Table 1

July 1, 2010 — December 31, 2010		
Model Years	**Model**	**Credit Amount**
2009	Audi Q7 3.0L TDI	$575
2010	Audi Q7 3.0L TDI	$575
2010	Audi A3 2.0L TDI	$650
2010	Volkswagen Golf 2.0L TDI (automatic)	$850
2010	Volkswagen Golf 2.0L TDI (manual)	$650
2009	Volkswagen Jetta 2.0L TDI Sedan	$650
2010	Volkswagen Jetta 2.0L TDI Sedan	$650
2009	Volkswagen Jetta 2.0L TDI SportWagon	$650
2010	Volkswagen Jetta 2.0L TDI SportWagon	$650
2009	Volkswagen Touareg 3.0L TDI	$575
2010	Volkswagen Touareg 3.0L TDI	$575

Table 2

On or after January 1, 2011		
Model Years	**Model**	**Credit Amount**
2009	Audi Q7 3.0L TDI	$0.00
2010	Audi Q7 3.0L TDI	$0.00
2010	Audi A3 2.0L TDI	$0.00
2010	Volkswagen Golf 2.0L TDI (automatic)	$0.00
2010	Volkswagen Golf 2.0L TDI (manual)	$0.00
2009	Volkswagen Jetta 2.0L TDI Sedan	$0.00
2010	Volkswagen Jetta 2.0L TDI Sedan	$0.00
2009	Volkswagen Jetta 2.0L TDI SportWagon	$0.00
2010	Volkswagen Jetta 2.0L TDI SportWagon	$0.00
2009	Volkswagen Touareg 3.0L TDI	$0.00
2010	Volkswagen Touareg 3.0L TDI	$0.00

The principal author of this notice is Patrick S. Kirwan of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, contact Mr. Kirwan at (202) 622–3110 (not a toll-free call).

Qualifying Therapeutic Discovery Project Credit

Notice 2010–45

SECTION 1. PURPOSE

This notice establishes the qualifying therapeutic discovery project program under § 48D of the Internal Revenue Code (Code), as added to the Code by section 9023(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (the Affordable Care Act). This notice provides the procedures under which an eligible taxpayer may apply for certification from the Internal Revenue Service (Service) of a qualified investment with respect to a qualifying therapeutic discovery project as eligible for a credit, or for certain taxpayers, a grant under the program. The Service will consult with the Department of Health and

Human Services (HHS) in conducting this program as described below.

SECTION 2. BACKGROUND

.01 Section 46 of the Code provides that the amount of the investment credit for any taxable year is the sum of the credits listed in § 46. That list includes the qualifying therapeutic discovery project credit.

.02 The qualifying therapeutic discovery project credit is provided under § 48D. Section 48D(a) of the Code provides that the qualifying therapeutic discovery project credit for any taxable year is an amount equal to 50 percent of the qualified investment (as defined in § 48D(b)) for that taxable year with respect to any qualifying therapeutic discovery project (as defined in § 48D(c)(1)) of an eligible taxpayer (as defined in § 48D(c)(2)). The amount that is treated as a qualified investment shall not exceed the amount certified under section 5 of this notice as eligible for the credit under §48D.

.03 Section 48D(d)(1)(B) of the Code provides that the total amount of credits that may be allocated under the qualifying therapeutic discovery project program may not exceed $1 billion for the 2-year period beginning with 2009.

.04 Section 48D(d)(3) of the Code specifies the criteria that must be considered in determining the qualifying therapeutic discovery projects with respect to which qualified investments may be certified under § 48D(d)(1)(A).

.05 The at-risk rules in § 49 of the Code and the recapture and other special rules in § 50 apply to the qualifying therapeutic discovery project credit.

.06 Section 48D applies to amounts paid or incurred after December 31, 2008, in taxable years beginning after that date under section 9023(f) of the Affordable Care Act.

.07 Section 9023(e) of the Affordable Care Act provides that taxpayers may receive grants in lieu of qualified therapeutic discovery project credits.

SECTION 3. ESTABLISHMENT OF THE QUALIFYING THERAPEUTIC DISCOVERY PROJECT PROGRAM

Section 48D(d)(1) of the Code provides that not later than 60 days after March 23, 2010, the date of the enactment of the Affordable Care Act, the Secretary of the Treasury or his delegate (the Secretary), in consultation with the Secretary of Health and Human Services, shall establish a qualifying therapeutic discovery project program to consider and award certifications for qualified investments eligible for the credit to qualifying therapeutic discovery project sponsors. The Treasury Department and the Service hereby establish the qualifying therapeutic discovery project program under the procedures set forth in sections 5 through 11 of this notice.

SECTION 4. DEFINITIONS

The following definitions apply for purposes of § 48D and this notice:

.01 *Qualified Investment*.

(1) For purposes of § 48D(a), a qualified investment under § 48D(b) of the Code for any taxable year is the aggregate amount of the costs paid or incurred in the taxable year for expenses necessary for and directly related to the conduct of a qualifying therapeutic discovery project (as defined in section 4.02 of this notice).

(2) The amount that is treated as qualified investment for all taxable years with respect to any qualifying therapeutic discovery project may not exceed the amount certified by the Secretary as eligible for the credit.

(3) The qualified investment for any taxable year with respect to any qualifying therapeutic discovery project will not take into account any cost (a) for remuneration for any employee described in § 162(m)(3) of the Code, (b) for interest expenses, (c) for facility maintenance expenses (as defined in section 4.04 of this notice), (d) that is identified as a service cost under § 1.263A–1(e)(4) of title 26, Code of Federal Regulations, or (e) for any other expense as determined by the Secretary.

(4) For purposes of section 4.01(3)(e) of this notice, the Secretary has determined that a qualified investment should be reduced by the amount of any grant excluded from gross income under § 61 of the Code, unless the grant can only be used for costs not included in the definition of a qualified investment under section 4.01(1) of this notice.

(5) In the case of costs described in section 4.01(1) of this notice that are paid for property of a character subject to an allowance for depreciation, rules similar to rules of § 46(c)(4) and (d) of the Code (as in effect on the day before the date of enactment of the Revenue Reconciliation Act of 1990) apply.

(6) An investment will be considered a qualified investment only if that investment is made in a taxable year beginning in 2009 or 2010.

.02 *Qualifying Therapeutic Discovery Project*. A qualifying therapeutic discovery project under § 48D(c)(1) of the Code means a project that is designed:

(1) To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act,

(2) To diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or

(3) To develop a product, process, or technology to further the delivery or administration of therapeutics.

.03 *Eligible Taxpayer*. An eligible taxpayer is a taxpayer who employs not more than 250 employees in all businesses of the taxpayer at the time of the submission of the application under § 48D(d)(2) of the Code. All persons treated as a single employer under § 52(a) or (b), or § 414(m) or (o), must be so treated for purposes of the definition of an eligible taxpayer. For purposes of this section, the term "employee" includes both full-time and part-time employees but does not include leased employees.

.04 *Facility Maintenance Expenses*. Facility maintenance expenses are costs paid or incurred to maintain a facility, including (1) mortgage or rent payments, (2) insurance payments, (3) utility and maintenance costs, and (4) costs of employment of maintenance personnel.

SECTION 5. QUALIFYING THERAPEUTIC DISCOVERY PROJECT PROGRAM

.01 *In General*. The Service will certify an eligible taxpayer's qualified investment associated with a qualifying therapeutic discovery project under the qualifying therapeutic discovery project program,

for which an application has been submitted pursuant to section 6 of this notice, only if:

(1) HHS determines that the taxpayer's project is a qualifying therapeutic discovery project (as defined in section 4.02 of this notice);

(2) HHS determines that the taxpayer's project shows reasonable potential (a) to result in new therapies (i) to treat areas of unmet medical need, or (ii) to prevent, detect, or treat chronic or acute diseases and conditions, (b) to reduce long-term health care costs in the United States, or (c) to significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010; and

(3) The Service determines that the taxpayer's project is among those projects that have the greatest potential (a) to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States, and (b) to advance United States competitiveness in the fields of life, biological, and medical sciences.

.02 *Program Specifications*.

(1) A taxpayer must file with the Service a separate application under § 48D(d)(2)(A) of the Code for each qualifying therapeutic discovery project for which it is seeking certification of a qualified investment. A primary allocation round will be conducted in accordance with the procedures set forth in this notice to issue certifications for both qualified investments made in taxable years beginning in 2009 and qualified investments made in taxable years beginning in 2010. If any portion of the $1 billion available under § 48D(d)(1)(B) for allocation remains unallocated after this primary allocation, one or more additional allocation rounds may be conducted.

(2) For the primary 2009–2010 allocation round, an application for certification may be filed from the date the application form is released (see section 6.02 of this notice), through July 21, 2010. Applications for certification will not be accepted if delivered after July 21, 2010. Section 7502 applies in determining the timeliness of any application for § 48D certification. Under § 7502, the date of the United States postmark stamped on the cover of an application shall be deemed the date of delivery. See section 6 of this notice and Appendix A to this notice for the information required to be filed as part of the application. See section 10 of this notice and Appendix B of this notice for a consent to disclosure that an applicant may file with the application. Each application will be subject to a preliminary review, which will enable the Service to determine whether the applicant is an eligible taxpayer (as defined in section 4.03 of this notice) and whether the application is otherwise complete. Preliminary review of timely-filed applications will end on September 30, 2010.

(3) Under § 48D(d)(2)(B) of the Code, the Secretary is required to take action to approve or deny any application within 30 days of the submission of the application. Applications will be considered submitted for purposes of § 48D(d)(2)(B) on October 1, 2010, the day after the preliminary review ends. An application for certification may include a request for certification of a project's costs under section 4.01(1) of this notice for taxable years beginning in 2009, 2010, or both.

(4) The Service will determine whether to certify all or a portion of a taxpayer's qualified investment eligible for the therapeutic discovery project credit or grant after HHS has completed its review of all applications submitted by eligible taxpayers in accordance with section 5.01(1) and (2) of this notice (see section 6 of this notice for the requirements applicable to the application for § 48D certification).

(5) The Service will certify all or a portion of an eligible taxpayer's qualified investment for each qualifying therapeutic discovery project for which an application has been submitted pursuant to section 6 of this notice that meets the certification requirements under section 5.01 of this notice. The aggregate amount of qualified investments that will be certified by the Service will not exceed $2 billion. The total amount of credits and grants allocated under the program will not exceed the $1 billion limitation of § 48D(d)(1)(B). The Service will certify an equal amount of qualified investment for each project that meets the certification requirements under section 5.01 of this notice. Nevertheless, in no case will the Service certify more than the amount of the qualified investment attributable to a project. If a project would otherwise receive certification for an amount of qualified investment that exceeds the qualified investment described in the application as attributable to the project, the unused certification amount will be apportioned equally among all other projects receiving a certification for only a portion of their qualified investments. Such reapportionment will continue until no project receives certification for an amount that exceeds the qualified investment described in the application as attributable to the project.

(6) For purposes of applying the limitation specified in section 5.02(5) of this notice, a project's qualified investment will be considered to include any qualified investment made or expected to be made in a taxable year beginning in 2009 or 2010 or both, in each case as represented by the taxpayer in its application for certification. See Appendix A for further information regarding the information required to be submitted with respect to qualified investments made or expected to be made in connection with a qualifying therapeutic discovery project.

(7) In addition to the limitation specified in section 5.02(5) of this notice, the Service will not certify more than $10 million as a qualified investment for any single taxpayer, such that no taxpayer shall be allocated more than $5 million in credits or grants in the aggregate for 2009 and 2010, regardless of the number of projects the taxpayer sponsors. If a taxpayer would otherwise receive certification for an amount of qualified investment that exceeds this $10 million threshold, the amount in excess of $10 million will be apportioned equally among all other projects receiving a certification for only a portion of their qualified investments. Such reapportionment will continue until no taxpayer receives certification for an amount that exceeds the $10 million threshold.

(8) In the primary 2009–2010 allocation round, the Service will approve or deny the taxpayer's application for § 48D certification no later than October 29, 2010, which is within 30 days after the date timely-filed applications will be considered to be submitted pursuant to section 5.02(3), and will notify the taxpayer, by letter, of its decision. If the application for certification is approved, the date of the certification letter will be treated as the approval date.

(9) If the taxpayer's application for § 48D certification is approved by the Service, then a certification letter approving the application will state the amount of qualified investment that is certified

as eligible for the credit or grant under § 48D and the amount of the credit or grant allocated to the taxpayer for the taxpayer's project(s). If the amount of the taxpayer's qualified investment certified by the Service is less than the taxpayer's total qualified investment for 2009 and 2010, then the taxpayer may attribute the certification to any of the qualified investment costs of the project(s) to which the certification relates, subject to the provisions of section 5.02(10) of this notice.

(10) If the taxpayer requests a grant for both 2009 and 2010 and the aggregate amount of the taxpayer's qualified investment certified by the Service for both 2009 and 2010 is less than the taxpayer's total qualified investment for 2009 and 2010, then the taxpayer's qualified investment will be attributed to 2009 before 2010.

(11) If the amount of the taxpayer's certification by the Service is based on a qualified investment expected to be made, and the amount certified exceeds the taxpayer's actual qualified investment for 2009 and 2010, then the credit allocated to the taxpayer shall be reduced by 50 percent of the difference between the qualified investment certified by the Service and the taxpayer's actual qualified investment.

(12) If an applicant has an overpayment after receiving a certification and claiming a credit under § 48D, the rules of the Code with respect to overpayments of tax, including the rules of § 6402 relating to offsets, will apply. If an applicant elects to receive a grant, the offset provisions under Title 31, rather than § 6402 of the Code, will apply.

SECTION 6. APPLICATION FOR § 48D CERTIFICATION

.01 A separate application for certification must be submitted for each project for which an eligible taxpayer is seeking certification of a qualified investment. If an application for certification does not include all of the information required by section 6.02 of this notice and meet the requirements of section 7.01 and 7.02 of this notice, the Service and HHS may decline to consider the application.

.02 *Application for § 48D Certification*. Applications for § 48D certification will be made on Form 8942, *"Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program."* Form 8942 and its instructions will provide the manner for submitting applications. Form 8942 will be released no later than June 21, 2010, and will be available to the public on *www.irs.gov*.

SECTION 7. OTHER REQUIREMENTS

.01 *Signature*. Each submission under section 6 of this notice must be signed and dated by the taxpayer in accordance with instructions to Form 8942. A stamped signature or faxed signature is not permitted.

.02 *Penalties of Perjury Statement*.

(1) Each application under section 6 of this notice must be accompanied by the following declaration: "Under penalties of perjury, I declare that I have examined this submission, including the accompanying documents, and, to the best of my knowledge and belief, all of the facts contained herein are true, correct, and complete."

(2) The declaration must be signed and dated by the taxpayer in accordance with instructions to Form 8942. The person signing for the taxpayer must have personal knowledge of the facts. Further, the declaration must be signed by a person authorized to bind the taxpayer such as an officer on behalf of a corporation, a general partner on behalf of a local-law partnership, a member-manager on behalf of a limited liability company, a trustee on behalf of a trust, and the proprietor in the case of a sole proprietorship. A stamped signature or faxed signature is not permitted.

.03 *Significant Change in Plans*. The taxpayer must inform the Service if the plans for a qualifying therapeutic discovery project change in any significant respect from the information set forth in the application for § 48D certification at any time prior to the date of certification. A significant change is any change, including any change that would affect the continuing accuracy of a statement made in the application, that a reasonable person would conclude might have influenced HHS' evaluation. The taxpayer must contact Candace Fisher of the Small Business and Self-Employed Division at (651) 312–2109 (not a toll-free number), or by e-mail at *acasec9023@irs.gov*, at the time the taxpayer determines there has been a significant change to the plans for the project.

.04 *Effect of Certification and Allocation*. A certification and allocation by the Service is not a determination that the costs described in the application were or will be, in fact, paid or incurred or that the costs were or will be necessary for and directly related to the conduct of a qualified therapeutic discovery project under § 48D(b) of the Code.

.05 *No Right to a Conference or Appeal*. A taxpayer does not have a right to a conference relating to any matters under this notice. Further, a taxpayer does not have a right to appeal the decisions made under this notice (including the amount of credit allocated to the project and whether or not to certify the project) to any official of HHS or the Service or the Department of the Treasury.

SECTION 8. GRANTS IN LIEU OF TAX CREDITS FOR QUALIFIED INVESTMENTS IN A QUALIFYING THERAPEUTIC DISCOVERY PROJECT

.01 *Background*.

(1) Section 9023(e)(1) of the Affordable Care Act provides that upon application, the Secretary will provide a grant to each person who makes a qualified investment in a qualifying therapeutic discovery project in the amount of 50 percent of the investment. No grant will be made with respect to any investment unless the investment is made during a taxable year beginning in 2009 or 2010.

(2) Section 9023(e)(2)(A) of the Affordable Care Act provides that, at the stated election of the applicant, an application for certification under § 48D(d)(2) of the Code for a credit for the taxable year of the applicant which begins in 2009 will be considered to be an application for a grant under section 9023(e)(1) for the taxable year.

(3) Section 9023(e)(2)(B) of the Affordable Care Act provides that an application for a grant under section 9023(e)(1) for a taxable year beginning in 2010 must be submitted (i) not earlier than the day after the last day of the taxable year, and (ii) not later than the due date (including extensions) for filing the return of tax for the taxable year.

(4) Section 9023(e)(2)(C) of the Affordable Care Act provides that an application for a grant under section 9023(e)(1)

must include the information and be in the form as the Secretary may require to state the amount of the credit allowable (but for the receipt of the grant under section 9023(e)(1)) under § 48D for the taxable year for the qualified investment with respect to which the application is made.

(5) Section 9023(e)(3)(A) of the Affordable Care Act provides that the Secretary must make payment of the amount of any grant during the 30-day period beginning on the later of (i) the date of the application for the grant, or (ii) the date the qualified investment for which the grant is being made is made.

(6) Section 9023(e)(4) of the Affordable Care Act provides that the term qualified investment means a qualified investment that is certified under § 48D(d) of the Code for purposes of the credit under § 48D.

.02 *Application Procedures for Grants*.

(1) For taxable years beginning in 2009 or 2010, at the election of an applicant on Form 8942, an application for § 48D certification for a credit will be an application for a grant. The applicant must affirmatively elect on Form 8942 to apply for a grant for 2009 or 2010. If an applicant is submitting an application for certification of a qualified investment made in both 2009 and 2010, then the applicant may apply for a grant for 2009 only, 2010 only, or both 2009 and 2010.

(2) A valid election on Form 8942 to apply for a grant for a taxpayer's 2010 taxable year will be considered effective the day after the last day of the taxpayer's 2010 taxable year. If a taxpayer receives a certification for a credit for its 2010 taxable year but did not request a grant on Form 8942 at the time it filed its application, the taxpayer may request a grant in lieu of the credit by filing an amended Form 8942, including all information required in section 8.02(3) and (4) of this notice, requesting a grant not later than the due date (including extensions) for filing the return of tax for the taxpayer's 2010 taxable year in which the certified qualified investment to which the grant relates was made.

(3) An election on Form 8942 to apply for a grant must include the applicant's Data Universal Numbering System (DUNS) number from Dun and Bradstreet. If the applicant does not already have a DUNS number, it may request one at no cost by calling the dedicated toll-free DUNS Number request line at 1–866–705–5711.

(4) To make a valid election, applicants for a grant must also register with the Central Contractor Registration (CCR). To register, go to *www.ccr.gov/startregistration.aspx*. The registration must be completed before a payment can be made.

(5) When an application for certification of qualified investment in a qualifying therapeutic discovery project is approved and the applicant has requested a grant in lieu of a credit, the Service will send a letter to the applicant in the same manner as described in section 5 of this notice. The notice will inform the grant applicant that the payment of the grant will be made by the Department of Treasury.

(6) *Payment of Grants for Taxpayers with Taxable Years Beginning in 2009*.

(a) For a certified applicant that requests a grant for its 2009 taxable year on a timely-filed Form 8942, or on an amended Form 8942 filed no later than September 30, 2010, the Department of Treasury will authorize payment to the certified applicant for its 2009 taxable year no later than October 29, 2010. If an applicant files an amended Form 8942 requesting a grant for its 2009 taxable year after September 30, 2010, and not later than the due date (including extensions) for filing the return for the 2009 taxable year, then the Department of Treasury will authorize payment to the certified applicant for its 2009 taxable year within 30 days after the request for the grant is filed.

(b) For an applicant with a 2009 fiscal year ending on or before September 30, 2010, the Department of Treasury will authorize full payment to the certified applicant no later than October 29, 2010, if the applicant's qualified investment reported on Form 8942 as having been paid or incurred by September 30, 2010, is equal to, or greater than, the amount of the qualified investment certified by the Service.

(c) For an applicant with a 2009 taxable year ending after September 30, 2010, if the applicant's qualified investment as reported on Form 8942 as having been paid or incurred by September 30, 2010, is less than the qualified investment certified by the Service, then the Department of Treasury will authorize payment to the certified applicant no later than October 29, 2010, for a grant equal to 50 percent of the applicant's qualified investment as reported on Form 8942 as having been paid or incurred by September 30, 2010. The remaining amount of the grant will be authorized for payment within 30 days after the end of the applicant's 2009 taxable year.

(7) The Department of Treasury will make payment to the certified applicant for its 2010 taxable year during the 30-day period beginning on the day after the last day of the 2010 taxable year if the applicant requested a grant on the Form 8942 filed by July 21, 2010, or if the taxpayer files an amended Form 8942 requesting a grant pursuant to section 8.02(2) of this notice no later than the last date of its 2010 taxable year. If the taxpayer files an amended Form 8942 requesting a grant pursuant to section 8.02(2) of this notice after the end of its 2010 taxable year and not later than the due date (including extensions) for filing the return for the 2010 taxable year, then the Department of Treasury will authorize payment to the certified applicant for its 2010 taxable year within 30 days after the request for the grant is filed.

.03 *Special Rules*.

(1) Section 48D(f)(1) of the Code provides that in the case of any investment with respect to which the Secretary makes a grant under section 9023(e) of the Affordable Care Act, no credit will be determined with respect to the investment for the taxable year in which the grant is made or any subsequent taxable year.

(2) Section 48D(f)(2) of the Code provides that if a credit was determined under § 48D with respect to the investment for any taxable year ending before the grant is made (A) the tax imposed under subtitle A on the taxpayer for the taxable year in which the grant is made will be increased by so much of the credit as was allowed under § 38, (B) the general business carryforwards under § 39 will be adjusted so as to recapture the portion of the credit which was not so allowed, and (C) the amount of the grant will be determined without regard to any reduction in the basis of any property of a character subject to an allowance for depreciation by reason of the credit.

(3) Section 48D(f)(3) of the Code provides that a grant made by the Secretary under section 9023(e) of the Affordable Care Act will not be includible in the gross income of the taxpayer.

(4) Section 9023(e)(5)(A) of the Affordable Care Act provides that in making grants, the Secretary will apply rules similar to the rules of § 50 of the Code. In applying such rules, any increase in tax under chapter 1 of the Code by reason of an investment ceasing to be a qualified investment will be imposed on the person to whom the grant was made.

(5) Section 9023(e)(5)(B)(i) of the Affordable Care Act provides that if the amount of the grant made under section 9023(e) exceeds the amount allowable as a grant, the excess must be recaptured under section 9023(e)(5)(A) as if the investment to which the excess portion of the grant related had ceased to be a qualified investment immediately after the grant was made.

(6) Section 9023(e)(5)(B)(ii) of the Affordable Care Act provides that in no event will the amount of a grant, the identity of the person to whom the grant was made, or a description of the investment with respect to which the grant was made be treated as return information for purposes of § 6103 of the Code.

(7) Section 9023(e)(6) of the Affordable Care Act provides that the Secretary will not make any grant to (A) any Federal, State, or local government (or any political subdivision, agency, or instrumentality thereof), (B) any organization described in § 501(c) of the Code and exempt from tax under § 501(a), (C) any entity referred to in § 54(j), or (D) any partnership or other pass-thru entity any partner (or other holder of an equity or profits interest) of which is described in section 9023(e)(6)(A) through (C). A partnership or pass-thru entity is not eligible for a grant if any direct or indirect partner (or other holder of an equity or profits interest) is described in section 9023(e)(6)(A) through (C). A partnership or other pass-thru entity must determine if any of its partners or other holders of any equity or profits interest is described in section 9023(e)(6)(A) through (C) before the partnership or the pass-thru entity may apply for a grant.

SECTION 9. SPECIAL RULES FOR CREDITS AND GRANTS IN LIEU OF TAX CREDITS

.01 Section 48D(e)(1) of the Code provides that if a credit is allowed for an expenditure related to property of a character subject to an allowance for depreciation, the basis of the property must be reduced by the amount of the credit.

.02 Section 48D(e)(2)(A) of the Code provides that a credit will not be allowed for any investment for which bonus depreciation is allowed under § 168(k), § 1400L(b)(1), or § 1400N(d)(1).

.03 Section 48D(e)(2)(B) of the Code provides that no deduction will be allowed for the portion of the expenses otherwise allowable as a deduction taken into account in determining the credit for the taxable year which is equal to the amount of the credit determined for the taxable year attributable to that portion. This rule does not apply to expenses related to property of a character subject to an allowance for depreciation the basis of which is reduced under § 48D(e)(1), or which are described in § 280C(g).

.04 Section 48D(e)(2)(C)(i) of the Code provides that, except as provided in § 48D(e)(2)(C)(ii), any expenses taken into account for a taxable year must not be taken into account for purposes of determining the credit allowable under § 41 or § 45C for the taxable year.

.05 Section 48D(e)(2)(C)(ii) of the Code provides that any expenses for any taxable year which are qualified research expenses (within the meaning of § 41(b)) must be taken into account in determining base period research expenses for purposes of applying § 41 to subsequent taxable years.

.06 Section 280C(g)(1) of the Code provides that, in general, no deduction will be allowed for that portion of the qualified investment (as defined in § 48D(b)) otherwise allowable as a deduction for the taxable year which (A) would be qualified research expenses (as defined in § 41(b)), basic research expenses (as defined in § 41(e)(2)), or qualified clinical testing expenses (as defined in § 45C(b)) if the credit under § 41 or § 45C were allowed with respect to the expenses for the taxable year, and (B) is equal to the amount of the credit determined for the taxable year under § 48D(a), reduced by (i) the amount disallowed as a deduction by reason of § 48D(e)(2)(B), and (ii) the amount of any basis reduction under § 48D(e)(1).

.07 Section 280C(g)(2) of the Code provides that, in the case of expenses described in § 280C(g)(1) taken into account in determining the credit under § 48D for the taxable year, if (A) the amount of the portion of the credit determined with respect to the expenses, exceeds (B) the amount allowable as a deduction for the taxable year for the expenses (determined without regard to § 280C(g)(1)), the amount chargeable to capital account for the taxable year for the expenses must be reduced by the amount of the excess.

.08 For controlled groups, § 280C(g)(3) of the Code provides that § 280C(b)(3) applies for purposes of § 280C(g).

.09 The rules under this section 9 apply to credits under § 48D of the Code and grants in lieu of tax credits.

SECTION 10. DISCLOSURE OF INFORMATION

.01 *Announcement*. Consistent with § 48D(d)(4) of the Code and section 9023(e)(5)(B)(ii) of the Affordable Care Act, the Service will, upon making a certification for credit or grant, publicly disclose the identity of the applicant and the amount of the credit or grant with respect to the applicant. In addition, upon making a certification with respect to taxpayers that have either elected to receive a grant for the 2009 tax year or provided the consent as provided in section 10.02 of this notice with respect to their application for credit, the Service will also publish the type and location of the project that is the subject of the application for § 48D qualifying therapeutic discovery project certification in the event the project receives an allocation.

.02 *Consent to disclosure of information concerning the allocation*. Section 48D(d)(4) of the Code provides that the Service will, upon making a certification, publicly disclose the identity of the applicant and the amount of the credit with respect to the applicant. Section 9023(e)(5)(B)(ii) of the Affordable Care Act provides that in no event will the amount of a grant, the identity of the person to whom the grant was made, or a description of the investment with respect to which the grant was made be treated as return information for purposes of § 6103. Thus, the statute authorizes public disclosure of more information for taxpayers awarded allocation for a grant than for taxpayers awarded allocation for a credit. In order to provide the public with the same information on taxpayers

who are allocated credits as receive grants, the Service is seeking authorization to publish the type of qualifying therapeutic discovery project that is the subject of the application for § 48D certification in those instances where disclosure of that information is not authorized by the statute. Therefore, the Service requests that each taxpayer that applies for a credit, or for a grant for a taxable year beginning in 2010, submit with the application for § 48D certification a declaration, consenting to the Service's disclosure of the type and location of the project that is the subject of the application for § 48D qualifying therapeutic discovery project certification in the event the project receives an allocation. To provide a valid consent, the declaration must be in the form set forth in Appendix B. A taxpayer is not required to provide a declaration consenting to disclosure of certain information in order to receive an allocation of the qualifying therapeutic discovery project credit. Nor is a declaration consenting to disclosure needed if the taxpayer elects to receive a grant for a taxable year beginning in 2009. The Service will not publish any return information with respect to applications that are not awarded an allocation of the qualifying therapeutic discovery project credit or grant.

.03 *FOIA Requests*. Anyone interested in submitting a request for records under the FOIA with respect to the qualifying therapeutic discovery project program under § 48D (including a request for records relating to the HHS recommendation) should direct a request that conforms to the Service's FOIA regulations, found at 26 C.F.R. § 601.702, to the following address:

IRS FOIA Request
HQ FOIA
Stop 211
2385 Chamblee Tucker Road
Chamblee, GA 30341

Except for the information the Service is authorized to make available to the public under § 48D(d)(4) of the Code, section 9023(e)(5)(B)(ii) of the Affordable Care Act, or pursuant to an applicant's consent, the Service expects that such information would be exempt from disclosure under one or more of the following Freedom of Information Act (FOIA) exemptions: 5 U.S.C. § 552(b)(3), in conjunction with § 6103 of the Code with respect to returns and return information, 5 U.S.C. § 552(b)(4) with respect to trade secret or other confidential commercial or financial information, 5 U.S.C. § 552(b)(5) with respect to predecisional and deliberative material, and 5 U.S.C. § 552(b)(6) with respect to personal information.

SECTION 11. EFFECTIVE DATE

This notice is effective May 21, 2010.

SECTION 12. PAPERWORK REDUCTION ACT

The collection of information contained in this notice has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (44 U.S.C. § 3507) under control number 1545–2175.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

The collections of information in this notice are in sections 5, 6, 7, 8, and Appendix A of this notice. Form 8942, *Application for Certification of Qualified Investments Eligible for Credits*, will be used to collect the information in sections 5, 6, 7, and 8. This information is required to obtain an allocation of qualifying therapeutic discovery project credit or grant. This information will be used by the Service to verify that the taxpayer is eligible for the qualifying therapeutic discovery project credit or grant. The collection of information is required to obtain benefit. The likely respondents are business or other for-profit institutions.

The estimated total annual reporting burden is 14,544 hours.

The estimated annual burden per respondent varies, depending on the individual circumstances, with an estimated average of 12 hours, 7 minutes. The estimated number of respondents is 1,200.

The estimated annual frequency of responses is on occasion.

Books or records relating to a collection of information must be retained as long as the contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by 26 U.S.C. § 6103.

SECTION 13. DRAFTING INFORMATION

The principal author of this notice is Julie Hanlon Bolton of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, contact Julie Hanlon Bolton at (202) 622–3040 (not a toll-free call). For further information regarding the application for certification, the documentation to be submitted to the Service establishing that the requirements of § 48D(d)(3) of the Code are satisfied, and the issuance of the certification that the requirements of § 48D(d)(3) are satisfied, contact Candace Fisher of the Small Business and Self-Employed Division at (651) 312–2109 (not a toll-free number) or by e-mail at *acasec9023@irs.gov*. For further information regarding the selection criteria for HHS' evaluation, contact JoAnne Goodnight at *QTDP@mail.nih.gov*.

APPENDIX A

APPLICATIONS FOR CERTIFICATION OF QUALIFIED INVESTMENTS ATTRIBUTABLE TO QUALIFYING THERAPEUTIC DISCOVERY PROJECTS

The Internal Revenue Service (Service), in consultation with the Department of Health and Human Services (HHS), will select for certification applications from eligible taxpayers under § 48D(c)(2) of the Internal Revenue Code (Code) for one or more projects that are qualifying therapeutic discovery projects under § 48D(c)(1) and that meet the selection criteria in § 48D(d)(3)(A) and (B).

This Appendix A:

1. Describes the content and format of information to be provided by an applicant for certification,
2. Provides the questions that must be answered in a Project Information Memorandum to be filed with the applicant's Form 8942, *"Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program,"* and
3. Identifies the evaluation criteria to be used by the Service and HHS in the review of applications for certification.

The Service and HHS reserve the right to request clarifications and/or supplemental information from some or all applicants through written submissions and/or oral presentations. No additional written submissions, or requests to make oral presentations, will be accepted if not explicitly solicited by the Service or HHS. It is expected that the Service and HHS will determine whether to approve an application at any time after the application has been received without any further exchanges or discussions with the applicant. Therefore, all applicants are advised to submit complete and fully responsive applications.

Applications will not be returned to applicants.

SUBMISSION INFORMATION FOR CERTIFICATION

A. General

A complete application for certification includes Form 8942, completed in accordance with instructions, an attached Project Information Memorandum as described below, and, if the applicant elects to consent to certain limited disclosure (see Section 10.2 of Notice 2010–45 (Notice)), a properly executed copy of the "Consent to Public Disclosure of Certain Qualifying Therapeutic Discovery Project Program Application Information" (Consent) contained in Appendix B to the Notice. A complete application must be submitted for each qualifying therapeutic discovery project that the applicant sponsors for which the applicant is requesting a credit or a grant. All applications shall be prepared in accordance with this Appendix A in order to provide a standard basis for review and to ensure that each application will be uniform as to format and content.

Each application should clearly respond to each question to demonstrate the applicant's capability, knowledge, and experience regarding the requirements addressed herein.

Applicants should fully address the requirements of the notice, including this Appendix A, and should **not** rely on the presumed background knowledge of reviewers. The Service and HHS may reject an application that does not follow the instructions regarding the organization and content of the application when the nature of the deviation and/or omission precludes complete or meaningful review of the application.

B. Unnecessarily Elaborate Applications

Brochures or other presentations are not permitted as part of the application and will not be considered.

C. Application Submission for Certification

An application for certification will not be considered in the primary allocation round for the taxpayer's 2009 and 2010 taxable years unless the application is filed by July 21, 2010. (See section 5.02(2) of the Notice.)

D. Final Application Content, Format, and Evaluation

This section describes the information to be submitted by the applicant for certification on Form 8942 and in the Project Information Memorandum.

Part I: Form 8942, Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program

The applicant must submit a Form 8942 in accordance with the instructions to the form. The Form 8942 will require the following information:

1. The applicant's general information, including the applicant's name, address and taxpayer identification number.

2. The name of a contact person for the applicant. The contact person is the person whom the Service or HHS may contact if there is an issue with the application. If the contact person does not have legal authority to bind the applicant, the applicant must attach to Form 8942 a properly executed power of attorney on Form 2848, *"Power of Attorney and Declaration of Representative."*

3. The type of entity of the applicant.

4. The ownership of the applicant.

5. The number of full-time and part-time employees employed by the applicant.

6. Whether the applicant is requesting a grant in lieu of a qualifying therapeutic discovery project credit.

7. A description of the applicant's qualified investments for 2009, 2010 or both, as applicable, and the amounts thereof. Such qualified investments may include expenses for wages, supplies and lab costs, depreciable property, contractor costs, and any other costs that would be considered part of the qualified investment for the project. (See section 4.01 of the Notice.)

8. The number of full-time and part-time employees in the United States whose work is directly billed to the project and the average salaries of the employees in each category. For this purpose, both actual employees of the applicant and leased employees may be included. The Service will review the information described in this paragraph 8 in order to determine (as described in section 5.01(3) of the Notice) which projects have the greatest potential to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States.

9 The number of contractors in the United States paid for work on the project, and the average monthly compensation and average monthly hours of the contractors. The Service will review the information described in this paragraph 9 in order to determine (as described in section 5.01(3) of the Notice) which projects have the greatest potential to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States.

10. Whether, as of the date on which the application is submitted, the project is active, terminated, or suspended and, if the project is terminated or suspended, whether this is because the project failed a clinical trial, failed a pre-clinical research milestone, or failed to secure FDA licensure. The Service will review the information described in this paragraph 10 in determining (as described in section 5.01(3) of the Notice) which projects have the greatest potential to advance United States competitiveness in the fields of life, biological, and medical sciences. A project that has been terminated or suspended because the project failed a clinical trial, failed a pre-clinical research milestone, or failed to secure FDA licensure will be determined to have insufficient potential to advance United States competitiveness in the fields of life, biological and medical sciences and thus will be determined to be ineligible for certification.

11. Whether the project:

a. Will produce a new or significantly improved technology, or a new application or significant improvement to existing technology, as compared to commercial technologies currently in service; and

b. Is expected to lead to the construction or use of a contract production facility in the United States in the next 5 years.

The Service will review the information described in this paragraph 11 in determining (as described in section 5.01(3) of the Notice) which projects have the greatest potential to advance United States competitiveness in the fields of life, biological, and medical sciences.

Form 8942 will also contain a Penalties of Perjury Statement. Each applicant must sign and date this statement. The person signing for the applicant must have personal knowledge of the facts. Further, the declaration must be signed by a person authorized to bind the applicant. The Penalties of Perjury statement is effective for ALL information submitted as a complete application.

Part II: Project Information Memorandum

HHS will review information provided by the applicant in the Project Information Memorandum in order to determine whether a project meets the definition of "qualifying therapeutic discovery project" and whether the applicant has demonstrated that its project shows a "reasonable potential" to meet one or more of the goals specified in the statute.

The Project Information Memorandum must follow the format specified herein. It must contain the questions specified and the answers as to which the applicant must check yes or no. The form also requires, as stated, that the applicant provide written narratives with respect to certain questions, including narratives supporting and explaining the basis for each yes answer. The statements included in the Project Information Memorandum shall not exceed the stated word limits. If statements exceed the stated word limits, words beyond those limits will not be considered. Statements that otherwise fail to comply with the instructions set out in the application will not be considered. All text shall be typed, single spaced, using 12 point font, 1 inch margins, and unreduced 8½ inch by 11 inch pages (A Project Information Memorandum that is submitted using the form provided on the IRS website will be deemed in compliance with spacing, font, margins, and page size requirements with regard to the information submitted on such form). All applications shall be legible. Pages shall be sequentially numbered and identified with the name of the applicant and the date. No material may be incorporated in any application by reference.

Note: **Any language beyond any word limits in the application will be disregarded for purposes of review.**

If elements of the Project Information Memorandum contain information the applicant considers to be trade secrets, confidential, privileged or otherwise exempt from disclosure under the Freedom of Information Act (FOIA, 5 U.S.C. 552), the applicant shall assert a claim of exemption at the time of application by placing the following text on the **first** page of the Project Information Memorandum, and specify the page or pages of the application to be restricted.

"The data contained in pages [ ] of this document which hereby forms a part of the application have been submitted in confidence and contain trade secrets or proprietary information, and such data shall be used or disclosed only for review purposes. This restriction does not limit the government's right to use or disclose data obtained without restriction from any source, including the applicant."

To further protect trade secret, confidential, privileged or otherwise exempt information, each line or paragraph on the page or pages containing such data must be specifically identified and marked with text that is similar to the following:

"The following contains proprietary information that [name of applicant] requests not to be released to persons outside of the Government, except for purposes of review."

Note: Any text used to protect confidentiality will not be counted against the total word limits of the Project Information Memorandum.

Project Information Memorandum

A. Provide an overview of the project for which you are seeking a credit or grant, including a description of the product, process or technology under development. The description may not exceed 250 words. If the project involves a new therapy, the description must include an explanation of why that therapy is novel.

B. Check each applicable box in the following and provide a short **(not more than 50 words)** statement supporting each positive assertion (*i.e.*, where "Yes" is checked). Check all that apply, but you need check only one Yes for answers 1 through 4 for initial qualification.

Qualifying Therapeutic Discovery Project definition

1. Is the project
   - designed to develop a product to treat or prevent a disease or condition;
   - by conducting pre-clinical activities, clinical trials, or clinical studies, or by carrying out research protocols; and
   - for the purpose of securing approval of a product under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act? ☐ Yes ☐ No

2. Is the project designed to diagnose a disease or condition? ☐ Yes ☐ No
3. Is the project designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions? ☐ Yes ☐ No
4. Is the project designed to develop a product, process, or technology to further the delivery or administration of therapeutics? ☐ Yes ☐ No

Selection criteria

5. Is the project likely to result in one or more new therapies? ☐ Yes ☐ No
6. If the answer to question 5 is Yes, are the new therapy(ies) expected to:
   a. treat areas of unmet medical need? ☐ Yes ☐ No
   b. prevent, detect, or treat chronic or acute diseases or conditions? ☐ Yes ☐ No

7. Is the project likely to reduce long-term health care costs in the United States? ☐ Yes ☐ No
8. Is the project likely to significantly advance the goal of curing cancer within the next 30 years? ☐ Yes ☐ No

For each of questions 9, 10, and 11, provide a short statement, not to exceed a total of 250 words, including responses to bulleted items. For question 9, applicants may also submit up to five literature citations in the specified format that will not be counted against the 250-word limit.

9. Explain the scientific rationale, based on prior conceptual and empirical work, which supports the belief that the proposed project will lead to the outcome the applicant has identified above. Explain the research and development plan that will lead

to the outcome identified above. Describe the scientific evidence relied on by the applicant, including a description of any peer review of the project and a list of no more than five literature citations using the following format:

- Include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication.
- When citing articles that were authored or co-authored by the applicant and arose from NIH support, if available, provide the NIH Manuscript Submission reference number (*e.g.*, NIHMS97531) or the Pubmed Central (PMC) reference number (*e.g.*, PMCID234567) for each citation.
- Citations for which an NIH Manuscript Submission reference number is not available but are publicly available in a free, online format should include URLs or PMCID numbers along with the full reference. The references should be limited to relevant and current literature.

10. Describe the stage of development of the project, including a description of pre-clinical and clinical trial results that are relevant to the proposal.

    - If the project involves the development of a product that is regulated by the Food and Drug Administration, an explanation of whether an investigational new drug application or an investigational device exemption has been filed with the Food and Drug Administration, and whether an application for approval, license, or clearance has been filed, and, if so, the status of that application as of the date of application as of the date this project information memorandum is submitted.
    - If the project involves testing in humans, information about the phase(s) of the testing that has been completed and the number of subjects tested in each phase and information about trials for which the applicant is actively recruiting subjects. Summarize the results of the trails, noting any failed trials or successful trials.
    - The planned research and development strategy for the test or treatment being researched and a summary schedule for development of the project, including timelines and milestones planned and completed.

11. Describe the resources, management experience and organizational capacity of the applicant and explain how applicant believes that such resources, experience and capacity will support successful completion of the project. Include in this description

    - A statement of the revenue levels and sources for this project over the past three years.
    - A statement of the revenue levels and sources for the proposed research and development plan delineated in response to question 10.
    - A description of any significant public or private investment, such as by venture capitalists, in the development or commercialization of the project.
    - A description of any strategic partnerships for the development or commercialization of the project.
    - A statement of whether the applicant has suspended operations for the project and, if so, whether the suspension is temporary or permanent. If the project has been suspended, terminate, or is otherwise inactive, explain why, including whether the cause is a lack of financial resources or other reasons.

Evaluation Criteria and Factors for the Project Information Memorandum

HHS will make the determination described in sections 5.01(1) and (2) of the Notice based on the information provided in the Project Information Memorandum and on the following eligibility and evaluation criteria and factors:

Definitions

A project that does not meet the definition of "qualifying therapeutic discovery project" will be found to be ineligible. A project that does not support an affirmative response to any of questions 1 – 4 does not meet the statutory definition of a qualifying therapeutic discovery project. The applicant must effectively support each yes answer through the accompanying narrative.

Question 1 focuses on the requirement of § 48D(c)(1)(A) of the Code. To satisfy this provision, the project must be designed to treat or prevent diseases or conditions. It must be designed to do so by conducting pre-clinical activities, clinical trials, or clinical studies or carrying out a clinical protocol. It must also be for the purpose of obtaining approval of a product under one of two statutory provisions—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (a new drug application) or Section 351(a) of the Public Health Service Act (PHSA) (a biologic license application) . For example, a medical countermeasure against a known threat or emerging infectious disease that is developed for the purpose of securing approval under one of these provisions would satisfy this provision.

Note that generic drugs, which are approved under Section 505(j) of the FFDCA, and biosimilar products, which are approved under Section 351(k) of the PHSA, would be excluded. Dietary supplements and most cosmetics would also be excluded because they are generally not the subject of a new drug or biologic license application.

Questions 2 and 3 focus on the requirements of § 48D(c)(1)(B) of the Code. This provision covers two separate categories of products. The first, covered by question 2, is a product to diagnose a disease or condition. Any product that diagnoses a disease or condition would meet this criterion, whether or not it determines molecular factors or is a molecular diagnostic. Relevant products would include point of care diagnostics for infectious agents.

Question 3 covers a product that determines molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions. This might include, for example, a test that would determine which patients with a particular disease or condition would be likely to respond best to a particular drug or device.

Question 4 focuses on the requirement of § 48D(c)(1)(C) of the Code. To qualify under question 4, a product, process, or technology must further the delivery or administration of therapeutics. For the purposes of § 48D(c)(1)(C), the term "therapeutics" means drugs or medical devices, as those terms are defined in Section 201(g) and (h) of the FFDCA, 21 U.S.C. 321(g) and (h). Biologics that are licensed under the PHSA will generally be either drugs or medical devices. Thus, a drug-eluting stent or infusion pump would be an example of a product that furthers the delivery or administration of a drug and would meet the requirements of this provision. However, a medical device, or other product, process or technology that does not further the delivery or administration of a drug or medical device would not meet the requirements of this provision because such products do not deliver or administer a therapeutic within the meaning of § 48D(c)(1)(C). The term "therapeutic" is narrower than the term "therapy," which appears elsewhere in section 48D. Therefore, products, processes or technologies that deliver other therapies which are not therapeutics, such as speech, physical, and cognitive therapies, would for the same reasons be excluded.

Reasonable potential selection criteria

If HHS determines that a project meets the definition of "qualifying therapeutic discovery project," HHS will proceed to determine whether the applicant has demonstrated, through responses to questions 5–11, that its project shows a reasonable potential to meet a statutory goal. This determination will be based on an evaluation of whether the project is designed to achieve one or more of the goals specified in section 48D and, if so, whether the applicant has shown a reasonable potential to achieve the goal(s). Specifically, the applicant must show that its project is designed to achieve one of the statutory goals by checking yes for one or more of the following:

- question 5 and question 6.a;
- question 5 and question 6.b;
- question 7; or
- question 8.

In addition, the applicant must effectively support each yes answer through the accompanying narrative.

Question 5 addresses the requirement of § 48D(d)(3)(A)(i) of the Code that, to satisfy the statutory goal of that provision, the project must be a "new therapy." Thus, the therapy must be novel and cannot be the same as, or difficult to meaningfully distinguish from, a therapy currently on the market. For example, this means the therapy should not be in the same class as existing therapies, unless such therapy is expected to offer a significant enhancement in safety or effectiveness. HHS will evaluate the information provided as to the novelty of the product based on the explanation provided with any Yes response to this question and the initial narrative description of the project (Section A of the Project Information Memorandum).

Question 6 addresses the requirement of § 48D(d)(3)(A)(i) of the Code that a new therapy either treats areas of unmet medical need, or prevents, detects, or treats chronic or acute diseases or conditions. For example, unmet medical needs would include novel influenza vaccine technologies, broad spectrum anti-viral medications, novel antibiotics, and platform vaccine technologies. In addition to new therapies that treat diseases and conditions, such products that detect or prevent diseases and conditions are also covered by this provision.

Question 7 addresses the requirement of § 48D(d)(3)(A)(ii) of the Code, which covers projects that will reduce long-term health care costs in the United States. The narrative accompanying any Yes response should explain how the project is likely to reduce health care costs, including a description of how the project will lead to actual cost reductions, not just substituting one cost for another and the basis of this determination. The narrative should provide a reasonable estimate of savings and demonstrate a reasonable potential to achieve these savings.

Question 8 addresses the requirement of § 48D(d)(3)(A)(iii) of the Code, which covers projects that will significantly advance the goal of curing cancer within the next 30 years.

If HHS determines that the applicant satisfies the requirements to which questions 5 through 8 are addressed, regarding the specific statutory selection criteria, HHS will proceed to review the responses to questions 9–11 and evaluate whether the information provided supports a determination that there is a reasonable potential that the project will achieve one or more of the statutory goals. HHS will make this determination based on an analysis of the scientific rationale for the project (question 9), the current stage of development of the project (question 10), and the evidence that the applicant has the capacity to bring the project to fruition (question 11). HHS will notify the Service of the results of the HHS evaluation as to whether the project is a qualifying therapeutic discovery project and shows a reasonable potential to achieve one or more of the statutory goals.

E. Certification

Only those qualifying therapeutic development projects that have both (a) a reasonable potential to achieve one or more of the statutory goals set forth in section 48D(d)(3)(A) as determined by HHS and (b) the greatest potential to (i) create and sustain (directly or indirectly) high quality, high-paying jobs in the United States, and (ii) advance United States competitiveness in the fields of life, biological, and medical sciences as determined by the Service will receive a certification for all or a portion of their qualified investment. The Service will certify an amount of qualified investment made by an eligible taxpayer for qualifying therapeutic development projects in accordance with the provisions of section 5.02(5) through (7) of the Notice.

APPENDIX B

CONSENT TO PUBLIC DISCLOSURE OF CERTAIN QUALIFYING THERAPEUTIC DISCOVERY PROJECT PROGRAM APPLICATION INFORMATION

In the event that the Application for § 48D Certification of [insert name of applicant-taxpayer here): _____] (the Applicant-Taxpayer) for an allocation of qualifying therapeutic discovery project credit under § 48D of the Internal Revenue Code is approved, the undersigned authorized representative of the Applicant-Taxpayer hereby consents to the disclosure by the Internal Revenue Service of the type of the project that is the subject of the Application for § 48D Certification. The undersigned understands that this information might be published, broadcast, discussed, or otherwise disseminated in the public record.

This authorization shall become effective upon the execution thereof. I certify that I have the authority to execute this consent to disclose on behalf of the taxpayer named below.

Date: _____ Signature: _____

Print name: _____

Title: _____

Name of Applicant-Taxpayer: _____

Taxpayer Identification Number: _____

Taxpayer's Address: _____

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26 CFR 601.602: Tax forms and instructions. (Also: Part 1, §§ 1, 223.)

Rev. Proc. 2010–22

SECTION 1. PURPOSE

This revenue procedure provides the 2011 inflation adjusted amounts for Health Savings Accounts (HSAs) as determined under § 223 of the Internal Revenue Code. The amounts for 2011 are unchanged from the amounts for 2010 because, after the application of the cost-of-living adjustment rules of § 223(g) (including the rounding rule of § 223(g)(2)), the changes in the Consumer Price Index for the relevant period do not result in changes to the amounts for 2011.

SECTION 2. 2011 INFLATION ADJUSTED ITEMS

Annual contribution limitation. For calendar year 2011, the annual limitation on deductions under § 223(b)(2)(A) for an individual with self-only coverage under a high deductible health plan is $3,050. For calendar year 2011, the annual limitation on deductions under § 223(b)(2)(B) for an individual with family coverage under a high deductible health plan is $6,150.

High deductible health plan. For calendar year 2011, a "high deductible health plan" is defined under § 223(c)(2)(A) as a health plan with an annual deductible that is not less than $1,200 for self-only coverage or $2,400 for family coverage, and the annual out-of-pocket expenses (deductibles, co-payments, and other amounts, but not premiums) do not exceed $5,950 for self-only coverage or $11,900 for family coverage.

SECTION 3. EFFECTIVE DATE

This revenue procedure is effective for calendar year 2011.

SECTION 4. DRAFTING INFORMATION

The principal author of this revenue procedure is Frank W. Dunham III of the Office of Associate Chief Counsel (Income Tax & Accounting). For further information regarding § 223 and HSAs, contact Leslie Paul at (202) 622–6080 (not a toll-free call). For further information regarding the calculation of the inflation adjustments in this revenue procedure, contact Mr. Dunham at (202) 622–4920 (not a toll-free call).