted. Some plan documents may refer to eligible expenses in such a way (e.g., by reference to the Code or to specific Code sections) that an amendment might not be required to allow reimbursement of OTC expenses without a prescription. In other cases, however, the prescription requirement may be set forth in the plan document, thus requiring a plan amendment to remove it.

Employers should review the specific terms of their plan documents to determine whether the change is automatic or requires an amendment. Whether or not an amendment is needed, the change must be communicated to employees. SPDs, claim forms, enrollment materials, and other documents may also need to be updated. See the sample amendment allowing reimbursement of OTC drugs without a prescription and related sample SMM behind Appendix Tab 10.

Although the change was enacted in March 2020, it applies to expenses incurred after December 31, 2019, and is therefore retroactive. As discussed in Section VII, cafeteria plans generally may not be amended retroactively. However, IRS guidance allows health FSAs to be amended to provide for tax-favored reimbursement of expenses for OTC drugs without prescriptions incurred for any period beginning on or after January 1, 2020, notwithstanding the general rule that reimbursements will not qualify for exclusion from income unless the plan covered the expense when it was incurred.^{231.1} The impact of the change on electronic payment card programs for health FSAs is discussed in Section XXI.

This subsection L.2 addresses the prescription requirement, as well as the other legal requirements that must be met for medicines and drugs to be reimbursable. We also discuss how plan documents should be written to cover (or not cover) OTC drugs, and we provide other practical tips to help employers administer medicine and drug coverage under their health FSAs.

OTC Drugs Are Still Not Deductible. Amounts paid for medicines or drugs that may be purchased without the prescription of a physician are not taken into account when determining an individual's medical expense deduction under Code § 213.*

Consequently, individuals may not deduct OTC drugs (other than insulin) on their federal income tax returns (that is, on Schedule A of Form 1040).

* See Code § 213(b).

a. Medicines and Drugs Must Be for Medical Care Under Code § 213(d) and Must Meet the Other Code Requirements

In order to be reimbursable, medicines and drugs must be for medical care under Code § 213(d) and meet the other Code requirements. Like other expenses, they must be “for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body” under Code § 213(d)(1). IRS regulations state that payments for “medicine and drugs” as defined in Treas. Reg. § 1.213-1(e)(2) constitute medical care.²³² Treas. Reg. § 1.213-1(e)(2) provides the following:

The term “medicine and drugs” shall include only items which are legally procured and which are generally accepted as falling within the category of medicine and drugs (whether or not requiring a prescription). Such term shall not include toiletries or similar preparations (such as toothpaste, shaving lotion, shaving cream, etc.) nor shall it include cosmetics (such as face creams,

²³⁰ Code § 106(f), as added by PPACA, Pub. L. No. 111-148 (2010), and prior to amendment by the CARES Act, Pub. L. No. 116-136, § 3702 (2020). Note that this restriction also applied to other employer-sponsored health plans (e.g., HRAs and major medical plans). A similar restriction applied to HSAs and Archer MSAs under Code §§ 223(d)(2)(A) and 220(d)(2)(A), as amended by PPACA, Pub. L. No. 111-148 (2010), and prior to amendment by the CARES Act, Pub. L. No. 116-136, § 3702 (2020). HRAs and HSAs are covered in *Consumer-Driven Health Care* (Thomson Reuters/Tax & Accounting, 2004-present, updated quarterly).

²³¹ Code § 106(f), as amended by the CARES Act, Pub. L. No. 116-136, § 3702 (2020). For the effective date of the change, see the CARES Act, Pub. L. No. 116-136, § 3702(d) (2020).

^{231.1} IRS Notice 2021-15, 2021-10 I.R.B. 898.

²³² Treas. Reg. § 1.213-1(e)(1)(ii).

deodorants, hand lotions, etc., or any similar preparation used for ordinary cosmetic purposes) or sundry items. Amounts expended for items which, under this subparagraph, are excluded from the term medicine and drugs shall not constitute amounts expended for "medical care."

Three requirements regarding a medicine or drug flow from this regulation—it must be (1) legally procured; (2) generally accepted as a medicine or drug; and (3) not a toiletry or cosmetic. We discuss the second and third items next, followed by the "legally procured" requirement.

(i) *The Medicine or Drug Must Be "Generally Accepted as Falling Within the Category of Medicine or Drugs"*

A determination as to whether an item is a medicine or drug may affect its eligibility for reimbursement. When is an item "generally accepted as a medicine or drug"? Obviously, prescription drugs would meet this requirement. Any item that has formerly been a prescription drug should also qualify. But what about the various other OTC substances and preparations that could be used to treat disease? The 2003 OTC Ruling expressly provided that antacids, allergy medicines, pain relievers, and cold medicines would qualify, so long as they were used to alleviate or treat personal injuries or sickness. But apart from that, the IRS regulations only define medicine and drugs by what they are not—they cannot be toiletries or cosmetics,²³³ as discussed in the following subsections.

Just because an item serves a medical purpose does not mean that it is a medicine or drug. One IRS private letter ruling concludes that "distilled water used to store and asepticize contact lenses serves a medical purpose, but is not generally considered to be a medicine or drug."²³⁴ Likewise, nutritional supplements and vitamins might be for medical care but likely would not be considered medicines or drugs.²³⁵ How can health FSA administrators determine which items are "generally accepted as medicine or drugs"?

Various resources may serve as a starting point. For example, the Food, Drug and Cosmetic Act (FD&C Act) contains a definition of "drug" that seems helpful (though not directly incorporated into the Code) in determining whether some items are "generally accepted" as a drug.²³⁶ This definition would include certain homeopathic treatments, as well as other medicines and drugs. The *Prescribers' Digital Reference (PDR)* contains a detailed listing of prescription drugs, OTC medicines, and dietary supplements. Health FSA administrators may use this resource as guidance for determining which items are medicines or drugs.

What's the Difference Between a Drug and a Medicine? Nothing in the Code or IRS regulations clarifies the distinction, and IRS guidance seems to use the terms interchangeably. Note: We sometimes use the shorthand term "OTC drugs" in this manual to include both drugs and medicines.

²³³ Treas. Reg. § 1.213-1(e)(2).

²³⁴ Priv. Ltr. Rul. 7308270520A (Aug. 27, 1973) (cost of distilled water used in this manner was deductible as a medical expense without being subject to additional limitation then applicable to medicine and drugs that the item be available only by prescription).

²³⁵ Informal, nonbinding remarks of Kevin Knopf, Attorney-Advisor, Office of Tax Policy of the Treasury Department, Mar. 4, 2011 ECFC Annual Conference.

²³⁶ The FD&C Act defines "drug" in 21 U.S.C. § 321(g)(1) as follows:

(g)(1) The term "drug" means

(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause

(C) solely because the label or the labeling contains such a statement.