

Health Care Reform: IRS Releases Guidance on Comparative Effectiveness Research Fee

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On April 12, 2012, the Internal Revenue Service ("IRS") issued proposed regulations regarding the payment of fees by insurers and plan sponsors of group health plans to fund the Patient-Centered Outcomes Research Institute (the "Institute"). The Institute was established by the Affordable Care Act (the "Act") and is tasked with conducting research to evaluate and compare health outcomes and the clinical effectiveness, risks and benefits of medical treatments, services, procedures, drugs, and other strategies or items that treat, manage, diagnose, or prevent illness or injury. In order to fund the institute, the Act requires issuers of "specified health insurance policies" and plan sponsors of "applicable self-insured health plans" to pay annual fees based upon the number of individuals covered by these arrangements. The new proposed regulations implement these fees.

Effective Date

The fees generally apply to policy and plan years ending on or after October 1, 2012 and before October 1, 2019. Pending final regulations, insurers and plan sponsors of self-insured plans should rely on these proposed regulations, particularly because any final regulations issued will apply retroactively to the date these proposed regulations were published in the federal register (i.e., April 17, 2012). To the extent future guidance is more restrictive than these proposed regulations, the final regulations will not be applied retroactively. For calendar year plans, the regulations and the requirement to pay fees generally apply to the 2012 through 2018 plan years.

What Policies or Plans Are Covered

Fees are owed by issuers of "Specified Health Insurance Policies" and sponsors of "Applicable Self-Insured Health Plans."

A "Specified Health Insurance Policy" is any health insurance policy issued with respect to individuals residing in the U.S., including prepaid health coverage arrangements but excluding insurance policies that provide for coverage substantially all of which is for "HIPAA-excepted benefits."^[1] Health maintenance organizations (HMOs) are specifically included by the proposed regulations.

An "Applicable Self-Insured Health Plan" is any self-insured group health plan established or maintained by one or more employers for the benefit of their employees or former employees, or by certain other employee organizations, multiple employers, trusts, etc., but excluding plans that provide benefits substantially all of which are "HIPAA-excepted benefits."^[1] Health care reform grandfathered status is irrelevant. Retiree-only plans are not excluded, despite generally being excluded from the Act's market reform provisions.

Treatment of Account-Based Plans. The proposed regulations apply special rules to account-based health plans. Although Health Savings Accounts and Archer MSAs are not subject to the fee, there is no broad exclusion for health reimbursement arrangements ("HRAs") or health flexible spending accounts ("FSAs"). However, FSAs that satisfy the requirements to be treated as HIPAA-excepted benefits are not treated as applicable self-insured health plans and, therefore, are not subject to the fees.^[1] In limited circumstances, certain HRAs also may be treated as providing HIPAA-excepted benefits.^[2] For HRAs and FSAs that are not HIPAA-excepted, special rules apply with respect to counting participants and the fees applicable to such arrangements, as further described below.

Multiple Self-Insured Plans. The proposed regulations include a special rule that multiple self-insured arrangements established and maintained by the same plan sponsor and with the same plan year are subject to a single fee. For example, if a sponsor maintains separate self-insured medical and prescription drug plans with the same plan year, the two plans are treated as one self-insured plan so that covered individuals under both plans are counted only once for purposes of the fee. However, this special rule does not apply in the case of an individual account plan like an HRA that is integrated with an insured health plan – even when the HRA and insured health plan are sponsored by the same plan sponsor. In this case, the plan sponsor will be subject to fees for the HRA and the insurer will be subject to the fees for the insured coverage.

Wellness/Employee Assistance Programs. The proposed regulations specifically exclude from the definition of "applicable self-insured health plan" an employee assistance program (EAP), disease management program or wellness program, if the program does not provide significant benefits in the nature of medical care or treatment.[\[3\]](#)

Stop Loss/Indemnity Reinsurance. The proposed regulations specifically provide that stop loss and indemnity reinsurance policies are not considered specified health insurance policies subject to the fees imposed by these rules.

Non-US Residents and Expatriates. The proposed regulations provide that the term "specified health insurance policy" includes only those policies that are issued with respect to individuals residing in the United States. With respect to group policies, the proposed regulations provide that policies that are designed and issued specifically to cover employees who are working and residing outside the United States are not included in the definition of "specified health insurance policy." Note there is no similar corresponding rule for self-insured group health plans covering employees working outside the United States.

Governmental Entities. The proposed regulations provide that governmental entities are not exempt from the fees, while certain governmental programs (i.e., Medicare, Medicaid, CHIP, US Military/Veteran programs and programs for members of Indian tribes) are exempt.

Responsible Party for Payment

For an insured plan, the insurer is responsible for paying the fee, regardless of whether the plan is maintained by a single employer or multiple employers, or is a multiemployer plan.

The responsible payor for a self-insured plan is the "plan sponsor," which varies by the type of plan. For example, the employer or employee organization is the "plan sponsor" of a plan established or maintained by a single employer or employee organization. For a multiemployer plan, the joint board of trustees is the plan sponsor;[\[4\]](#) and for a multiple employer welfare arrangement, the committee (if any) is the plan sponsor. In the case of a plan that is not sponsored by one of the entities specifically mentioned in the proposed regulations (for example, a plan maintained by two or more employers that is not a multiemployer plan), the plan sponsor is the person identified as such under the terms of the plan, or the person designated by the terms of the plan as the plan sponsor for purposes of this requirement, provided that the designation and acceptance is completed by the filing due date. The proposed regulations further provide that if no designation has been made, then each employer that maintains the plan is the plan sponsor (with respect to that employer's employees).

This rule is particularly noteworthy because the proposed regulations do not include controlled group rules that would treat related entities as a single entity for purposes of paying the fee (which, again, is imposed on the sponsor of a self-insured health plan). Therefore, if a plan is adopted by multiple members of a controlled group for the benefit of each company's employees, employers should make sure the plan documentation clearly states which entity is the plan sponsor for purposes of paying this fee. If the documents do not specify a plan sponsor, each controlled group member could owe a fee for its covered employees (and their dependents).

Amount of Fees

The amount of fees payable by each issuer of a "specified health insurance policy" and sponsor of an "applicable self-insured health plan" is \$1 for each covered life for the 2012 policy or plan year, \$2 for each covered life for the 2013 policy or plan year, and an increased amount each year thereafter based upon the percentage increase of the projected per capita amount of National Health Expenditures ("NHE"). NHE data is released by the Department of Health and Human Services annually. These fees are paid and reported as taxes in a manner similar to COBRA, HIPAA, and PPACA excise taxes.

Counting Covered Lives/Participants

The fees imposed by these proposed regulations are based upon the average number of lives covered by the policies, and the average number of lives covered by the self-insured plans, respectively. Lives include all persons covered, including employees, spouses, dependents, domestic partners, and retirees, unless an exception applies. There are different methods for counting the number of covered lives under insurance policies and self-insured plans.

Counting Methods for Insurance Policies. The proposed regulations allow insurers to choose from four different methods to determine the average number of lives covered, as described below:

- Actual Count method: Insurers may calculate the sum of lives covered for each day of the policy year and then divide that sum by the number of days in the year.
- Snapshot method: Insurers may calculate the sum of the lives covered on one date in each quarter of the policy year (or an equal number of dates in each quarter) and then divide that number by the number of days on which a count was made.
- Member Months method: Insurers may determine the average number of lives covered based on the "member months" reported on the National Association of Insurance Commissioners Supplemental Health Care Exhibit (the "Exhibit") divided by 12.
- State Form method: An insurer that is not required to file the Exhibit may use data in any form that is equivalent to the Exhibit that is filed with the applicable state if the state form reports lives covered in the same manner as member months reported on the Exhibit.

Counting Methods for Self-Insured Plans. The proposed regulations provide plan sponsors the choice of using three different methods to determine the average number of lives covered by the plans, as described below:

- Actual Count method: Plan sponsors may calculate the sum of the lives covered for each day in the plan year and then divide that sum by the number of days in the year.
- Snapshot method: Plan sponsors may calculate the sum of the lives covered on one date in each quarter of the year (or an equal number of dates in each quarter) and then divide that number by the number of days on which a count was made. The number of lives covered on any one day may be determined by counting the actual number of lives covered on that day or by treating those with self-only coverage as one life and those with coverage other than self-only as 2.35 lives.

- Form 5500 method: Sponsors of plans offering self-only coverage may add the number of employees covered at the beginning of the plan year to the number of employees covered at the end of the plan year, in each case as reported on Form 5500, and divide by 2. For plans that offer more than self-only coverage, sponsors may simply add the number of employees covered at the beginning of the plan year to the number of employees covered at the end of the plan year, as reported on Form 5500.

Special counting rules apply to FSAs and HRAs. In general, the plan sponsor of an HRA or an FSA that is not HIPAA-excepted^[5] (and therefore, subject to the fees discussed herein) may treat each participant's HRA or FSA as covering a single covered life for counting purposes, and therefore, the plan sponsor is not required to count any spouse, dependent or other beneficiary of the participant. If the plan sponsor maintains another self-insured health plan, participants in the HRA or non-excepted FSA who also participate in the other self-insured health plan only need to be counted once for purposes of determining the fees applicable to the self-insured plans.

For plan years beginning before July 16, 2012 and ending on or after October 1, 2012 (i.e., for calendar year plans, the 2012 plan year), self-insured plan sponsors are permitted to use any reasonable method to determine the average number of lives covered under the plans(s). Special rules for 2012 and 2019 apply to insurers as well, as a result of how certain counting methods above are performed. The proposed regulations generally prohibit insurers and plan sponsors from using different methods for determining covered lives in the same year with respect to the same policies or plans. However, except in the case of insurers using the Member Months method or the State Form method, insurers and plan sponsors are generally permitted to change methods from one year to the next.

Remittance of Fees

Insurers and plan sponsors must report and pay these fees annually on IRS Form 720, which will be due by July 31 of each year. The first due date is July 31, 2013. A return will generally cover policy or plan years that end during the preceding calendar year.^[6] In other words, fees for a plan year are due by July 31 of the calendar year following the calendar year containing the plan year end. Form 720 may be filed electronically. The IRS has not yet updated Form 720 to reflect the reporting of these fees.

Please feel free to contact your Proskauer attorney or any member of our Health Care Reform Task Force should you have questions regarding the comparative effectiveness research fee or any other aspect of health care reform.

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[1] HIPAA-excepted group health plan benefits include, but are not limited to, certain limited-scope dental or vision benefits, coverage for on-site medical clinics, certain benefits for long-term care and certain accident benefits. In addition, benefits provided under a health flexible spending account (FSA) are HIPAA-excepted benefits to the extent that: (i) the maximum benefit payable for the employee under the health FSA for a plan year does not exceed two times the employee's salary reduction election (or, if greater, the amount of the employee's salary reduction election, plus \$500); (ii) the employee has other coverage available under a group health plan of the employer for the year; and (iii) the other coverage is not limited to benefits that are excepted benefits.

[2] HRAs are HIPAA-excepted if they satisfy the criteria applicable to Health FSAs; therefore, an HRA is generally not HIPAA-excepted if its annual value exceeds \$500.

[3] This standard is also used in determining whether medical benefits cause an individual to be ineligible to contribute to a Health Savings Account.

[4] In that regard, it is unclear whether this fee can be paid from plan assets of a multiemployer plan, since the sponsor, rather than the plan, is liable for the fee. The preamble to the regulations states that the Department of Labor is considering this issue.

[5] For the reasons noted earlier, most FSAs will be HIPAA-excepted, and therefore, not subject to the fees at all.

[6] For insurers that use either the Member Months method or the State Form method for counting covered lives, the return will cover all policies *in effect* during the previous calendar year.

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