Part III – Administrative, Procedural, and Miscellaneous

Request for Comments on Funding of Patient-Centered Outcomes Research Through Fees Payable by Issuers of Health Insurance Policies and Self-Insured Health Plan Sponsors

Notice 2011-35

Section 1. PURPOSE

This notice requests public comments on the implementation of provisions of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), (Affordable Care Act) to fund comparative clinical effectiveness research relating to patient-centered outcomes. The Affordable Care Act includes provisions that promote 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.

As required by the Affordable Care Act, a nonprofit corporation – the Patient-Centered Outcomes Research Institute (Institute) – was established to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing comparative clinical effectiveness research. The Affordable Care Act provides that the Institute will not be an agency or establishment of the United States Government, and will be funded by a Patient-Centered Outcomes Research Trust Fund

(Trust Fund). The Trust Fund, in turn, is to be funded in part by fees to be paid by issuers of health insurance policies and sponsors of self-insured health plans.

The Department of the Treasury (Treasury) and the Internal Revenue Service (Service) intend to publish proposed regulations implementing and providing guidance on the statutory requirements applicable to issuers and plan sponsors that pay those fees. To inform the development of the proposed regulations, this notice invites comments on how the fees should be determined and paid, including comments on several possible rules, safe harbors, and issues outlined below. Accordingly, while this notice does not provide guidance, it describes potential guidance that Treasury and the Service expect to propose to implement the new fees and seeks comments on this potential guidance.

Section 2. BACKGROUND

.01 Section 6301 of the Affordable Care Act added new § 9511 to the Internal Revenue Code (Code) to establish the Patient-Centered Outcomes Research Trust Fund as a funding source for the Patient-Centered Outcomes Research Institute. The Trust Fund, in turn, will be funded in part through fees payable by issuers of health insurance policies and sponsors of self-insured health plans. Section 6301 of the Affordable Care Act also added new §§ 4375, 4376, and 4377 to the Code to impose those fees on what the statute refers to as “specified health insurance policies” and “applicable self-insured health plans” based on the average number of lives covered under the policy or plan. The fees are effective for policy and plan years ending after September 30, 2012.

Fees on Specified Health Insurance Policies Under § 4375

.02 Section 4375(a) imposes a fee on each specified health insurance policy for each policy year ending after September 30, 2012. Therefore, the first policy year to which the fee on a specified health insurance policy applies would be a policy year that ends on October 1, 2012. The fee does not apply to policy years ending after September 30, 2019. Accordingly, if the policy year were the calendar year, the fee would apply to calendar policy years 2012 through 2018.

.03 The fee under § 4375 is equal to two dollars (one dollar in the case of policy years ending before October 1, 2013) multiplied by the average number of lives covered under the policy. Under § 4375(b), the fee must be paid by the issuer of the policy.

.04 Section 4375(c) defines "specified health insurance policy" as 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 also includes an arrangement under which 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 such coverage is provided or arranged to be provided. In such a case, the person agreeing to provide or arrange for the provision of coverage is treated as the issuer. "Specified health insurance policy" does not include any insurance if substantially all of its coverage is of excepted benefits described in § 9832(c).

.05 Section 4375(d) provides that, for any policy year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under § 4375(a) is

equal to the sum of (1) the dollar amount for policy years ending in the previous fiscal year, plus (2) the amount equal to the product of (A) the dollar amount for policy years ending in the previous fiscal year, and (B) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year. For purposes of § 4375, the term "fiscal year" means the Federal government's fiscal year, which runs from October 1 to September 30. Because Treasury does not publish the National Health Expenditures, Treasury and the Service intend that the proposed regulations will refer to the National Health Expenditures published by the Department of Health and Human Services.

Fees on Applicable Self-Insured Health Plans Under § 4376

.06 Section 4376(a) imposes a fee on any applicable self-insured health plan for each plan year ending after September 30, 2012. Therefore, the first plan year to which the fee on an applicable self-insured health plan applies would be a plan year that ends on October 1, 2012. The fee does not apply to plan years ending after September 30, 2019. Accordingly, if the plan year were the calendar year, the fee would apply to calendar plan years 2012 through 2018. The fee is equal to two dollars (one dollar in the case of plan years ending before October 1, 2013) multiplied by the average number of lives covered under the plan.

.07 Under § 4376(b)(1), the fee must be paid by the plan sponsor. Section 4376(b)(2) defines "plan sponsor" 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. Section 4376(b)(2) provides

that, in the case of (1) a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, (2) a multiple employer welfare arrangement, or (3) a voluntary employees' beneficiary association described in § 501(c)(9), the "plan sponsor" is the association, committee, joint board of trustees, or other similar group of representatives of the parties that establish or maintain the plan, and, in the case of a plan established or maintained by a cooperative or association described in § 4376(c)(2)(F), the "plan sponsor" is the cooperative or association.

.08 Section 4376(c) defines "applicable self-insured health plan" as any plan for providing accident or health coverage if any portion of the coverage is provided other than through an insurance policy, and the plan is established or maintained (1) by one or more employers for the benefit of their employees or former employees, (2) by one or more employee organizations for the benefit of their members or former members, (3) jointly by one or more employers and one or more employee organizations for the benefit of employees or former employees, (4) by a voluntary employees' beneficiary association described in § 501(c)(9), (5) by any organization described in § 501(c)(6), or (6) in the case of a plan not previously described, by a multiple employer welfare arrangement (as defined in § 3(40) of the Employee Retirement Income Security Act of 1974 (ERISA)), a rural electric cooperative (as defined in § 3(40)(B)(iv) of ERISA), or a rural telephone cooperative association (as defined in § 3(40)(B)(v) of ERISA).

.09 Section 4376(d) provides that, for any plan year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under § 4376(a) is

equal to the sum of (1) that dollar amount for plan years ending in the previous fiscal year, plus (2) an amount equal to (A) that dollar amount for plan years ending in the previous fiscal year, multiplied by (B) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year. For purposes of § 4376, the term "fiscal year" means the Federal government's fiscal year, which, as noted, runs from October 1 to September 30. As noted, because Treasury does not publish National Health Expenditures, Treasury and the Service intend that the proposed regulations will refer to the National Health Expenditures published by the Department of Health and Human Services.

Definitions and Special Rules Under § 4377 for the Fees Imposed Under §§ 4375 and 4376

.10 Section 4377(a)(1) defines "accident and health coverage" for purposes of §§ 4375 and 4376 as any coverage that, if provided by an insurance policy, would cause the policy to be a specified health insurance policy (as defined in § 4375(c)).

.11 Section 4377(a)(2) defines "insurance policy" as any policy or other instrument whereby a contract of insurance is issued, renewed, or extended.

.12 Section 4377(a)(3) defines "United States" to include any possession of the United States. Section 4377(d) provides that no amount collected under §§ 4375-4377 is to be covered over to any possession of the United States.

.13 Governmental entities that are issuers of specified health insurance policies or plan sponsors of applicable self-insured plans are generally subject to the fees

imposed under §§ 4375 and 4376. However, § 4377(b) provides that no such fee will be imposed on any covered life under an "exempt governmental program." Section 4377(b) defines "exempt governmental program" as (A) any insurance program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) (Medicare), (B) the medical assistance program established by title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (Medicaid) or title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) (Children's Health Insurance Program), (C) any program established by Federal law for providing medical care (other than through insurance policies) to individuals (or their spouses and dependents) by reason of the individuals being members of the Armed Forces of the United States or veterans, and (D) any program established by Federal law for providing medical care (other than through insurance policies) to members of Indian tribes (as defined in § 4(d) of the Indian Health Care Improvement Act, 25 U.S.C. 1603).

.14 Section 4377(c) provides that, for purposes of subtitle F of the Code, the fees imposed by §§ 4375 and 4376 are treated as if they were taxes.

Data Reported on the NAIC Supplemental Health Care Exhibit

.15 State insurance departments currently require issuers operating in their jurisdictions to provide a primary financial report referred to as an Annual Statement. The format of the Annual Statement and the rules to be followed in preparing it are established by the National Association of Insurance Commissioners (NAIC). After the Affordable Care Act was enacted, the NAIC developed a Supplemental Health Care Exhibit (Exhibit) for the purpose of collecting comprehensive major medical data by

company, state, and market. Information collected on the Exhibit includes the number of individual policies (for individual and association business) or certificates issued to individuals covered under a group policy in force as of the end of the reporting period and the total number of lives insured, including dependents, under individual policies and group certificates as of the end of the reporting period. Many issuers of specified health insurance policies are required by one or more state insurance commissioners to file the Exhibit.

Section 3. REQUEST FOR COMMENTS

Treasury and the Service anticipate proposing regulations under §§ 4375 and 4376. To inform the development of the proposed regulations, Treasury and the Service request comments on the following topics:

Average Number of Lives Covered Under the Policy Under § 4375

.01 The fee imposed by § 4375(a) on specified health insurance policies is based on the "average number of lives covered under the policy." Treasury and the Service invite comments on reasonable methods an issuer may use to determine the average number of lives covered under the policy for purposes of § 4375. Under any such method other than the safe harbor described below, it is contemplated that issuers that are required to file the NAIC Supplemental Health Care Exhibit would be expected to be able to account for any differences between the numbers computed under the alternative method and the data reported on the Exhibit.

.02 Treasury and the Service also invite comments on whether guidance should provide a safe harbor for issuers that are required to report the number of lives covered

on the NAIC Supplemental Health Care Exhibit. For example, a safe harbor might provide that the Service will not challenge an issuer's calculation of the fee based on the number of lives reported on the most recently filed Exhibit, or based on the average of the number of lives reported on the most recently filed Exhibit and the Exhibit filed one year before the most recently filed Exhibit. Comments are requested on the scope and operation of a safe harbor rule, including comments on the circumstances, if any, under which amounts so determined may be too unrepresentative to form a sufficiently reliable basis for calculating the fee.

Applicable Self-Insured Health Plan Under § 4376

.03 Under § 4376(c), an applicable self-insured health plan is a plan that provides "accident and health coverage" any portion of which is provided other than through an insurance policy and that meets certain other conditions. Section 4377(a)(1) defines "accident and health coverage" as any coverage that, if provided by an insurance policy, would cause the policy to be a specified health insurance policy (as defined in § 4375(c)). Section 4375(c)(2) provides that a specified health insurance policy does not include any insurance if substantially all of its coverage is of excepted benefits described in § 9832(c). Benefits provided under a health flexible spending arrangement (health FSA), as described in § 106(c)(2), are excepted benefits for purposes of § 9832(c) if:

(1) Other group health plan coverage, not limited to excepted benefits, is made available to the eligible class of participants; and

(2) The arrangement is structured so that the maximum benefit payable to

any eligible participant cannot exceed two times the participant's salary reduction election (or, if greater, $500 plus the amount of the salary reduction election).

See § 54.9831-1(c)(3)(v) of the regulations relating to group health plans. Because coverage under a health FSA that satisfies these requirements is treated as excepted benefits for purposes of § 9832(c), such coverage would not, if provided by an insurance policy, cause the policy to be a "specified insurance policy," as defined in § 4375(c). Accordingly, the coverage under a health FSA that satisfies these requirements is not "accident and health coverage" within the meaning of § 4377(a)(1), and such a health FSA is not an "applicable self-insured health plan" within the meaning of § 4376(c).

With respect to health FSAs that do not satisfy the requirements to be treated as an excepted benefit, comments are invited on the variations that exist and which types would be excluded from the definition of an applicable self-insured health plan under § 4376 because they provide a type of coverage that, if provided by an insurance policy, would not be treated as a specified health insurance policy (as defined in § 4375(c)).

.04 Treasury and the Service invite comments on the type or types of health reimbursement arrangements (HRAs), as described in Notice 2002-45, 2002-2 C.B. 93, that would be excluded from the definition of applicable self-insured health plan under § 4376 because they provide a type of coverage that, if provided by an insurance policy, would not cause the policy to be treated as a specified health insurance policy (as defined in § 4375(c)). If so, what would be the basis for reaching such a conclusion?

For example, to what extent does a limitation on annual contributions, or the availability of other employer-sponsored health coverage affect the determination as to whether an HRA provides coverage that, if provided by an insurance policy, would not cause the policy to be treated as a specified health insurance policy? Comments are also invited on whether there are types of HRAs that should be treated as applicable self-insured health plans under § 4376.

Average Number of Lives Covered Per Applicable Self-Insured Health Plan Under § 4376

.05 The fee imposed by § 4376(a) on applicable self-insured health plans is based on the "average number of lives covered under the plan." Treasury and the Service invite comments on how future guidance could reduce administrative burden by providing for reasonable methods to determine the average number of lives covered under an applicable self-insured plan; on whether guidance should provide a safe harbor that would permit sponsors of applicable self-insured health plans to compute the average number of lives covered using a formula based on the number of participants and one or more additional factors that account for the number of dependents without requiring that actual dependents covered under the plan be counted; and on formulas and factors that could be used to determine the number of dependents for applicable self-insured health plans.

Administration of the Fees

.06 Under § 4377(c), the fees imposed by §§ 4375 and 4376 are treated as taxes for purposes of subtitle F of the Code (§§ 6001-7874). Thus, references in

subtitle F to “taxes imposed by this title,” “internal revenue tax,” and similar references are also references to the fees imposed by §§ 4375 and 4376. For example, the fees imposed by §§ 4375 and 4376 are assessed (§ 6201), collected (§ 6301), enforced (§ 7602), and subject to confidentiality rules (§ 6103), in the same manner as taxes imposed by other sections of the Code.

.07 The deficiency procedures of §§ 6211-6216 apply only to income, estate, and gift taxes imposed by subtitles A and B and excise taxes imposed by chapters 41, 42, 43, and 44. The fees imposed by §§ 4375 and 4376 are imposed by chapter 34 and, therefore, the deficiency procedures of §§ 6211-6216 do not apply to those fees.

.08 Future proposed regulations could require each issuer and plan sponsor to report and pay the §§ 4375 and 4376 fees annually as opposed to quarterly. Proposed regulations might also require the reporting and payment to occur on the same calendar date regardless of the “policy year” or “plan year” of any individual issuer or plan sponsor. Comments are invited on this approach and possible alternatives.

Other Issues That Should be Addressed in Guidance

.09 In addition to comments on the topics described above, comments are invited on the following specific issues:

(1) What transition rules, if any, would be appropriate for the first “policy year” or first “plan year” ending after September 30, 2012? For example, would any of the information necessary to determine the average number of lives covered be unavailable for the first year for which the fee is in effect?

(2) Is guidance needed concerning the definition of “policy year” or “plan year” for purposes of §§ 4375 and 4376? If so, how should these terms be defined?

(3) Are there circumstances under which an issuer or plan sponsor might not know whether a covered individual resides in the United States? If so, how should those circumstances be addressed? Is guidance needed on the application of §§ 4375 and 4376 to plans that cover expatriates?

(4) Should future guidance permit all employers treated as a single employer under § 414 to be treated as a single employer for purposes of § 4376(b)? If so, under what conditions?

(5) In the case of the fee imposed on self-insured health plans, what guidance is needed concerning the ability of a third-party administrator to act on behalf of a plan sponsor in complying with the § 4376 fee requirements?

.10 Comments will be considered if submitted in writing by September 6, 2011. All comments will be available for public inspection and copying. Comments may be submitted in one of three ways:

(1) By mail to CC:PA:LPD:PR (Notice 2011-35), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

(2) Electronically to Notice.Comments@irscounsel.treas.gov. Please include “Notice 2011-35” in the subject line of any electronic

communications.

(3) By hand-delivery Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2011-35), Courier's Desk, Internal Revenue Service, 1111 Constitution Ave., NW, Washington, DC 20224.

DRAFTING INFORMATION

The principal author of this notice is Rebecca L. Baxter of the Office of Associate Chief Counsel (Financial Institutions & Products). For further information regarding this notice contact Ms. Baxter at (202) 622-7117 (not a toll-free call).