On December 5, 2012, the Department of the Treasury and the Internal Revenue Service (collectively, the “Service”) released for public inspection final regulations (“Final Regulations”) that implement and provide guidance on the fees imposed by the Patient Protection and Affordable Care Act (“PPACA”) on issuers of certain health insurance policies and plan sponsors of certain self-insured health plans to fund the Patient-Centered Outcomes Research Trust Fund (“PCORI fee”). The Final Regulations were published in the December 6, 2012 Federal Register and became effective on that date. The Final Regulations apply to policy and plan years ending on or after October 1, 2012 and before October 1, 2019. The Service previously requested comments regarding the PCORI fee via Notice 2011-35, and it published proposed regulations on April 17, 2012 (“Proposed Regulations”).

The PPACA established the Patient-Centered Outcomes Research Institute (“PCORI”), which is intended to, through research, “assist patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of evidence-based medicine through the synthesis and dissemination of comparative clinical effectiveness research findings.” PCORI is to be funded through the Patient-Centered Outcomes Research Trust Fund (“Fund”) (as established by Section 9511 of the Internal Revenue Code of 1986 (“Code”), as added by the PPACA), and Code sections 4375, 4376, and 4377 (as added by the PPACA) are intended to provide a funding source for the Fund. The Final Regulations implement the requirements under Code sections 4375 through 4377.
OVERVIEW AND AMOUNT OF THE PCORI Fee

Code Section 4375 imposes the PCORI fee on an issuer of a “specified health insurance policy” for each policy year ending on or after October 1, 2012 and before October 1, 2019. Code Section 4376 imposes the PCORI fee on a plan sponsor of an “applicable self-insured health plan” for each plan year ending on or after October 1, 2012 and before October 1, 2019.

The PCORI fee is two dollars (one dollar in the case of policy or plan years ending before October 1, 2013) multiplied by the average number of lives covered under the policy or plan. For policy or plan years ending on or after October 1, 2014, the amount of the PCORI fee will be adjusted based on increases in the projected per capita amount of National Health Expenditures.

With respect to insured plans, a “specified health insurance policy” is any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States. The term does not include a policy if substantially all of its coverage consists of excepted benefits described in Code Section 9832(c). Therefore, the following types of coverage are excluded:

- The following benefits in general:
  - Coverage only for accident, or disability income insurance, or any combination thereof
  - Coverage issued as a supplement to liability insurance
  - Liability insurance, including general liability insurance and automobile liability insurance
  - Workers’ compensation or similar insurance
  - Automobile medical payment insurance
  - Credit-only insurance
  - Coverage for on-site medical clinics
  - Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits

- The following benefits, if offered separately:
  - Limited scope dental or vision benefits
  - Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof
  - Such other similar, limited benefits as are specified in regulations

- The following benefits, if offered as independent, noncoordinated benefits:
  - Coverage only for a specified disease or illness
  - Hospital indemnity or other fixed indemnity insurance
The following benefits, if offered as a separate insurance policy:
  o Medicare supplemental health insurance (as defined under Section 1395ss(g)(1) of title 42),
  o Coverage supplemental to the coverage provided under chapter 55 of title 10
  o Similar supplemental coverage provided to coverage under a group health plan

Prepaid health coverage arrangements (i.e., arrangements whereby fixed payments or premiums are received as consideration for a person’s agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how the coverage is provided or arranged to be provided) are included in the definition of specified health insurance policy.

With respect to self-insured plans, an “applicable self-insured health plan” is any plan providing “accident or health coverage” (i.e., any coverage that, if provided by an insurance policy, would cause the policy to be a specified health insurance policy) if any portion of the coverage is provided other than through an insurance policy, and the plan is established or maintained (i) by one or more employers for the benefit of their employees or former employees, (ii) by one or more employee organizations for the benefit of their members or former members, (iii) jointly by one or more of the foregoing for the benefit of employees or former employees, (iv) by a voluntary employees’ beneficiary association described in Code Section 501(c)(9), (v) by any organization described in Code Section 501(c)(6), or, (vi) if not previously described, by a multiple employer welfare arrangement, a rural electric cooperative, or a rural telephone cooperative association.

As is the case with a specified health insurance policy, the term “applicable self-insured health plan” excludes excepted benefits described in Code Section 9832(c), as set forth above.

**Comment:** The Proposed Regulations excluded 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. The Final Regulations extend the exclusion to the definition of specified health insurance policy, providing that the term does not include any insurance policy to the extent that the policy provides for an EAP, disease management program, or wellness program if the program does not provide significant benefits in the nature of medical care or treatment. The Final Regulations provide no additional guidance regarding what constitutes “significant benefits.”
With respect to insured plans, the issuer is responsible for paying the PCORI fee. With respect to self-insured plans, the plan sponsor is responsible for paying the PCORI fee.

The plan sponsor is defined as the employer in the case of a plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization. In the case of (i) a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, (ii) a multiple employer welfare arrangement, or (iii) a voluntary employees’ beneficiary association described in Code Section 501(c)(9), the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan. Code Section 4376 further provides that, in the case of a plan established or maintained by a rural electric cooperative or rural telephone cooperative association, the plan sponsor is the cooperative or association that establishes or maintains the plan.

Comment: The Final Regulations note in a footnote that the Department of Labor (“DOL”) has advised that, because the PCORI fee is imposed on the plan sponsor with respect to a self-insured plan (instead of the plan itself), payment of the PCORI fee generally does not constitute a permissible expense of a benefit plan for purposes of Title I of the Employee Retirement Income Security Act (“ERISA”). The preamble to the Final Regulations states that the DOL will provide guidance on this topic in the near future on its website. Significantly, this is in contrast to the per capita fee payable by self-insured plans with respect to the transitional reinsurance program, as set forth in PPACA Section 1341. In a footnote to recently proposed guidance, the Department of Health and Human Services indicates that the DOL has stated that the transitional reinsurance fee may properly be paid from plan assets.

Determining the Average Number of Covered Lives

The amount of the PCORI fee is based on the average number of lives covered under the policy or plan during the policy or plan year.

The Final Regulations do not provide for a flat rule that the PCORI fee may apply only once with respect to each covered life, stating that it would be contrary to the explicit statutory language applying the fee to each specified health insurance policy or applicable self-insured health plan. The preamble to the Final Regulations states that there are no allocation rules or other methods of applying the PCORI fee on an aggregated basis in the statute or legislative history, and thus there is no evidence of an intent to apply the statutory provisions in a manner that aggregates these separate arrangements for a single covered individual.
The Final Regulations do, however, permit an applicable self-insured health plan that provides accident and health coverage through both fully-insured options and self-insured options to determine the fee imposed by Code Section 4376 by disregarding the lives that are covered solely under the fully-insured options. Significantly, however, the issuer of such fully-insured options would appear to remain liable itself for the PCORI fee with respect to enrollees in such options (and plan sponsors should expect that this fee will be passed on to enrollees and/or plan sponsors depending on the manner in which the premiums are funded).

As with the Proposed Regulations, the Final Regulations also adopt a rule designed to prevent the double-counting of individuals covered by multiple self-insured arrangements. Specifically, the Final Regulations provide that, for purposes of Code Section 4376, two or more arrangements established or maintained by the same plan sponsor that provide for accident and health coverage other than through an insurance policy and that have the same plan year may be treated as a single applicable self-insured health plan for purposes of calculating the fee. The Service did not extend this exception to insured arrangements.

Comment: In declining to extend the double-counting rules to insured arrangements, the Service pointed out that the Code specifically applies the PCORI fee to an issuer of a specified health insurance policy and to the sponsor of an applicable self-insured health plan (subject to certain exceptions), respectively. The Service noted that the statute specifically contemplates that different arrangements involving different plan sponsors or issuers would be subject to separate fees. The Service noted that the double-counting rule implemented for self-insured arrangements is workable under the statute because there is no significant difference between maintaining multiple self-insured plans and having a single “umbrella” plan. In contrast, if the two arrangements are sponsored by two different plan sponsors or issuers, the Service indicated there is no single plan equivalent.

Issuers and plan sponsors are permitted to use alternative methods for determining the average number of lives for the year. Issuers may choose from the following four methods:

(i) the actual count method, whereby an issuer may determine the average number of lives covered for a policy year by adding the total number of lives covered for each day of the policy year and dividing by the number of days in the policy year;

(ii) the snapshot method, whereby an issuer may determine the average number of lives covered under a policy for a policy year by adding the total number of
lives covered on a date or dates during the first, second, or third month of each quarter and dividing by the number of dates on which a count is made;

(iii) the *member months method*, whereby an issuer may determine the average number of lives covered under all policies in effect for a calendar year based on the member months reported on the National Association of Insurance Commissioners (“NAIC”) Supplemental Health Care Exhibit filed for that calendar year; or

(iv) the *state form method*, whereby an issuer that is not required to file NAIC annual financial statements may use a form that is filed with the issuer’s state of domicile.

Plan sponsors can choose from one of three alternative methods with respect to an applicable self-insured health plan:

(i) the *actual count method* (similar to the above);

(ii) the *snapshot method* (similar to the above); or

(iii) the *Form 5500 method*, whereby the plan sponsor may determine the average number of lives covered based on the number of participants reported on the Form 5500 for that plan year, so long as it is filed no later than the due date for the PCORI fee.

**Comment:** With respect to the snapshot method, which requires issuers and plan sponsors to count the number of individuals on a date (or an equal number of dates) in each quarter and to determine the number of covered individuals on average covered over those dates, the Final Regulations require that the date or dates used in each quarter must be within three days of the date in that quarter that corresponds to the date in the first quarter.

**Comment:** The Final Regulations, consistent with the Proposed Regulations, provide special rules for the first year the PCORI fee is in effect. Specifically, an issuer using the actual count method for determining the average number of lives covered under a policy with a policy year that ends on or after October 1, 2012 could begin counting lives covered under a policy as of May 14, 2012 (30 days after the date the Proposed Regulations were published in the Federal Register) rather than the first day of the policy year, and divide by the appropriate number of days remaining in the policy year. Similarly, for policy years ending on or after October 1, 2012 but beginning before May 14, 2012, issuers using the snapshot method could use counts from quarters beginning on or after May 14, 2012, to determine the average number of lives covered under the
policy. The Final Regulations also permit a plan sponsor to use any reasonable method to determine the average number of lives covered under an applicable self-insured health plan for a plan year beginning before July 11, 2012 (90 days after the date that the Proposed Regulations were published in the Federal Register) and ending on or after October 1, 2012.

TREATMENT OF CERTAIN TYPES OF PLANS AND POLICIES

Retiree-Only Plans

The preamble to the Final Regulations confirms that the PCORI fee does apply to a retiree-only plan. Even though group health plans with fewer than two participants who are current employees are excluded from the requirements of chapter 100 of the Code (which sets forth requirements applicable to group health plans including portability, nondiscrimination, and market reform), the Code sections that implement the PCORI fee are not in chapter 100, and thus the chapter 100 exclusion for retiree-only plans does not apply with respect to the PCORI fee. In addition, Code Section 4376 states explicitly that an applicable self-insured health plan includes a plan established or maintained by one or more employers for the benefit of their employees or former employees.

Comment: The preamble to the Final Regulations notes that some commentators urged exclusion of retiree-only plans from the PCORI fee on public policy grounds, but states that there is no statutory basis for such an exclusion. Significantly, the treatment of retiree-only plans differs for purposes of the PCORI fee and for purposes of Section 1341 of the PPACA, which provides for a per capita fee to help fund a transitional reinsurance program for the individual insurance market. The per capita fee under the transitional reinsurance program is applied based on the Medicare Secondary Payer (“MSP”) rules – where an individual has both Medicare coverage and employer-provided group health coverage, the fee under Section 1341 of the PPACA only applies to the group health coverage if it is the primary payer of medical expenses.

Continuation Coverage

The Final Regulations do not provide an exception from the PCORI fee for continuation coverage required under the Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”) or similar continuation coverage under other federal or state law. The preamble to the Final Regulations states that if the coverage provided under the continuation coverage is accident and health coverage, there is no basis to exclude the arrangement from the PCORI fee and continuation coverage must be taken into account in determining the PCORI fee, unless the arrangement is otherwise excluded.
Comment: In light of the statements contained in the preamble to the Final Regulations, it appears that all individuals enrolled in coverage by reason of federal COBRA, state mini-COBRA or the like, or voluntary continuation coverage, must be counted for purposes of the fee.

Exempt Governmental Programs

Code Section 4377 provides that, notwithstanding any other law or rule of law, governmental entities will be exempt from the PCORI fee only if the policy or plan is an exempt governmental program. An “exempt governmental program” is defined by statute to be:

(i) any insurance program established under Medicare;

(ii) the medical assistance program established by Medicaid or the Children’s Health Insurance Program;

(iii) any program established by federal law for providing medical care (other than through insurance policies) to individuals (or the spouses and dependents thereof) by reason of such individuals being members of the Armed Forces of the United States or veterans; and

(iv) any program established by federal law for providing medical care (other than through insurance policies) to members of Indian tribes.

Comment: A governmental entity that is the plan sponsor of an applicable self-insured health plan that does not meet the definition of an exempt governmental program is subject to the PCORI fee with respect to such plan.

HRAs and FSAs

The Final Regulations continue to include in the definition of applicable self-insured health plan health reimbursement arrangements (“HRAs”) and health flexible spending arrangements (“FSAs”) that do not satisfy the requirement to be treated as an excepted benefit within the meaning of Code Section 9832(c). The preamble to the Final Regulations points out that an HRA or FSA that is sponsored by an employer that also sponsors another self-insured plan with the same plan year will not be subject to a separate fee. However, an HRA or FSA that is offered by an employer that only sponsors an insured plan will be subject to the PCORI fee.
Comment: The viability of stand-alone HRAs under the PPACA remains unclear; at present, the agencies appear to be of the view that such arrangements are impermissible to the extent they provide for the reimbursement of essential health benefits (and perhaps to the extent they allow for the reimbursement of premiums for insurance that would cover essential health benefits). Although stand-alone HRAs would give rise to additional PCORI fee liability, HRAs that are integrated with a major medical plan generally would not give rise to additional fee liability (unless, perhaps, the HRA is insured and the major medical coverage is self-funded, or vice-versa).

“Residing in the United States”

The term specified health insurance policy includes only an accident and health insurance policy that is issued with respect to an individual residing in the United States. The Final Regulations adopt the rule in the Proposed Regulations that provides that if the address on file with the issuer or plan sponsor for the primary insured is outside of the United States, the issuer or plan sponsor may treat the primary insured and the primary insured’s spouse, dependents, or other beneficiaries covered under the policy as having the same place of abode and not residing in the United States. The determination of place of abode is based on the most recent address on file with the issuer or plan sponsor.

Comment: The term “primary insured” refers to the individual covered by the policy whose eligibility for coverage was not due to his or her status as a spouse, dependent or other beneficiary of another insured individual. Also, for purposes of the PCORI fee, “an individual residing in the United States” means an individual who has a place of abode in the United States. Since, as noted above, the issuer or plan sponsor may treat the primary insured’s spouse, dependents, or other beneficiaries covered under the policy as having the same place of abode as the primary insured (and thus, as not residing in the United States), it appears that even where the primary insured’s spouse, dependents or other beneficiaries actually do live in the United States, they will not be covered enrollees for purposes of the PCORI fee.

Comment: The Final Regulations conclude that an individual on a temporary U.S. visa who has a place of abode in the United States is residing in the United States.

Expatriate Plans

The Proposed Regulations provided for an exception from the fee for insured expatriate coverage. In response to stakeholder comments, the Final Regulations
confirm that the term applicable self-insured health plan does not include a self-insured plan if the facts and circumstances show that the self-insured plan was designed specifically to cover primarily employees who are working and residing outside of the United States.

**Stop-Loss and Indemnity Reinsurance**

Stop-loss and indemnity reinsurance policies are not subject to the PCORI fee.

**Comment:** Questions remain regarding what constitutes stop-loss versus health insurance where the stop-loss coverage uses a low attachment or triggering point. In connection with other rulemaking projects, the agencies have requested comments on low attachment point stop-loss generally, with suggestions that there may be a point at which low attachment point stop-loss should be treated not as stop-loss but as health insurance, at least for purposes of the PPACA.

**REPORTING AND PAYMENT DEADLINE**

As with the Proposed Regulations, the Final Regulations require an issuer of a specified health insurance policy and plan sponsor of an applicable self-insured health plan to report and pay the PCORI fee for a policy year or plan year no later than July 31 of the year following the last day of the policy year or plan year. The PCORI fee must be reported and paid on the Form 720, “Quarterly Federal Excise Tax Return.”

Applicable penalties related to late filing of the applicable form or late payment of the applicable fee may be waived or abated if the issuer or plan sponsor has reasonable cause and the failure was not due to willful neglect.

The Final Regulations do not permit or include rules for third-party reporting or payment of the PCORI fee. The Service states that the burden and complexity that would have to be addressed by issuers, plan sponsors and the Service to develop and operate a third-party reporting and payment regime significantly outweigh the benefits of such a regime.

**Comment:** Stakeholders had requested that plan sponsors be permitted to delay the filing and payment of the fee until the filing of the related Form 5500 for the plan/arrangement at issue. The preamble to the Final Regulations states that the Service considered such a request but that the Service believed allowing for such a rule – given the delayed filing date of Form 5500s with extensions, i.e., typically October 15th of the following year – would hinder the funding and efficacy of the PCORI.
TAX TREATMENT OF PCORI Fee

The PCORI fee is treated as an excise tax for purposes of subtitle F of the Code. Unlike certain other ACA fees and taxes that are expressly *not* deductible by statute, the applicable Code language regarding the PCORI Fee does not include similar limiting language. Generally excise taxes are deductible under Code section 162 to the extent they are an ordinary and necessary business expense in carrying on a trade or business. Like the statutory provisions, the Final Regulations also do not clarify the deductibility of the PCORI Fee by issuers or employer plan sponsors. It is our understanding that the issue remains under consideration by the IRS. Some have suggested that the time-limited nature of the PCORI Fee and its unusual purpose (i.e., to fund research by an institute on comparative effectiveness), as well the relatively small amount of the PCORI Fee itself (i.e., just $1 in its first year of application) could lead the IRS to conclude that the fee is not deductible. It is also conceivable that the IRS could reach different conclusions on the deductibility of the Fee by employers versus issuers.

Comment: In the event that the PCORI Fee is determined by the IRS to not be tax deductible, the PCORI Fee would be effectively more costly than the stated per capita fee amount because of the employer’s lost deduction. Very generally, the increased cost would be equal to the issuer or plan sponsor’s marginal federal income tax rate.

ABILITY TO REIMBURSE THE PCORI Fee FROM ERISA PLAN ASSETS

The Final Regulations make clear that the PCORI Fee is a liability of the plan sponsor by statute – and not the underlying ERISA plan – and, thus, may not be reimbursed from ERISA plan assets. This is in contrast to the transitional reinsurance contribution, which DOL has indicated may be properly charged to the respective ERISA plan.

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