Internal Revenue
bulletin

Bulletin No. 2009-48
November 30, 2009

HIGHLIGHTS OF THIS ISSUE

These synopses are intended only as aids to the reader in identifying the subject matter covered. They may not be relied upon as authoritative interpretations.

INCOME TAX

T.D. 9469, page 687.

Final regulations under section 108 of the Code provide guidance on the manner in which an S corporation reduces its tax attributes under section 108(b) for taxable years in which the S corporation has discharge of indebtedness income that is excluded from gross income under section 108(a).

Notice 2009–89, page 714.

This notice sets forth a process that allows manufactures to certify to the Service that a particular vehicle meets the requirements of section 30D of the Code. Taxpayers purchasing such vehicles can rely on the domestic manufacturer's (or, in the case of a foreign manufacturer, its domestic distributor's) certification that a particular make, model, and model year of vehicle qualifies as a plug-in electric drive motor vehicle under section 30D, and certification of the amount of the credit allowable with respect to the vehicle. The notice also defines when the amended section 30D applies. Notices 2009–54 and 2009–58 amplified.

EMPLOYEE PLANS

T.D. 9464, page 692.
REG–123829–08, page 719.

Final, temporary, and proposed regulations under section 9802 of the Code provide guidance on the requirements that group health plans not charge higher rates based on genetic information, not request or require individuals to undergo genetic tests, and not collect or use genetic information for underwriting purposes.

Announcement 2009–82, page 720.

Effective date of regulations under section 411(b)(5)(B)(i); relief under section 411(d)(6); and notice to pension plan participants. The Treasury Department and the Service are announcing relief for sponsors of statutory hybrid plans that must amend the interest crediting rate in those plans. Plan sponsors may rely on this announcement pending publication of the anticipated additional guidance described in the announcement.

EMPLOYMENT TAX

Notice 2009–91, page 717.

This notice modifies the rules in Notice 2005–76, 2005–2 C.B. 947, for determining the amount of income tax employers must withhold under section 3402 from wages paid on or after January 1, 2010, for services performed by nonresident alien employees within the United States. Notice 2005–76 modified.

EXCISE TAX

T.D. 9464, page 692.
REG–123829–08, page 719.

Final, temporary, and proposed regulations under section 9802 of the Code provide guidance on the requirements that group health plans not charge higher rates based on genetic information, not request or require individuals to undergo genetic tests, and not collect or use genetic information for underwriting purposes.

Finding Lists begin on page ii.
Index for July through November begins on page iv.

Department of the Treasury
Internal Revenue Service

The IRS Mission

Provide America's taxpayers top quality service by helping them understand and meet their tax responsibilities and by applying the tax law with integrity and fairness to all.

Introduction

The Internal Revenue Bulletin is the authoritative instrument of the Commissioner of Internal Revenue for announcing official rulings and procedures of the Internal Revenue Service and for publishing Treasury Decisions, Executive Orders, Tax Conventions, legislation, court decisions, and other items of general interest. It is published weekly and may be obtained from the Superintendent of Documents on a subscription basis. Bulletin contents are compiled semiannually into Cumulative Bulletins, which are sold on a single-copy basis.

It is the policy of the Service to publish in the Bulletin all substantive rulings necessary to promote a uniform application of the tax laws, including all rulings that supersede, revoke, modify, or amend any of those previously published in the Bulletin. All published rulings apply retroactively unless otherwise indicated. Procedures relating solely to matters of internal management are not published; however, statements of internal practices and procedures that affect the rights and duties of taxpayers are published.

Revenue rulings represent the conclusions of the Service on the application of the law to the pivotal facts stated in the revenue ruling. In those based on positions taken in rulings to taxpayers or technical advice to Service field offices, identifying details and information of a confidential nature are deleted to prevent unwarranted invasions of privacy and to comply with statutory requirements.

Rulings and procedures reported in the Bulletin do not have the force and effect of Treasury Department Regulations, but they may be used as precedents. Unpublished rulings will not be relied on, used, or cited as precedents by Service personnel in the disposition of other cases. In applying published rulings and procedures, the effect of subsequent legislation, regulations, court decisions, rulings, and procedures must be considered, and Service personnel and others concerned are cautioned against reaching the same conclusions in other cases unless the facts and circumstances are substantially the same.

The Bulletin is divided into four parts as follows:

Part I.—1986 Code.
This part includes rulings and decisions based on provisions of the Internal Revenue Code of 1986.

Part II.—Treaties and Tax Legislation.
This part is divided into two subparts as follows: Subpart A, Tax Conventions and Other Related Items, and Subpart B, Legislation and Related Committee Reports.

Part III.—Administrative, Procedural, and Miscellaneous.
To the extent practicable, pertinent cross references to these subjects are contained in the other Parts and Subparts. Also included in this part are Bank Secrecy Act Administrative Rulings. Bank Secrecy Act Administrative Rulings are issued by the Department of the Treasury's Office of the Assistant Secretary (Enforcement).

Part IV.—Items of General Interest.
This part includes notices of proposed rulemakings, disbarment and suspension lists, and announcements.

The last Bulletin for each month includes a cumulative index for the matters published during the preceding months. These monthly indexes are cumulated on a semiannual basis, and are published in the last Bulletin of each semiannual period.

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Part I. Rulings and Decisions Under the Internal Revenue Code of 1986

Section 108.—Income From Discharge of Indebtedness

26 CFR 1.108–7: Reduction of attributes.

T.D. 9469

DEPARTMENT OF THE TREASURY
Internal Revenue Service
26 CFR Parts 1 and 602

Section 108 Reduction of Tax Attributes for S Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance on the manner in which an S corporation reduces its tax attributes under section 108(b) for taxable years in which the S corporation has discharge of indebtedness income that is excluded from gross income under section 108(a). In particular, the regulations address situations in which the aggregate amount of the shareholders' disallowed section 1366(d) losses and deductions that are treated as a net operating loss tax attribute of the S corporation exceeds the amount of the S corporation's excluded discharge of indebtedness income. The regulations affect S corporations and their shareholders.

DATES: *Effective Date:* These regulations are effective on October 30, 2009.

Applicability Date: For dates of applicability, see §1.108–7(f)(2).

FOR FURTHER INFORMATION CONTACT: Jennifer N. Keeney, (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations were previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–2155. The collections of information in this final regulation are in §1.108–7(d)(4). This information must be provided by S corporations that exclude discharge of indebtedness income from gross income under section 108(a) and shareholders of those S corporations. The information provided by shareholders will be used by S corporations to properly reduce their tax attributes under section 108(b). The information provided by S corporations will be used by shareholders of those S corporations to calculate their taxable income in succeeding taxable years.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their 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.

Background

This document contains amendments to the Income Tax Regulations (26 CFR Part 1) under section 108 of the Internal Revenue Code (Code).

Section 61(a) provides that *gross income* means all income from whatever source derived, including (but not limited to) income from discharge of indebtedness, also known as cancellation of debt income (COD income). Section 108(a) provides an exclusion from gross income for COD income if the discharge occurs while the taxpayer is bankrupt or insolvent, or if the indebtedness discharged is qualified farm indebtedness, certain qualified real property business indebtedness, or certain qualified principal residence indebtedness. In the case of a discharge of indebtedness during insolvency, the exclusion from income is limited to the amount by which the taxpayer is insolvent. Section 108(b) provides that the taxpayer must reduce certain specified tax attributes to the extent COD income is excluded from gross income under section 108(a)(1)(A), (B), or (C). Section 108(b) also provides the order in which these tax attributes must be reduced. Unless the taxpayer makes an election under section 108(b)(5) to first reduce the basis of depreciable property, section 108(b)(2)(A) provides that the first tax attribute to be reduced is any net operating loss for the taxable year of the discharge, and any net operating loss carryover to such taxable year.

A notice of proposed rulemaking and a notice of public hearing (REG–102822–08, 2008–38 I.R.B. 744) were published in the **Federal Register** (73 FR 45656) on August 6, 2008, proposing amendments to the regulations regarding the manner in which an S corporation reduces its tax attributes under section 108(b) for taxable years in which the S corporation has discharge of indebtedness income that is excluded from gross income under section 108(a). A public hearing on the proposed regulations was scheduled for December 8, 2008, but was cancelled because no one requested to speak. However, comments responding to the proposed regulations were received. After consideration of these comments, the proposed regulations are adopted as revised by this Treasury decision. These final regulations generally retain the provisions of the proposed regulations, with the modifications discussed in this preamble.

Summary of Comments and Explanation of Revisions

A. *Allocation of Excess Losses and Deductions After Section 108(b) Tax Attribute Reduction*

Section 108 provides special rules for an S corporation that has COD income. Section 108(d)(7)(A), as amended by the Job Creation and Worker Assistance Act of 2002, Public Law 107–147, provides, in part, that the rules under section 108(a) for the exclusion of COD income and under section 108(b) for the reduction of tax attributes are applied at the corporate level, including by not taking into account under section 1366(a) any amount excluded

under section 108(a). Therefore, if an S corporation excludes COD income from its gross income under section 108(a), the amount excluded is applied to reduce the S corporation's tax attributes under section 108(b)(2). Under section 108(b)(4)(A), the reduction of tax attributes occurs after the S corporation's items of income, loss, deduction and credit for the taxable year of the discharge pass through to its shareholders under section 1366(a). Under section 1366(d)(1), the aggregate amount of losses and deductions a shareholder can take into account under section 1366(a) cannot exceed the shareholder's adjusted basis in the shareholder's stock in the S corporation and the shareholder's adjusted basis of any indebtedness of the S corporation to the shareholder. For purposes of the tax attribute reduction rule under section 108(b)(2), section 108(d)(7)(B) provides that any loss or deduction that is disallowed for the taxable year of the discharge under section 1366(d)(1) is treated as a net operating loss of the S corporation (deemed NOL).

Several commentators recommended that net operating losses of an S corporation carried forward from one or more C corporation taxable years (C Year NOLs) should be considered S corporation tax attributes for purposes of section 108(b)(2). The proposed regulations are silent on whether attributes such as net operating losses, capital losses, and business credits arising in a C corporation taxable year should be considered tax attributes of the S corporation for purposes of section 108(b)(2). Section 1371(b)(1) states that no carryforward, and no carryback, arising for a taxable year for which a corporation is a C corporation may be carried to a taxable year for which such corporation is an S corporation. This prohibition applies to tax attribute carryovers described in section 108(b)(2). For example, section 108(b)(2)(A) describes a net operating loss tax attribute as "any net operating loss for the taxable year of discharge and any net operating loss carryover to such taxable year." Accordingly, section 1371(b)(1) prohibits an S corporation from using a C Year NOL as an S corporation tax attribute for purposes of section 108(b)(2). The same analysis applies to capital losses and business credits that arose in a C corporation taxable year. Therefore, the final regulations do not adopt this recommendation.

One commentator suggested that the final regulations clarify how the allocation rules in §1.108–7(d)(2) of the proposed regulations apply when an S corporation, with the consent of all affected shareholders, makes an election under section 1377(a)(2) (a terminating election). Regardless of whether a terminating election is made, all disallowed losses and deductions of a shareholder under section 1366(d)(1), including disallowed losses and deductions of a terminating shareholder, are treated as an S corporation's deemed NOL. The impact of a terminating election on the allocation of the COD income, however, may result in a different allocation of the S corporation's excess deemed NOL among the shareholders. Therefore, the final regulations add an example to clarify how the allocation rules apply when a terminating election is made.

Commentators asked whether a deemed NOL described in section 108(d)(7)(B) includes any losses that are suspended under section 465 or section 469. Section 108(d)(7)(B) provides that a deemed NOL is any loss or deduction which is disallowed for the taxable year of the discharge under section 1366(d)(1). Section 1366(d)(1) specifically provides for the disallowance of losses due only to lack of basis. Therefore, a deemed NOL does not include losses suspended under section 465 or section 469.

One commentator requested that the final regulations clarify whether disallowed losses and deductions under section 1366(d)(1) of a shareholder that is an employee stock ownership plan (ESOP) are included in the S corporation's deemed NOL. Section 108(d)(7)(B) provides that any loss or deduction that is disallowed for the taxable year of the discharge under section 1366(d)(1) is treated as a deemed NOL of the S corporation. Accordingly, section 108(d)(7)(B) applies to any shareholder, including an ESOP shareholder, that has disallowed losses and deductions for the taxable year of the discharge under section 1366(d)(1).

One commentator asked whether nondeductible, noncapital expenses that reduce basis under section 1367(a)(2)(D) are treated as disallowed losses and deductions under section 1366(d)(1) for purposes of section 108(d)(7)(B). These expenses, including any that are carried over as a result of the elective ordering rule in §1.1367–1(g) of the Income Tax Regulations, are not losses and deductions that can be taken into account by a shareholder under section 1366(a) and therefore are not included as disallowed losses and deductions under section 1366(d)(1) for purposes of section 108(d)(7)(B).

One commentator noted that in some situations, an S corporation shareholder may have a different taxable year than the S corporation. The commentator asked whether, in these situations, a shareholder determines its disallowed losses and deductions under section 1366(d)(1) for purposes of section 108(d)(7) as of the close of the S corporation's taxable year. The basis adjustments under section 1367 are determined as of the close of the S corporation's taxable year. See §1.1367–1(d)(1) and §1.1367–2(d)(1). Therefore, a shareholder's disallowed losses and deductions under section 1366(d)(1) are determined for purposes of section 108(d)(7) as of the close of the S corporation's taxable year.

Finally, one commentator recommended that the final regulations provide that all shareholders share tax attribute reductions in proportion to their ownership interests in the S corporation in all situations. The preamble to the proposed regulations noted that shareholders may be disproportionately impacted where the shareholders' respective disallowed losses or deductions are disproportionate to their respective interests. However, the disproportionate impact that occurs in certain situations is a result of the statutory provisions of section 108. Therefore, the final regulations do not adopt this recommendation. In certain situations, an S corporation may eliminate or mitigate inequitable results by making an election under section 108(b)(5) to reduce the basis of its depreciable property before reducing its net operating loss.

B. *Character of Excess Deemed NOL Allocated to a Shareholder*

The proposed regulations provide an ordering approach for determining the character of the amount of the S corporation's excess deemed NOL that is allocated to a shareholder. The approach in the proposed regulations is generally consistent

with the ordering rules of section 108(b)(2) in that ordinary losses are reduced before capital losses. One commentator recommended that the final regulations adopt an approach that is consistent with the method for determining the character of a shareholder's losses and deductions under section 1366(d). Under this approach, the S corporation's excess deemed NOL that is allocated to a shareholder consists of a proportionate amount of each item of the shareholder's loss or deduction that is disallowed for the taxable year of the discharge under section 1366(d)(1). After considering this comment, the IRS and Treasury have decided to adopt this approach in the final regulations.

C. *Information Sharing Requirements*

The proposed regulations require a shareholder of an S corporation that excludes COD income from its gross income in a taxable year to report to the S corporation the amount of the shareholder's losses and deductions that are disallowed for the taxable year of the discharge under section 1366(d)(1) (shareholder-information reporting requirement). The proposed regulations also require the S corporation to report to its shareholders the amount of any excess deemed NOL that is allocated to a shareholder (S corporation-information reporting requirement). Commentators recommended changes to the shareholder-information reporting requirement to minimize dependence on information furnished by shareholders who provide (intentionally or unintentionally) incorrect information or on shareholders who fail to furnish this information. One commentator explained that as a practical matter, an S corporation often maintains records for its shareholders and may possess all the requisite information to determine the amount of a shareholder's suspended loss under section 1366(d). Another commentator requested that the final regulations provide consequences for shareholders who do not comply with the shareholder-information reporting requirement or who provide incorrect information.

After considering these comments, the final regulations modify the shareholder-information reporting requirement to alleviate the dependence on shareholders who fail to furnish information or who provide incorrect information. The final regulations provide that in certain situations, the S corporation may rely on its own books and records as well as other information available to the S corporation to determine a shareholder's disallowed losses or deductions under section 1366(d)(1), provided that the S corporation knows that the amount reported by the shareholder is inaccurate, or the information, as provided, appears to be incomplete or incorrect. The final regulations do not adopt any special rules to provide for consequences to shareholders who either fail to report this information to the S corporation or report incorrect information to the S corporation. However, the IRS and Treasury note that section 6037(c) requires that a shareholder of an S corporation, on the shareholder's return, treat a "subchapter S item" in a manner consistent with the S corporation return. The IRS and Treasury believe that the S corporation's excess deemed NOL that is allocated to a shareholder is a "subchapter S item" for purposes of section 6037(c) and that the consequences of failure to comply with section 6037(c) are sufficient to encourage shareholders to cooperate with the S corporation in order to avoid inconsistencies between the S corporation's return and the shareholder's return.

Effective/Applicability Date

The final regulations apply to discharges of indebtedness occurring on or after October 30, 2009.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information contained in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the collection burden imposed on S corporations and their shareholders is minimal in that it requires S corporations and their shareholder(s) to share information that shareholders already maintain to determine their respective tax liabilities. Moreover, it should take an S corporation or a shareholder no more than one hour to satisfy the information sharing requirements in these regulations. Finally, the collection burden imposed applies only to S corporations that are required to reduce their tax attributes under section 108(b) of the Code — a group estimated to be less than 1 percent of all existing S corporations. Therefore, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking that preceded these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Jennifer N. Keeney, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury participated in their development. Reporting and recordkeeping requirements.

* * * * *

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 and part 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.108–7 is amended by:

1. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively.

2. Adding new paragraph (d).

3. Adding paragraph (e) *Example 5*, *Example 6*, and *Example 7* to newly-redesignated paragraph (e).

4. Revising newly-redesignated paragraph (f).

The additions and revision read as follows:

§1.108–7 Reduction of attributes.

* * * * *

(d) *Special rules for S corporations*—(1) *In general*. If an S corporation excludes COD income from gross income under section 108(a)(1)(A), (B), or (C), the amount excluded shall be applied to reduce the S corporation's tax attributes under paragraph (a)(1) of this section. For purposes of paragraph (a)(1)(i) of this section, the aggregate amount of the shareholders' losses or deductions that are disallowed for the taxable year of the discharge under section 1366(d)(1), including disallowed losses or deductions of a shareholder that transfers all of the shareholder's stock in the S corporation during the taxable year of the discharge, is treated as the net operating loss tax attribute (deemed NOL) of the S corporation for the taxable year of the discharge.

(2) *Allocation of excess losses or deductions*—(i) *In general*. If the amount of an S corporation's deemed NOL exceeds the amount of the S corporation's COD income that is excluded from gross income under section 108(a)(1)(A), (B), or (C), the excess deemed NOL shall be allocated to the shareholder or shareholders of the S corporation as a loss or deduction that is disallowed under section 1366(d) for the taxable year of the discharge.

(ii) *Multiple shareholders*—(A) *In general*. If an S corporation has multiple shareholders, to determine the amount of the S corporation's excess deemed NOL to be allocated to each shareholder under paragraph (d)(2)(i) of this section, calculate with respect to each shareholder the shareholder's excess amount. The shareholder's excess amount is the amount (if any) by which the shareholder's losses or deductions disallowed under section 1366(d)(1) (before any reduction under paragraph (a)(1) of this section) exceed the amount of COD income that would have been taken into account by that shareholder under section 1366(a) had the COD income not been excluded under section 108(a).

(B) *Shareholders with a shareholder's excess amount*. Each shareholder that has a shareholder's excess amount, as determined under paragraph (d)(2)(ii)(A) of this section, is allocated an amount equal to the S corporation's excess deemed NOL multiplied by a fraction, the numerator of which is the shareholder's excess amount and the denominator of which is the sum of all shareholders' excess amounts.

(C) *Shareholders with no shareholder's excess amount*. If a shareholder does not have a shareholder's excess amount as determined in paragraph (d)(2)(ii)(A) of this section, none of the S corporation's excess deemed NOL shall be allocated to that shareholder.

(iii) *Terminating shareholder*. Any amount of the S corporation's excess deemed NOL allocated under paragraph (d)(2) of this section to a shareholder that had transferred all of the shareholder's stock in the corporation during the taxable year of the discharge is permanently disallowed under §1.1366–2(a)(5), unless the transfer of stock is described in section 1041(a). If the transfer of stock is described in section 1041(a), the amount of the S corporation's excess deemed NOL allocated to the transferor under paragraph (d)(2) of this section shall be treated as a loss or deduction incurred by the corporation in the succeeding taxable year with respect to the transferee. See section 1366(d)(2)(B).

(3) *Character of excess losses or deductions allocated to a shareholder*. The character of an S corporation's excess deemed NOL that is allocated to a shareholder under paragraph (d)(2) of this section consists of a proportionate amount of each item of the shareholder's loss or deduction that is disallowed for the taxable year of the discharge under section 1366(d)(1).

(4) *Information requirements*. If an S corporation excludes COD income from gross income under section 108(a) for a taxable year, each shareholder of the S corporation during the taxable year of the discharge must report to the S corporation the amount of the shareholder's losses and deductions that are disallowed for the taxable year of the discharge under section 1366(d)(1), even if that amount is zero. If a shareholder fails to report the amount of the shareholder's losses and deductions that are disallowed for the taxable year of the discharge under section 1366(d)(1) to the S corporation, or if the S corporation knows that the amount reported by the shareholder is inaccurate, or if the information, as reported, appears to be incomplete or incorrect, the S corporation may rely on its own books and records, as well as other information available to the S corporation, to determine the amount of the shareholder's losses and deductions that are disallowed for the taxable year of the discharge under section 1366(d)(1), provided that the S corporation knows or reasonably believes that its information presents an accurate reflection of the shareholder's disallowed losses and deductions under section 1366(d)(1). The S corporation must report to each shareholder the amount of the S corporation's excess deemed NOL that is allocated to that shareholder under paragraph (d)(2) of this section, even if that amount is zero, in accordance with applicable forms and instructions.

(e) * * *

Example 5. (i) *Facts*. During the entire calendar year 2009, A, B, and C each own equal shares of stock in X, a calendar year S corporation. As of December 31, 2009, A, B, and C each have a zero stock basis and X does not have any indebtedness to A, B, or C. For the 2009 taxable year, X excludes from gross income $45,000 of COD income under section 108(a)(1)(A). The COD income (had it not been excluded) would have been allocated $15,000 to A, $15,000 to B, and $15,000 to C under section 1366(a). For the 2009 taxable year, X has $30,000 of losses and deductions that X passes through *pro rata* to A, B, and C in the amount of $10,000 each. The losses and deductions that pass through to A, B, and C are disallowed under section 1366(d)(1). In addition, B has $10,000 of section 1366(d) losses from prior years and C has $20,000 of section 1366(d) losses from prior years. A's ($10,000), B's ($20,000) and C's ($30,000) combined $60,000 of disallowed losses and deductions for the taxable year of the discharge are treated as a current year net operating loss tax attribute of X under section 108(d)(7)(B) (deemed NOL) for purposes of the section 108(b) reduction of tax attributes.

(ii) *Allocation*. Under section 108(b)(2)(A), X's $45,000 of excluded COD income reduces the $60,000 deemed NOL to $15,000. Therefore, X has a $15,000 excess net operating loss (excess deemed NOL) to allocate to its shareholders. Under paragraph (d)(2)(ii)(C) of this section, none of the $15,000 excess deemed NOL is allocated to A because A's section 1366(d) losses and deductions immediately prior to the section 108(b)(2)(A) reduction ($10,000) do not exceed A's share of the excluded COD income for 2008 ($15,000). Thus, A has no shareholder's excess amount. Each of B's and C's respective section 1366(d) losses and deductions immediately prior to the section 108(b)(2)(A) reduction exceed each of B's and C's respective shares of the excluded COD income for 2008. B's excess amount is $5,000 ($20,000 - $15,000) and C's excess amount is $15,000 ($30,000 - $15,000). Therefore, the total of all shareholders' excess amounts is $20,000. Under paragraph (d)(2) of this section, X will allocate $3,750 of the $15,000 excess deemed NOL to B ($15,000 x $5,000 / $20,000) and $11,250 of the $15,000 excess deemed NOL to C ($15,000 x $15,000 / $20,000). These amounts are treated as losses and deductions disallowed under section 1366(d)(1) for the taxable year of the discharge. Accordingly, at the beginning of 2010, A has no section

1366(d)(2) carryovers, B has $3,750 of carryovers, and C has $11,250 of carryovers.

(iii) *Character*. Immediately prior to the section 108(b)(2)(A) reduction, B's $20,000 of section 1366(d) losses and deductions consisted of $8,000 of long-term capital losses, $7,000 of section 1231 losses, and $5,000 of ordinary losses. After the section 108(b)(2)(A) tax attribute reduction, X will allocate $3,750 of the excess deemed NOL to B. Under paragraph (d)(3) of this section, the $3,750 excess deemed NOL allocated to B consists of $1,500 of long-term capital losses (($8,000 / $20,000) x $3,750), $1,312.50 of section 1231 losses (($7,000 / $20,000) x $3,750), and $937.50 of ordinary losses (($5,000 / $20,000) x $3,750). As a result, at the beginning of 2010, B's $3,750 of section 1366(d)(2) carryovers consist of $1,500 of long-term capital losses, $1,312.50 of section 1231 losses, and $937.50 of ordinary losses.

Example 6. (i) A and B each own 50 percent of the shares of stock in X, a calendar year S corporation. On March 1, 2009, X realizes $12,000 of COD income and excludes this amount from gross income under section 108(a)(1)(A) for X's 2009 taxable year. On June 30, 2009, A sells all of her shares of stock in X to C in a transfer not described in section 1041(a). X does not make a terminating election under section 1377(a)(2). The COD income (had it not been excluded) would have been allocated $3,000 to A, $6,000 to B, and $3,000 to C under section 1366(a). Prior to the section 108(b)(2)(A) reduction, for the taxable year of the discharge the shareholders have disallowed losses and deductions under section 1366(d) (including disallowed losses carried over to the current year under section 1366(d)(2)) in the following amounts: A - $5,000, B - $13,000, and C - $2,000. The combined $20,000 of disallowed losses and deductions for the taxable year of the discharge are treated as a current year net operating loss tax attribute of X under section 108(d)(7)(B) (deemed NOL).

(ii) Under section 108(b)(2)(A), X's $12,000 of excluded COD income reduces the $20,000 deemed NOL to $8,000. Therefore, X has an $8,000 excess net operating loss (excess deemed NOL) to allocate to its shareholders. Under paragraph (d)(2)(ii)(C) of this section, none of the $8,000 excess deemed NOL is allocated to C because C's section 1366(d) losses and deductions immediately prior to the section 108(b)(2)(A) reduction ($2,000) do not exceed C's share of the excluded COD income for 2008 ($3,000). However, each of A's and B's respective section 1366(d) losses and deductions immediately prior to the section 108(b)(2)(A) reduction exceed each of A's and B's respective shares of the excluded COD income for 2009. A's excess amount is $2,000 ($5,000 - $3,000) and B's excess amount is $7,000 ($13,000 - $6,000). Therefore, the total of all shareholders' excess amounts is $9,000. Under paragraph (d)(2) of this section, X will allocate $1,777.78 of the $8,000 excess deemed NOL to A ($8,000 x $2,000 / $9,000) and $6,222.22 of the $8,000 excess deemed NOL to B ($8,000 x $7,000 / $9,000). However, because A transferred all of her shares of stock in X in a transaction not described in section 1041(a), A's $1,777.78 of section 1366(d) losses and deductions are permanently disallowed under paragraph (d)(2)(iii) of this section. Accordingly, at the beginning of 2010, B has $6,222.22 of section 1366(d)(2) carryovers and C has no section 1366(d)(2) carryovers.

Example 7. The facts are the same as in *Example 6*, except that X, with the consent of A and C, makes a terminating election under section 1377(a)(2) upon A's sale of her stock in X to C. Therefore, the COD income (had it not been excluded) would have been allocated $6,000 to A, $6,000 to B, and $0 to C. Under paragraph (d)(2)(ii)(C) of this section, none of the $8,000 excess deemed NOL is allocated to A because A's section 1366(d) losses and deductions immediately prior to the section 108(b)(2)(A) reduction ($5,000) do not exceed A's share of the excluded COD income for 2009 ($6,000). However, each of B's and C's respective section 1366(d) losses and deductions immediately prior to the section 108(b)(2)(A) reduction exceed each of B's and C's respective shares of the excluded COD income for 2009. B's excess amount is $7,000 ($13,000 - $6,000), C's excess amount is $2,000 ($2,000 - $0). Therefore, the total of all shareholders' excess amounts is $9,000. Under paragraph (d)(2) of this section, X will allocate $6,222.22 of the $8,000 excess deemed NOL to B ($8,000 x $7,000 / $9,000) and $1,777.78 of the $8,000 excess deemed NOL to C. Accordingly, at the beginning of 2010, B has $6,222.22 of section 1366(d)(2) carryovers and C has $1,777.78 of section 1366(d)(2) carryovers.

(f) *Effective/applicability date*—(1) Paragraphs (a), (b), (c), and *Examples 1*, *2*, *3*, and *4* of paragraph (e) of this section apply to discharges of indebtedness occurring on or after May 10, 2004.

(2) Paragraph (d) and *Examples 5*, *6*, and *7* of paragraph (e) of this section apply to discharges of indebtedness occurring on or after October 30, 2009.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 3. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 4. In §602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

§602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.108–7	1545–2155
* * * * *	

Linda E. Stiff,
Deputy Commissioner for Services and Enforcement.

Michael Mundaca,
Acting Assistant Secretary of the Treasury (Tax Policy).

(Filed by the Office of the Federal Register on October 29, 2009, 8:45 a.m., and published in the issue of the Federal Register for October 30, 2009, 74 F.R. 56109)

Approved October 21, 2009.

Section 9802.—Prohibiting Discrimination Against Individual Participants and Beneficiaries Based on Health Status

26 CFR 54.9802–1: Prohibiting discrimination against participants and beneficiaries based on a health factor.

T.D. 9464

DEPARTMENT OF THE TREASURY
Internal Revenue Service
26 CFR Part 54

DEPARTMENT OF LABOR
Employee Benefits Security Administration
29 CFR Part 2590

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
45 CFR Parts 144, 146, and 148

Interim Final Rules for Sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008. These provisions prohibit discrimination based on genetic information in health insurance coverage and group health plans.

DATES: *Effective date:* These interim final regulations are effective December 7, 2009.

Comment date. Comments are due on or before January 5, 2010.

Applicability dates: Group market rules. These interim final regulations for the group market apply to group health plans and group health insurance issuers for plan years beginning on or after December 7, 2009.

Individual market rules. These interim final regulations for the individual market apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210–AB27, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Email*: *E-OHPSCA.EBSA@dol.gov*.
- *Mail or Hand Delivery*: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, *Attention*: RIN 1210–AB27.

Comments received by the Department of Labor will be posted without change to *www.regulations.gov* and *www.dol.gov/ebsa*, and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210, including any personal information provided.

Department of Health and Human Services (HHS). Comments to HHS, identified by CMS–4137–IFC, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4137–IFC, P.O. Box 8017, Baltimore, MD 21244–8010.
- *Hand or courier delivery*. Comments may be delivered to either 7500 Security Boulevard, Baltimore, MD 21244–1850 or Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201. For delivery to Baltimore, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. For delivery to Washington, because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.

All submissions submitted to HHS will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters for the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

Internal Revenue Service. Comments to the IRS, identified by REG–123829–08, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail*: CC:PA:LPD:PR (REG–123829–08), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- *Hand or courier delivery*: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–123829–08), Courier's Desk, Internal Revenue Service, 1111

Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335.

Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622–6080.

Adam Shaw, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (877) 267–2323, extension 61091.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws, including the nondiscrimination protections, may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's website (*http://www.dol.gov/ebsa*). In addition, individuals may request a copy of CMS's publication entitled "*Protecting Your Health Insurance Coverage*" by calling 1–800–633–4227.

SUPPLEMENTARY INFORMATION:

I. Background

The Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110–233, was enacted on May 21, 2008. Title I of GINA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), the Internal Revenue Code of 1986 (Code), and the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information. GINA builds on existing protections added by titles I and IV of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[1] Specifically, the HIPAA portability provisions already prohibit a group health plan or group health insurance issuer from imposing a preexisting condition exclusion based solely on genetic information. See the 2004 final HIPAA portability regulations, published in the **Federal Register** on December 30, 2004 (T.D. 9166, 2005–1 C.B. 558 [69 FR 78720]). In addition, the HIPAA nondiscrimination provisions already prohibit a group health plan or group health insurance issuer from discriminating against an individual in eligibility, benefits, or premiums based on genetic information (and other health factors) of the individual or a dependent of the individual. See the 2006 final HIPAA nondiscrimination regulations, published in the **Federal Register** on December 13, 2006 (T.D. 9298, 2007–1 C.B. 434 [71 FR 75014]).

Sections 101 through 104 of Title I of GINA prohibit group health plans, health insurance issuers in the group and individual markets,[2] and issuers of Medicare supplemental (Medigap) policies from discriminating based on genetic information, and from collecting such information.[3] Section 105 of Title I adds section 1180 of the SSA to require HHS to revise the HIPAA privacy regulations to clarify that genetic information is health information under the rule and to prohibit the use or disclosure of genetic information for underwriting purposes.[4] Title II of GINA prohibits discrimination in employment based on genetic information, and limits the acquisition and disclosure by employers and other entities covered by GINA Title II of such information.[5] These interim final regulations (REG–123829–08) only interpret Sections 101 through 103 of Title I of GINA, which added provisions to Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Title XXVII of the PHS Act.[6] References to GINA in the remainder of this preamble refer to the group market provisions of sections 101 through 103 of GINA, unless the context clearly indicates otherwise.

On October 10, 2008, the Departments published in the **Federal Register** (Announcement 2008–107, 2008–46 I.R.B. 1162 [73 FR 60208]) a request for information (RFI) soliciting comments on the requirements of sections 101 through 104 of GINA. In addition, the Departments consulted with and obtained technical guidance from the scientific community, including the National Human Genome Research Institute within the National Institutes of Health and the Office for Human Research Protections, both within HHS. The Departments also coordinated with the Equal Employment Opportunity Commission (EEOC), which has responsibility for Title II of GINA, and the Office for Civil Rights within HHS, which has responsibility for section 105 of GINA.

After consideration of the comments received in response to the RFI and based on the consultations with other government agencies, the Departments are publishing these interim final regulations. For the group market, these regulations become applicable to plans and issuers on the first day of the plan year beginning on or after December 7, 2009. For the individual market, these regulations become applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

II. Overview of the Regulations

A. Group Market

While GINA does not mandate any specific benefits for health care services related to genetic tests, diseases, conditions,

[1] These HIPAA provisions generally apply to group health plans and health insurance coverage in the group and individual markets.

[2] Rules on GINA's application in the individual market are solely within the jurisdiction of the Centers for Medicare & Medicaid Services at the Department of Health and Human Services and are discussed later in this preamble.

[3] This regulation does not address the application of GINA to Medigap issuers, which are subject to provisions in section 1882 of the SSA that are implemented by the Centers for Medicare & Medicaid Services (CMS), and incorporate by reference certain provisions in a model regulation of the National Association of Insurance Commissioners (NAIC). The model regulation adopted by the NAIC on September 24, 2008 was published by CMS in the **Federal Register** on April 24, 2009 at 74 FR 18808. This regulation also does not address the additional enforcement authority given to the Secretaries of Labor and HHS, relating to the use of genetic information, which will be addressed in future regulatory guidance.

[4] The HIPAA privacy provisions are administered by the Office for Civil Rights within HHS, and will be the subject of a separate rulemaking.

[5] Title II of GINA is under the jurisdiction of the Equal Employment Opportunity Commission, which issued a notice of proposed rulemaking on March 2, 2009, 74 FR 9056.

[6] Compliance with GINA sections 101 through 103 is not determinative of compliance with any other provision of GINA or any other State or Federal law, including the Americans with Disabilities Act.

or genetic services, GINA establishes rules that generally prohibit a group health plan and a health insurance issuer in the group market from:

- Increasing the group premium or contribution amounts based on genetic information;
- Requesting or requiring an individual or family member to undergo a genetic test; and
- Requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

These three general prohibitions are subject to rules of construction or exceptions included in the statute which are discussed in further detail later in this preamble.

1. Conforming Changes to Existing Regulations

Sections 9801 and 9802 of the Code, 701 and 702 of ERISA, and 2701 and 2702 of the PHS Act, as originally added by HIPAA, included requirements pertaining to genetic information but did not define the term. The 2004 final HIPAA portability regulations included a definition of genetic information.

GINA contains a statutory definition of genetic information that differs from the definition in the 2004 final HIPAA portability regulations. These interim final regulations revise the existing regulations' definition of genetic information at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, to conform to the new statutory definition.

Sections 9802 of the Code, 702 of ERISA, and 2702 of the PHS Act, and the 2006 final HIPAA nondiscrimination regulations prohibit discrimination based on a health factor. GINA retained the prohibition against increasing an individual's premium or contribution amounts based on genetic information, and added a new provision to prevent plans and issuers from adjusting premium or contribution rates at the group level based on genetic information of one or more individuals in the group. Therefore, these interim final regulations amend the 2006 regulations to add clarifying cross-references. See 26 CFR 54.9802–1(c)(2)(i) and (iii), 29 CFR 2590.702(c)(2)(i) and (iii), and 45 CFR 146.121(c)(2)(i) and (iii).

2. Definitions

Paragraph (a) of these interim final regulations[7] provides most of the definitions used in GINA.[8] Some of these definitions repeat the statutory language, while others include regulatory clarifications.

a. Collect

The interim final regulations add the defined term "collect." While "collect" was not defined in the statute, this term was added to paraphrase the longer phrase "request, require or purchase." Thus, under the interim final regulations, "collect" means, with respect to information, to request, require, or purchase such information.

b. Family Member

GINA adds a definition of family member to sections 9832 of the Code, 733 of ERISA, and 2791 of the PHS Act. The definition of family member determines the application of GINA in two ways. First, the definition of genetic information for an individual includes information about the manifestation of a disease or disorder in family members of the individual. Also, a plan or issuer generally may not request or require an individual or family member of the individual to undergo a genetic test.

The statute defines a family member with respect to any individual as a dependent of such individual (as such term is used for purposes of sections 9801(f)(2) of the Code, 701(f)(2) of ERISA, and 2701(f)(2) of the PHS Act (the dependent special enrollment rules))[9], and any other individual that is a first-, second-, third-, or fourth-degree relative of the individual or of the dependent of the individual. The legislative history suggests that the term "family member" be broadly construed: "In general, it is intended that the term 'family member' be interpreted broadly so as to provide the maximum protection against discrimination." House Report 110–28, Part 2 at 27.

Sections 9801(f)(2) of the Code, 701(f)(2) of ERISA, and 2701(f)(2) of the PHS Act provide special enrollment rights to certain dependents that are eligible for coverage under a group health plan due to such family events as birth, adoption, or marriage. The statutory provisions of neither HIPAA nor GINA define dependent, but the term is defined in the 2004 final HIPAA portability regulations as any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant. This makes clear that it is necessary to consult the plan document and other applicable law to determine dependent status for purposes of GINA.

In determining who is a first-, second-, third-, or fourth-degree relation of an individual, the interim final regulations treat relatives by affinity (such as by marriage or adoption) the same as relatives by consanguinity (relatives who share a common biological ancestor, or blood relatives). The definition also treats relatives who are not full blood relatives (such as half siblings) the same as full blood relatives. In addition, the interim final regulations provide non-exhaustive lists of individuals who are first-, second-, third-, or fourth-degree relatives. The Departments invite public comments on this definition.

c. Genetic Information

The interim final regulations contain a definition of genetic information that restates and reorganizes the statutory provisions. Genetic information is defined, with respect to an individual, as information about the individual's genetic tests or the genetic tests of family members, the manifestation of a disease or disorder in family members of such individual (that is, family medical history), or any request of or receipt by the individual or family

[7] Because substantively similar regulation text is published separately by the three Departments, and the section numbers will all be different, the preamble refers only to the paragraph designations within those sections.

[8] The same definitions apply to the individual market regulations under GINA, which are discussed later in this preamble, to the extent that they are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market.

[9] This definition of the term "dependent" is solely for purposes of interpreting sections 101 through 103 of GINA, and is not relevant to interpreting the term under Title II of GINA, which is under the jurisdiction of the EEOC.

members of genetic services. The definition further clarifies that genetic information does not include information about the sex or age of any individual. It also clarifies how GINA applies to genetic information about a fetus or embryo. As previously noted, this definition is a change from the definition of genetic information that applied under the 2004 final HIPAA portability regulations.

d. Genetic Services

An individual's genetic information includes any request for or receipt of genetic services by such individual, or a family member. These interim final regulations follow the statutory definition. "Genetic services" means a genetic test, genetic counseling, or genetic education.

e. Genetic Test

GINA adds a definition of genetic test to sections 9832 of the Code, 733 of ERISA, and 2791 of the PHS Act.[10] These interim final regulations repeat the statutory language, which provides that a genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if it detects genotypes, mutations, or chromosomal changes.

The interim final regulations also follow the statutory language providing that a genetic test does not include an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could be reasonably detected by a health care professional with appropriate training and expertise in the field of medicine involved.

The interim final regulations include examples of certain tests that currently are regarded as genetic or non-genetic tests, as the case may be, based on research including consultations with representatives from the scientific community. However, due to rapidly evolving scientific knowledge, it is not an exhaustive list.

f. Manifestation or Manifested

The concept of manifestation of a disease arises in three contexts. First, a plan or issuer may increase the premium or contribution amount for a group health plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. Second, the definition of genetic information for an individual includes information about the manifestation of a disease or disorder in family members of such individual. Finally, the definition of genetic test excludes an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could be reasonably detected by a health care professional with appropriate training and expertise in the field of medicine involved.

The interim final regulations add a definition of manifestation or manifested. A disease, disorder, or pathological condition is manifested when an individual has been or could reasonably be diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. However, the definition further provides that a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

g. Underwriting Purposes

GINA includes a definition of underwriting purposes. This term is discussed later in this preamble, in connection with the discussion of the prohibition on collecting genetic information.

3. Prohibition on Adjusting Group Rates

GINA and these interim final regulations expand the HIPAA prohibitions against discrimination based on health factors, by prohibiting group health plans and health insurance issuers offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group health plan or group of similarly situated individuals on the basis of genetic information. This is a change from prior law, which allowed plans and issuers to adjust premium or contribution amounts for the group health plan or a group of similarly situated individuals (but not for individuals within the group) based on genetic information, as well as other health factors. This prohibition against discrimination is distinct from the prohibition on requesting or requiring an individual to undergo a genetic test and the prohibition on collecting genetic information. Therefore, even when a plan or issuer has lawfully obtained genetic test results or other genetic information (for example, an acquisition that took place prior to GINA's effective date), the plan or issuer is still prohibited — under GINA and paragraph (b) of these interim final regulations — from using that information to discriminate.

GINA and these interim final regulations also provide that the prohibition on adjusting premiums or contributions based on genetic information does not limit the ability of a plan or issuer to increase the premium or contribution amount for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan. However, a plan or issuer may not use the manifested disease or disorder of one individual as genetic information about other group members to further increase the premium or contribution amount. Moreover, the prohibitions on adjusting premium or contribution amounts based on genetic information do not prohibit a plan or issuer from including costs associated with providing benefits for covered genetic tests or genetic services within the costs of providing other benefits in determining premiums or contribution amounts. In particular, a plan or issuer is not required to reduce the aggregate costs of providing health benefits for the year by those costs relating to benefits for genetic tests and services when adjusting group rates. These interim final regulations also make conforming changes to the existing HIPAA nondiscrimination regulations regarding the ability to adjust premium or contribution amounts based on a health factor.

4. Limitation on Requesting or Requiring Genetic Testing

GINA generally prohibits plans and issuers from requesting or requiring individuals or their family members to undergo a genetic test. There are three exceptions to this prohibition, for certain health care

[10] This definition of the term "genetic test" is solely for purposes of interpreting Title I of GINA, and is not relevant to interpreting the term under Title II of GINA, which has a different statutory definition.

professionals, for determinations regarding payment, and for research.

The first exception allows a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test. The health care professional must actually be providing health care services to the individual for the exception to apply. Thus, for example, the performance of claims review by a health care professional would never be considered providing health care services to an individual. The term "health care professional" is not limited to physicians.

The second exception allows a plan or issuer to obtain and use the results of a genetic test to make a determination regarding payment. For this purpose, payment is defined by reference to 45 CFR 164.501 of the HIPAA privacy regulations. However, plans and issuers are only permitted to request the minimum amount of information necessary to make this determination. These interim final regulations incorporate the standard set forth at 45 CFR 164.502(b) of the HIPAA privacy regulations to determine the minimum amount of information necessary.

In some cases, the appropriateness of certain courses of treatment for a patient depends on the patient's genetic makeup. A plan or issuer is permitted to condition payment for an item or service based on medical appropriateness that depends on an individual's genetic makeup. Under these narrow circumstances, a plan or issuer may condition payment on the outcome of a genetic test, and may refuse payment for the item or service if the individual does not undergo the genetic test. Any information received by the plan to make a determination regarding payment, including the results of a genetic test, must be used in accordance with these interim final regulations and the 2006 final HIPAA nondiscrimination regulations.

Under the third exception relating to the limitation on requesting or requiring genetic testing, a group health plan or group health insurance issuer is permitted to request, but not require, that a participant or beneficiary undergo a genetic test[11] if all of the following conditions of the research exception are satisfied:

- The request must be made pursuant to research that complies with 45 CFR Part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. Moreover, to comply with the informed consent requirements of 45 CFR 46.116(a)(8), an investigator seeking the informed consent of a human subject must provide the subject with a statement that participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at anytime without penalty or loss of benefits to which the subject is entitled, except in limited circumstances in which an institutional review board has approved a waiver or alteration of this requirement under the requirements of 45 CFR 46.116(c) or (d). For research in which the investigator provides subjects with the statement required under 45 CFR 46.116(a)(8) when seeking their informed consent, no additional disclosures are required for purposes of the GINA research exception.
- The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits or premium or contribution amounts.
- None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.
- The plan or issuer must complete a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" (the Notice) and provide it to the address specified in its instructions. The Notice and instructions are available on the Department of Labor's website (*http://www.dol.gov/ebsa*).

5. Prohibition on Collection of Genetic Information

Paragraph (d) of these interim final regulations describes the statutory prohibitions against plans or issuers collecting genetic information, either for underwriting purposes or prior to or in connection with enrollment; sets forth the statutory definition of underwriting purposes; and clarifies that, if an individual seeks a benefit under a plan or coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate (and a determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes).

Underwriting purposes is defined under GINA and in these interim final regulations as including, with respect to group health plan coverage, rules for and determinations of eligibility (including enrollment and continued eligibility), computation of premium or contribution amounts, and application of preexisting condition exclusions. Under GINA, the definition of underwriting is broader than merely activities relating to rating and pricing a group policy. These interim final regulations clarify that underwriting purposes includes changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program.

GINA and paragraph (d) of the interim final regulations provide that plans and issuers are only prohibited from collecting genetic information for underwriting purposes or prior to or in connection with enrollment. Where an individual seeks a benefit under the plan, requesting family medical history or other genetic information to make a determination whether the benefit is medically appropriate for purposes of payment is neither for underwriting purposes nor prior to or in connection with enrollment. Therefore, although the statutory payment exception only applies to requests for individuals to undergo genetic tests, these interim final regulations provide it is permissible for a plan or issuer to request the minimum amount of genetic informa-

[11] Comments indicated that at least one issuer is engaging in a long-term research study involving genetic testing. Others may be planning similar research.

tion necessary to make determinations regarding payment. Specifically, these interim final regulations provide that, if an individual seeks a benefit under a plan or coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. However, a plan or issuer is permitted to request only the minimum amount of information necessary to determine medical appropriateness.

These interim final regulations provide clarifications of the statutory prohibition against a plan or issuer collecting genetic information prior to or in connection with enrollment. Under the interim final regulations, a collection of genetic information with respect to an individual is considered prior to enrollment if it is before the individual's effective date of coverage under the plan or health insurance coverage. The determination of whether a plan or issuer is collecting information before the individual's effective date of coverage is made at the time of collection. Providing that the determination is made at the time of collection means that if a plan or issuer collects genetic information with respect to an individual in circumstances that otherwise would not render the collection impermissible and at that time it is not being collected in connection with a future enrollment, the fact that a future enrollment may occur does not mean, for purposes of this rule, that the genetic information was collected before the enrollment. Thus, for example, if a plan collected genetic information with respect to an individual after initial enrollment (and not for underwriting purposes), and the individual later dropped coverage but then still later reenrolled in the plan, the collection of genetic information after the initial enrollment would not be considered prior to the reenrollment.

Similarly, if a plan affirmatively requires individuals to reenroll on an annual basis or allows individuals to change their enrollment, a collection of genetic information made after a current enrollment will not be considered made prior to a subsequent enrollment unless the collection of information is or will be used to affect that subsequent enrollment. Moreover, if genetic information is collected permissibly under one plan, the information is transferred to a second plan in connection with a merger or acquisition after this collection, and individuals covered under the first plan are enrolling for the first time in the second plan, the transfer of information to the second plan will not be considered a collection prior to the effective date of coverage under the second plan if the collection of information does not affect the enrollment status of individuals enrolling in the second plan.

These interim final regulations include the statutory exception (to the prohibition against collections of genetic information prior to or in connection with enrollment) for genetic information that is collected incidental to the collection of other information and is not used for underwriting purposes. Some commenters suggested that some questions that are typically included in some HRAs and similar documents could easily result in an individual providing genetic information, even if the question does not mention genetic tests or family medical history explicitly. An example given was, "Have you had any laboratory tests in the past 2 years?" These commenters suggested plans and issuers should be required to inform individuals that they should not reveal genetic information.

The interim final regulations clarify that if it is reasonable to anticipate that health information will be received as part of the collection of information, the incidental collection exception does not apply unless the collection explicitly states that genetic information should not be provided. If, in connection with a collection of information, it is reasonable to anticipate that health information will be received and the collection explicitly states that genetic information should not be provided, any genetic information provided will be considered within the incidental exception, as long as it is not used for underwriting purposes.

In response to the RFI, a number of comments were received concerning the application of the prohibition on requesting genetic information for underwriting purposes to plans and issuers that reward individuals for completing HRAs. Of particular concern are wellness programs including HRAs that request information about an individual's family medical history. Another concern is the application of the prohibition on requesting genetic information for underwriting purposes to screening processes for disease management programs that use genetic tests or family medical histories to identify individuals that can benefit from the program.

GINA prohibits collecting genetic information for underwriting purposes. As described earlier, underwriting purposes is defined broadly to include rules for eligibility for benefits and the computation of premium or contributions amounts, and not merely activities relating to rating and pricing a group policy. Moreover, GINA defines genetic information as including family medical history. Consequently, wellness programs that provide rewards for completing HRAs that request genetic information, including family medical history, violate the prohibition against requesting genetic information for underwriting purposes. This is the result even if rewards are not based on the outcome of the assessment, which otherwise would not violate the 2006 final HIPAA nondiscrimination rules regarding wellness programs.

Some comments received in response to the RFI urged strongly that a regulatory exception should allow wellness programs to provide rewards for completing HRAs that request such information, notwithstanding the statutory prohibition on collecting genetic information.[12] Other comments suggested equally strongly that the regulations clarify that wellness programs may not collect such information as a condition for rewards. These interim final regulations do not provide an exception from underwriting for rewards provided by wellness programs, regardless of the amount of the reward. Examples generally illustrate that any reward given for the completion of an HRA that solicits information about the individual's family medical history violates the requirements of paragraph (d).

However, plans and issuers can collect genetic information through HRAs under GINA in certain circumstances. A plan or issuer can collect genetic information

[12] Earlier bills (for example, S.358, 110th Cong. (as reported by S. Comm. on Health, Education, Labor, and Pensions) March 29, 2007; H.R. 493, 110th Cong. (as reported by H. Comm. on Energy and Commerce) March 29, 2007) included exceptions for wellness programs in both the Title I health coverage provisions and the Title II employment provisions. As enacted, GINA only includes an exception for wellness programs in the Title II employment provisions.

through an HRA as long as no rewards are provided (and if the request is not made prior to or in connection with enrollment). A plan or issuer can also provide rewards for completing an HRA as long as the HRA does not collect genetic information. Several examples are provided in these interim final regulations to illustrate these points. In one example, a plan administers two distinct HRAs, one that does not request genetic information and one that does. A reward is provided for completing the HRA that does not solicit genetic information; the instructions for the other HRA make clear that completion of the HRA is wholly voluntary and will not affect the reward given for completion of the first HRA. The example concludes that neither HRA violates the rules against collecting information for underwriting purposes or prior to or in connection with enrollment. Finally, another example illustrates the application of the exception for information obtained incidentally in the context of the acquisition of one issuer by another. The Departments invite comment on ways in which participation in HRAs can be encouraged while complying with the statutory prohibition on using genetic information for underwriting purposes.

6. Medical Appropriateness

Paragraph (e) of these interim final regulations provides examples illustrating how medical appropriateness is determined, in connection with both the payment exception under paragraph (c) and the prohibition against collecting genetic information for underwriting purposes under paragraph (d). Examples illustrate the minimum amount of genetic information necessary to determine payment, the restriction of benefits to medically appropriate treatment, and the application of the medical appropriateness rules to the use of genetic information to determine eligibility for a disease management program.

7. Special Rules Related to Very Small Group Health Plans

Generally, the provisions of HIPAA titles I and IV, as amended, do not apply to a group health plan for a plan year if the plan is a very small group health plan; that is, on the first day of the plan year, the group health plan has fewer than 2 participants who are current employees. GINA and these interim final regulations provide that this exception for very small group health plans is not available for the genetic information provisions in Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Title XXVII of the PHS Act.

8. Treatment of Non-Federal Governmental Plans

Section 2721(b)(2) of the PHS Act permits the sponsor of a self-funded non-Federal governmental plan as defined in 45 CFR 144.103 to elect to exempt the plan from most of the requirements of Title XXVII of the PHS Act. This is referred to herein as the "opt-out election." However, section 2721(b)(2)(C)(ii) states that no opt-out election is available with respect to the requirements for certification and disclosure of creditable coverage. The PHS Act regulations at 45 CFR 146.180 implement the foregoing opt-out rules under section 2721.

Section 102(c) of GINA added a second limitation on the opt-out rights of a self-funded non-Federal governmental plan sponsor. Section 2721(b)(2)(D) of the PHS Act precludes any exemption election by a self-funded non-Federal governmental plan sponsor from GINA's requirements. The Centers for Medicare & Medicaid Services (CMS) amended 45 CFR 146.180(h) accordingly.

CMS made certain additional conforming changes to other provisions of 45 CFR 146.180. In particular, CMS deleted the reference in 45 CFR 146.180(h) to CMS enforcement under 45 CFR 146.180(k) because paragraph (k) makes clear that CMS enforces all requirements of part 146 that apply to non-Federal governmental plans. CMS also revised the last sentence of 45 CFR 146.180(k), which refers to the imposition of a civil money penalty, by replacing "under § 150.305" with "under subpart C of part 150" because subpart C includes multiple sections that govern imposition of a civil money penalty, while 45 CFR 150.305 only applies to a determination of which entity is liable for a civil money penalty.

B. Individual Market

The regulations at 45 CFR Part 148 implement the individual market requirements of Title XXVII of the PHS Act. Section 102(b) of GINA added a new section 2753 (42 U.S.C. 300gg–53) to Title XXVII to prohibit discrimination on the basis of genetic information in the individual health insurance market. Section 2753 of the PHS Act generally parallels the group market genetic nondiscrimination provisions GINA added to the Code, ERISA and the PHS Act. Section 2753 and the interim final regulations prohibit issuers in the individual market from collecting genetic information prior to or in connection with such enrollment, and at any time for underwriting purposes. Section 2753 and the interim final regulations also prohibit issuers from requesting or requiring genetic tests. The exceptions and rules of construction that apply to the foregoing requirements in the group market (for example, the rule for incidental collections of genetic information and the research exception to the rule against requiring genetic tests) also apply in the individual market.

Since individual market issuers were not subject to the federal HIPAA nondiscrimination requirements applicable to issuers in the group market, it was necessary for GINA to amend the PHS Act in order to have similar protections against genetic discrimination applicable in both markets. Thus, new section 2753 of the PHS Act prohibits issuers of individual health insurance policies from using genetic information as a basis for making eligibility or premium determinations, or for imposing preexisting condition exclusions. Issuers in the individual market may continue to establish rules for eligibility, increase premiums, and impose preexisting condition exclusions based on the manifestation of a disease or disorder in an individual, or in a family member covered under the policy that covers the individual. However, they cannot use a manifestation of a disease or disorder in one individual as genetic information about family members covered under the same policy or another policy in order to further increase premiums.

These interim final regulations add a new § 148.180 to subpart C of part 148 to implement section 2753 of the PHS Act. To the extent that the provisions of section 2753 parallel the GINA amendments to section 2702 of the PHS Act which govern the group market, § 148.180 restates the corresponding group market provisions (with conforming changes and technical

corrections appropriate to the individual market) rather than incorporating the group market provisions by reference.

As discussed above, GINA amended the Social Security Act to include genetic nondiscrimination provisions that apply to issuers of Medigap policies. The PHS Act regulations at 45 CFR 148.220 state that Medigap policies are excepted benefits. Nevertheless, because Medigap policies are subject to GINA under the Social Security Act and NAIC model regulation, CMS made clarifying changes to § 148.220 to emphasize the foregoing.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS to promulgate any interim final rules that they determine are appropriate to carry out the provisions of Chapter 100 of Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Part A of Title XXVII of the PHS Act, which include the provisions of GINA.

Under Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

These rules are being adopted on an interim final basis because the Secretaries have determined that without prompt guidance some members of the regulated community may not know what steps to take to comply with the requirements of GINA, which may result in an adverse impact on participants and beneficiaries with regard to their health benefits under group health plans and the protections provided under GINA. Moreover, GINA's requirements will affect the regulated community in the immediate future.

The requirements of sections 101 through 103 of GINA are effective for all group health plans and for health insurance issuers offering coverage in connection with such plans for plan years beginning after May 21, 2009. Plan administrators and sponsors, issuers, and participants and beneficiaries will need guidance on how to comply with the new statutory provisions. As noted earlier, these interim rules take into account comments received by the Departments in response to the request for information on GINA published in the **Federal Register** on October 10, 2008 (73 FR 60208). For the foregoing reasons, the Departments find that the publication of a proposed regulation, for the purpose of notice and public comment thereon, would be impracticable, unnecessary, and contrary to the public interest.

IV. Economic Impact and Paperwork Burden

A. Summary—Department of Labor and Department of Health and Human Services

As discussed above, Title I of GINA generally prohibits group health plans and health insurance issuers in both the group and individual markets from discriminating based on genetic information, requesting or requiring an individual to undergo a genetic test, and collecting genetic information prior to or in connection with enrollment or for underwriting purposes. The Departments have crafted these interim final regulations to secure the protections from discrimination intended by Congress in as economically efficient a manner as possible. Although the Departments are unable to quantify the regulations' economic benefits, they have quantified their costs and have provided a qualitative discussion of some of the benefits that may stem from this rule.

One potential benefit associated with GINA and these interim final regulations is that genetic testing and research may expand when discrimination based on genetic information and the collection of such information is prohibited, if these protections allay individuals' fears of adverse health coverage-related consequences from undergoing genetic testing and participating in research studies examining genetic information. An increase in genetic testing and research, in turn, could provide greater knowledge regarding the genetic basis of disease, which could facilitate the early diagnosis and treatment of individuals with a genetic predisposition toward developing certain diseases and disorders and may allow scientists to develop new medicines, treatments, and therapies that could enhance the health and welfare of Americans.

B. Statement of Need for Regulatory Action

Congress directed the Departments to issue regulations implementing the GINA provisions not later than 12 months after the date of enactment. In response to this Congressional directive, these interim final regulations clarify and interpret the GINA nondiscrimination provisions under section 702 of ERISA, sections 2702 and 2753 of the PHS Act, and section 9802 of the Code. These regulations are needed to secure and implement GINA's nondiscrimination provisions and ensure that the rights provided to participants, beneficiaries, and other individuals under GINA are fully realized. The Departments' assessment of the expected economic effects of these interim final regulations is discussed in detail below.

C. Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Departments must determine whether a regulatory action is "significant" and therefore subject to the requirements of the Executive Order and review by the Office of Management and Budget (OMB). Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of the Executive Order, the Departments have determined that this action raises novel policy issues

arising out of legal mandates. Therefore, the interim final regulations are "significant" and subject to OMB review under Section 3(f)(4) of the Executive Order. Accordingly, the Departments have undertaken, as described below, an assessment of the costs and benefits of the regulation. Over the 10-year period of 2010 to 2019, the present value of the costs, using a discount rate of 7 percent, is estimated to be $294.8 million in 2009 Dollars, as is shown in Table 1.

All other numbers included in the text are not discounted.

TABLE 1.—*Total Discounted Costs of Rule (in millions of 2009 Dollars)*

Year	Wellness Plan Review (B)	Individual Market Review (C)	Medical Record Review (D)	Research Disclosure (E)	Total Costs — Discounted at 7% B+C+D+E
2010	$2.0	$5.3	$38.3	$0	$45.5
2011			$35.8		$35.8
2012			$33.4		$33.4
2013			$31.2		$31.2
2014			$29.2		$29.2
2015			$27.3		$27.3
2016			$25.5		$25.5
2017			$23.8		$23.8
2018			$22.3		$22.3
2019			$20.8		$20.8
			Total with 7% Discounting		**$294.8**
			Total with 3% Discounting		**$356.8**

Note: The displayed numbers are rounded and therefore may not add up to the totals. They are discounted using a 7 percent discount rate unless otherwise noted.

The Departments performed a comprehensive, unified analysis to estimate the costs and, to the extent feasible, provide a qualitative assessment of benefits attributable to the statute and regulations for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. The Departments' assessment and underlying analysis is set forth below.

1. Affected Entities and Other Assumptions

The Departments estimate that 137.1 million participants and beneficiaries[13] are covered by nearly 2.5 million private sector group health plans and 31.7 million individuals are covered by individual health insurance policies.[14] The Departments also estimate that approximately 630 insurers will be are affected by GINA, consisting of approximately 460 insurers offering coverage in connection with insured group health plans and approximately 490 health insurance issuers offering policies in the individual health insurance market.[15]

2. Benefits

One potential benefit associated with GINA and these interim final regulations is that genetic testing and research may increase if the protections provided under GINA allay the public's concerns that health plans and insurers will use genetic information to discriminate based on the collection and disclosure of such information. Comments received in response to the RFI indicate that genetic testing and research currently are being underutilized. A major reason cited for the lack of genetic testing is the public's fear of adverse employment-related or health coverage-related consequences associated with having genetic testing or participating in research studies that examine genetic information. Removing barriers that impede the growth of genetic testing and research has the potential to improve health and save lives by providing patients and physicians with critical knowledge to facilitate early intervention often before disease symptoms are manifested. It also could expand the development of scientific research, which could result in the development of new medicines, therapies, and treatments for diseases and disorders.

Additional economic benefits may derive directly from the improved clarity provided by the interim final regulations, which will reduce uncertainty and help group health plan sponsors and health insurers comply with GINA's requirements in a cost effective manner. Moreover, the prohibitions enacted in GINA and these interim final regulations should provide a benefit to individuals with genetic predispositions for diseases by decreasing the number of individuals that are denied coverage under a group health plan or priced out of the individual health insurance market.[16]

[13] Departments' estimates based on the March 2007 Current Population Survey.

[14] Departments' estimates based on the March 2008 Current Population Survey.

[15] Estimates are from 2007 NAIC financial statements data and the California Department of Managed Healthcare (*http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx*)

[16] When scoring the GINA bill the Congressional Budget Office estimated that the bill would increase health insurance coverage by about 600 people a year with most being in the individual market. Congressional Budget Office Cost Estimate, H.R. 493 Genetic Information Nondiscrimination Act of 2007, April 12, 2007.

Currently, the Departments are unable to quantify these benefits, because relatively few genetic tests and research studies are performed in the private sector[17] and a limited number of genetic tests are available. As stated above, the Departments expect the number of genetic tests and research studies to increase in the near future. The Departments, however, lack sufficient information to project the trajectory of this increase.

a. Health Risk Assessments

As discussed above, GINA and these interim final regulations prohibit group health plans and health insurance issuers offering coverage in the group and individual health insurance markets from collecting genetic information in connection with or prior to enrollment and for underwriting purposes. Comments received in response to the RFI indicate that the immediate impact of GINA and these interim final regulations on group health plans and health insurance issuers providing group health coverage should be minimal. Plans and issuers commented that they do not collect or use genetic information for underwriting purposes because pre-GINA laws and regulations prohibit them from discriminating against individuals based on any health status-related factors, including genetic information.[18]

Currently, many group health plans request family medical history information to be provided in response to questions on HRAs that are completed by new employees before enrollment in the plan and as part of open enrollment for current employees. HRAs are used in connection with wellness and disease management programs to identify individuals at risk for certain conditions and provide an opportunity for preventive treatment service referrals, disease management, and other behavioral change initiatives that are focused on creating higher quality medical outcomes. Some group health plans provide rewards and incentives to employees who complete HRAs, such as premium reductions, lower deductibles, and cash bonus payments.

The Departments expect that most of the cost of complying with GINA and these interim final regulations will be concentrated among the approximately 30,000 group health plans[19] that are associated with wellness and disease management programs that provide rewards and incentives to employees that complete HRAs. These plans will have to conduct a compliance review to ensure that their HRAs and any associated policies and procedures comply with GINA's prohibition on using genetic information prior to or in connection with enrollment or for underwriting purposes and to make any necessary changes to their HRAs and policies and procedures.

The Departments assume that insured plans will rely on the health insurance issuer providing coverage to ensure compliance and that self-insured plans will rely on wellness vendors and other service providers to ensure compliance. These interim final regulations provide several examples illustrating the application of the regulations to HRAs, which are intended to reduce the compliance burden. Moreover, the per plan compliance cost is expected to be low, because vendors and insurers will be able to spread these costs across multiple client plans.[20]

The Departments assume that the average burden per plan will be one-half hour of a legal professional's time at an hourly labor rate of $116,[21] and one-half hour of a clerical staff's time at an hourly labor rate of $26 to conduct the compliance review and make the needed changes to the HRAs. This results in a total cost of $2.1 million ($1.7 for legal services, and $0.4 million for clerical services) in the first year. The Departments invite public comments on this estimate.

To the extent that GINA and these interim final regulations prohibit group health plans and issuers from incentivizing employees to complete HRAs requesting genetic information, including family medical history, and response rates for HRAs drop as a consequence, a cost may be incurred that is associated with the forgone benefits of identifying disease risks early and preventing their onset. The Departments do not have adequate data to determine whether these forgone benefits would materialize, and, if so, what their extent may be. However, the Departments invite public comments on this issue, including evidence-based estimates of what the extent of these forgone benefits may be, if any, and ways in which these public health benefits may be realized while complying with the statutory prohibition on using genetic information for underwriting purposes.

b. GINA's Impact on the Individual Health Insurance Market

The Department of Health and Human Services expects that the individual health insurance market will incur higher costs of complying with these interim final regulations than group health plans. The Departments assume that health insurance issuers in the individual market will have to review their applications and underwriting policies and procedures to ensure that genetic information is not collected or used for underwriting purposes. Issuers also will need to train underwriters to avoid using genetic information in underwriting. The Departments estimate that the approximately 490 issuers in the individual health insurance market will spend approximately 100 hours in-house each conducting a compliance review, modifying their applications and policies and procedures, and drafting training materials and providing training sessions for underwriters to ensure compliance with GINA and these interim final regulations at a labor rate of $116. This results in a total cost of about $5.6 million. The Departments invite public comments on this estimate.

[17] Pollitz, Karen, *et.al.* "Genetic Discrimination in Health Insurance: Current Legal Protections and Industry Practices." *Inquiry* 44:350–368 (Fall 2007).

[18] *See e.g.*, Comments from BlueCross BlueShield Association, pg. 3 (*http://www.dol.gov/ebsa/pdf/cmt–12190808.pdf*) and Society for Human Resource Management, pg. 2 (*http://www.dol.gov/ebsa/pdf/cmt–12190813.pdf*).

[19] This estimate is based on the Kaiser Family Foundation Survey, Employer Health Benefits 2008 Annual Survey: Wellness Programs and Employer Opinions, section 12, which estimates that 10% of plans have health risk assessment and 12% of those offer a financial incentive to employees that complete HRAs (2.5 million group health plans x 10% of plans have health risk assessments x 12 % of those plans that offer financial rewards and incentives = 30,000 plans).

[20] There are about 30,000 plans with health risk assessments and about 460 insurers in the group market; this is an average of 65 plans per insurer.

[21] EBSA estimates based on the National Occupational Employment Survey (May 2007, Bureau of Labor Statistics) and the Employment Cost Index June 2008, Bureau of Labor Statistics).

One comment received in response to the RFI indicated that underwriters in the individual health insurance market request medical records from medical service providers for approximately 20 percent of applicants.[22] It is likely that most of these medical records contain information relating to family medical history. In a survey, 16 of 23 senior medical underwriters reported that while investigating an applicant's medical history they had encountered genetic information about an applicant at least once in the applicant's history.[23] As explained earlier, these interim final regulations would require health insurance issuers in the individual market to explicitly state that genetic information — including family medical history — should not be provided when an issuer requests medical records from medical services providers for underwriting purposes. In turn, issuers may request that medical services providers redact any family medical history information regarding an applicant that is contained in medical records requested by an issuer to ensure that the provisions of GINA and these interim final regulations are not violated. However, as explained earlier under the discussion of the incidental collection exception, if medical services providers do not comply with the issuers' requests to redact such information, the collection of genetic information would count as an "incidental collection" of genetic information on the part of issuers, and these interim final regulations would not be violated so long as the issuers do not use the genetic information for underwriting purposes.

The Departments assume that medical service providers will be responsible for redacting genetic information from medical records before submitting the records to insurers, and that trained medical staff will be used for this purpose. The Departments estimate that, on average, health insurance issuers will request 3 million medical records per year, and that medical records staff will spend one-half hour per request redacting genetic information from requested medical records, at a labor rate of $26 per hour. This results in a total annual cost of nearly $41 million. The Departments invite public comments on this estimate.

c. Research Exception

As discussed above, GINA and these interim final regulations provide an exception to the limitations on requesting or requiring genetic testing, which allows a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test[24] if all of the following conditions of the research exception are satisfied:

- The request must be made pursuant to research that complies with 45 CFR Part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), participants in the research must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the subject is otherwise entitled, and participation may be discontinued at anytime without penalty or loss of benefits to which the subject is entitled when the participant's informed consent is sought (the participant disclosure).[25] These interim final regulations provide that when participants receive the participant disclosure required under 45 CFR 46.116(a)(8) when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.
- The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits or premium or contribution amounts.
- None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.
- The plan or issuer must complete a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" (the Notice) and provide it to the address specified in its instructions. The Notice and instructions are available on the Department of Labor's website (*http://www.dol.gov/ebsa*).

The Departments estimate that up to five entities (consisting of group health plans and health insurance issuers in the group and individual markets) will use the genetic research exception and assume that the requirements of 45 CFR Part 46 will be satisfied. Based on the foregoing, the Departments assume that all group health plans and group health insurance issuers using the exemption will not have to send a disclosure to participants in the genetic research, because they will comply with the requirements of 45 CFR Part 46.116(a)(8). Therefore, the only incremental cost imposed by these interim final regulations will be for the group health plans and group health issuers to send the Notice to the appropriate Department.[26] Because this cost is *de minimis*, it has not been included in this Regulatory Impact Analysis.

[22] This comment may be accessed at the following URL: *http://www.dol.gov/ebsa/regs/cmt-geneticinfoND.html*

[23] Pollitz Karen, *et.al.* "Genetic Discrimination in Health Insurance: Current Legal Protections and Industry Practices." Inquiry, 44: 350–368 (Fall 2007)

[24] Comments indicated that at least one issuer is engaging in a long-term research study involving genetic testing. Others may be planning similar research.

[25] The regulations at 45 CFR 46.116(c) and (d) provide for the waiver or alteration of the requirements for obtaining informed consent in certain cases. However, given the second condition established for this research exception under GINA, it is unlikely that a waiver of informed consent could be granted under 45 CFR 46.116(c) or (d). According to 45 CFR 46.116 (c) and (d), one of the conditions that must be met in order for a waiver to be granted is that the research could not practicably be carried out without the waiver. The second condition of this research exception under GINA states that a plan or issuer may request, but not require, that a participant or beneficiary undergo genetic testing for research purposes only if the plan or issuer makes the request in writing and clearly indicates that compliance with the request is voluntary. Since it is difficult to envision a circumstance where it would be the case that research could not be practicably carried out without a waiver of informed consent under 45 CFR 46.116(c) or (d), and yet be able to satisfy the second condition of this research exception under GINA, we expect that for research studies conducted under the research exception under GINA, it is unlikely that informed consent could be waived under 45 CFR 46.116(c) or (d).

[26] The instructions to the notice will specify the appropriate Department to which the notice should be submitted.

4. Uncertainty

a. Adverse Selection

GINA's prohibition on the use and collection of genetic information could increase the potential for adverse selection in the individual health insurance market. Adverse selection arises when individuals seeking coverage have information about their health risks that issuers do not know.[27]

Such information asymmetry can prevent the insurer from assessing the individual's risk accurately enough to determine the appropriate premium to charge. On average, if issuers do not accurately assess the risks they assume, they will pay more in claims than they receive in premiums. To eliminate this shortfall, issuers may be forced to raise premiums for all insureds. If issuers raise premiums for all insureds, those with a perceived low risk of needing medical care might drop their coverage. This outcome in serious cases may lead to a continued cycle of across-the-board premium increases.

The Departments are not able to measure the extent to which GINA might lead to adverse selection and thereby raise premiums in the individual health insurance market, or whether GINA protections of genetic information will increase the total number of persons insured under individual health insurance policies relative to the number that might leave the market due to increased premiums. Currently, with few tests being performed, the Departments expect the impact to be minimal; however, as the number of tests increases, the effects of adverse selection on the individual health insurance market also could increase and the impact of adverse selection could grow.

b. Impact of GINA on Health Care Expenditures

Another uncertainty associated with GINA and these interim final regulations is whether total health care expenditures will increase or decrease. Whether expenditures will increase or decrease is dependent on a number of factors such as the following: the cost and predictive power of tests, how widely the tests are performed among the population, whether detected gene abnormalities are based on a single gene or also involve environmental and other confounding factors which lower the predictive value of the test and treatment, and whether treatments for detected gene abnormalities are less costly than treatments for the manifested disease.

Genetic testing typically is not covered under individual health insurance policies; group health plans are far more likely to cover both the tests and associated treatments.[28] As the number of genetic tests performed increases, the Departments expect group health care premiums will rise to offset the increased costs to insurers, and any increase or decrease in overall expenditures is expected to result in increased or decreased premiums for the group market.

D. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Because these rules are being issued as interim final regulations, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments expect the rules to reduce the compliance burden imposed on plans and insurers by clarifying definitions and terms contained in the statute and providing examples of acceptable methods to comply with specific provisions. Based on the foregoing, and as further discussed below, the Departments hereby certify that the rule will not have a significant economic impact on a substantial number of small entities.[29]

The Departments expect most of the cost of complying with GINA and the rules to be concentrated among group health plans associated with wellness and disease management programs providing rewards and incentives to employees who complete Health Risk Assessments (HRAs). The Departments estimate that approximately 15,000 (out of 2.4 million) small plans (or 0.00625 of all group health plans) will need to review their HRAs to ensure that genetic information is not used prior to or in connection with enrollment or for underwriting purposes and to make any necessary changes to forms and policies and procedures. This process is estimated to require one-half hour of a legal professional's time at an hourly labor rate of $116 and one-half hour of a clerical staff member's time at an hourly labor rate of $26 resulting in an average cost to the plans of $71 ($58 + $13).

Health insurers in both the group and individual health insurance markets will have to ensure compliance with the GINA and the rules. For this purpose, using the Small Business Administration's definition of a small business as a business with less than $7 million in revenues, premiums earned as a measure of revenue, and data obtained from the National Association of Insurance Commissioners, the Departments estimate that approximately 75 out of 630 insurers had revenues of less that $7 million, and, of these, about 25 had revenues of less than $1 million.

The Departments estimate that each insurer on average would spend 100 hours of professional time at an hourly labor rate of $116 to revise policies and procedures and train underwriters about GINA. This would result in an estimated one time average cost of $11,600 per insurer. For the ap-

[27] For example, individuals who obtain results from genetic tests indicating the risk of contracting a serious medical condition could benefit financially by "choosing the timing of purchases, and the type and level of benefits purchased. This biased selection would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone." American Academy of Actuaries, "Genetic Information and Medical Expense Insurance," June 2000.

[28] American Academy of Actuaries, *Genetic Information and Medical Expense Insurance*. June 2000

[29] For purposes of this certification, the Departments continue to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. The Departments consulted with The Department consulted with the Small Business Administration in making this determination as required by 5 U.S.C. 601(3) and 13 CFR 121.903(c).

proximately 25 insurers with revenues of less than $1 million, this burden could be more than one percent of premiums. However, the estimated costs are an average cost for plans of all sizes, and the Departments expect small insurers to have lower implementation costs, because they have fewer underwriters and other staff members to train.

The Departments invite public comments on this certification.

E. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the Bulletin. Pursuant to section 7805(f) of the Code, these interim final regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

F. Paperwork Reduction Act

1. Department of Labor and Department of the Treasury

As part of their continuing efforts to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

As discussed above, GINA and these interim final regulations provide an exception to the limitations on requesting or requiring genetic testing that allow a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test[30] if all of the following conditions of the research exception set forth in 29 CFR 2590.702A(c)(5) are satisfied:

- The request must be made pursuant to research that complies with 45 CFR Part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at anytime without penalty or loss of benefits to which the subject is entitled (the participant disclosure).[31] These interim final regulations provide that when the participant disclosure is received by participants when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.
- The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits or premium or contribution amounts.
- None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.
- The plan or issuer must complete a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" (the Notice) and provide it to the address specified in its instructions. The Notice and instructions are available on the Department of Labor's website (*http://www.dol.gov/ebsa*).

Two information collection requests (ICRs) are associated with the genetic research exception — the participant disclosure and the notice. The Departments estimate that up to three entities will take advantage of the research exception, and that all of the entities will comply with the requirements of 45 CFR Part 46, including providing the participant disclosure.

The Departments are not soliciting comments concerning an ICR pertaining to the participant disclosure, because these interim final regulations provide that group health plans and group health insurance issuers meeting the requirements of 45 CFR Part 46 are not required to provide additional disclosures, and the Departments have assumed that all entities using the research exemption will meet these requirements. The costs and burdens associated with complying with the participant disclosure requirement already are accounted for in the information collection request for the informed consent requirements contained in 45 CFR Part 46 approved under the Department of Health and Human Services' OMB Control Number (0990–0260).

Currently, the Departments are soliciting comments concerning the notice. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

[30] Comments indicated that at least one issuer is engaging in a long-term research study involving genetic testing. Others may be planning similar research.

[31] While 45 CFR 46.116(c) and (d) permit a waiver of the disclosure otherwise required under 45 CFR 46.116(a)(8), it is unlikely that such a waiver could be granted for research studies conducted under the research exception under GINA. See footnote 25.

- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395–7285 or by email to *oira_submission@omb.eop.gov.* Although comments may be submitted through December 7, 2009, OMB requests that comments be received within 30 days of publication of these interim final regulations to ensure their consideration. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers. E-mail: *ebsa.opr@dol.gov*. ICRs submitted to OMB also are available at reginfo.gov (*http://www.reginfo.gov/public/do/PRAMain*).

The Departments estimate that completing and mailing the notice will require 15 minutes of clerical time at an hourly rate of $26 per hour. Therefore, the total hour burden associated with completing the notice is estimated to be 0.75 hours of clerical time. The cost burden consists of material and mailing cost to mail the two-page notice and is estimated to total $20. Although the Departments share the burden for this ICR, the Departments have agreed to allocate the hour and cost burden associated with the rule entirely to the Department of Labor, because it is so minimal. The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.[32]

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, Department of the Treasury

Title: Notice of Research Exception under the Genetic Information Nondiscrimination Act

OMB Number: 1210–NEW.

Affected Public: Business or other for-profit; not-for-profit institutions.

Respondents: 3.

Responses: 3.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 0.75 hours

Estimated Total Annual Burden Cost: $20

2. Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

a. ICRs Regarding Additional Requirements Prohibiting Discrimination Based on Genetic Information (§146.122)

As stated in the interim final regulations at 45 CFR 146.122(c), there are limitations on requesting or requiring genetic testing. The interim final regulations at 45 CFR 146.122(c)(1) state that a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test. Section 146.122(c)(5) explains the research exception with respect to the limitations on requesting or requiring genetic testing as defined in 45 CFR 146.122(c)(1). Specifically, 45 CFR 146.122(c)(5) states that a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the following conditions are met:

- The request must be made pursuant to research that complies with 45 CFR Part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at anytime without penalty or loss of benefits to which the subject is entitled (the participant disclosure).[33] These interim final regulations provide that when the participant disclosure is received by participants when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.
- The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compli-

[32] 5 CFR 1320.1 through 1320.18

[33] While 45 CFR 46.116(c) and (d) permit a waiver of the disclosure otherwise required under 45 CFR 46.116(a)(8), it is unlikely that such a waiver could be granted for research studies conducted under the research exception under GINA. See footnote 25.

ance with the request is voluntary and noncompliance will have no effect on eligibility for benefits or premium or contribution amounts.
- None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.
- The plan or issuer must complete a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" (the Notice) and provide it to the address specified in its instructions. The notice and instructions are available on the Department of Labor's website (*http://www.dol.gov/ebsa*).

There are two information collection requirements associated with obtaining a GINA research exception. The first is the informed consent requirement as described above. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at anytime without penalty or loss of benefits to which the subject is entitled (the participant disclosure).[34] These interim final regulations provide that when the participant disclosure is received by participants when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.

The burden associated with this requirement is the time and effort necessary to develop, draft, and disseminate the information consent notice to patients. While this requirement is subject to the PRA, the associated burden is already approved under OMB control number 0990–0260. We are not soliciting comments on this requirement at this time.

The second information collection requirement associated with obtaining a GINA research exception is the Notice of Research Exception under the Genetic Information Nondiscrimination Act (the Notice). The burden associated with this requirement is the time and effort necessary for a plan or issuer to complete a copy of the notice and submit it to CMS. CMS also estimates that completing and mailing the notice will require 15 minutes of clerical time at an hourly rate of $26 per hour. Therefore, the total hour burden associated with completing the notice is estimated to be 0.5 hours of clerical time. The cost burden consists of material and mailing cost to mail the two-page notice and is estimated to total $13.

b. ICRs Regarding Prohibition of Discrimination Based on Genetic Information (§148.180)

The information collection requirements affecting the individual health insurance market as stated in 45 CFR 148.180 mirror the information collection requirements affecting the group health insurance market as stated in 45 CFR 146.122. The burden is discussed in detail in section IV.F.2.A. of this preamble. As stated in section IV.F.2.A. we expect no more than a combined total of 2 entities between the group health insurance market and the individual health insurance market to be subject to the information collection requirements contained in this interim final rule.

Estimated Annual Reporting and Recordkeeping Burden

OMB Control No.	Regulation Section(s)	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)
0938–New	45 CFR 146.122	2	2	.25	.50
	45 CFR 148.180				

We have submitted a copy of this interim final rule to OMB for its review and approval of the aforementioned information collection requirements. These requirements are not effective until approved by OMB. Although comments may be submitted through December 7, 2009, OMB requests that comments be received within 30 days of publication of these interim final regulations to ensure their consideration.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–4137–IFC

Fax: (202) 395–7285; or

Email: *OIRA_submission@omb.eop.gov*

Please reference "ICRs Regarding Prohibition of Discrimination Based on Genetic Information (§148.180)" when submitting your comments.

G. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

H. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), as well as Executive Order 12875, these interim final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include mandates which may impose an annual burden of $100 million or more (as adjusted for inflation) on the private sector.

[34] While 45 CFR 46.116(c) and (d) permit a waiver of the disclosure otherwise required under 45 CFR 46.116(a)(8), it is unlikely that such a waiver could be granted for research studies conducted under the research exception under GINA. See footnote 25.

I. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the federal GINA standards prohibiting discrimination based on genetic information.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting State requirements for group health insurance coverage. This amendment applies to the GINA nondiscrimination provisions. With respect to these provisions, States may continue to apply State law requirements except to the extent that such requirements prevent the application of the portability, access, and renewability requirements of HIPAA, which include GINA's nondiscrimination requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the federal requirements are unlikely to "prevent the application of" GINA, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.

GINA provides the Secretary of Labor with the express authority to impose a penalty against any health insurance issuer offering health insurance to a group health plan covered by ERISA for any failure by the issuer to meet the GINA requirements. The States may enforce the provisions of GINA as they pertain to issuers, but the Secretary of HHS is required to enforce any provisions that a State fails to substantially enforce. This relates to HHS' responsibility to enforce the HIPAA nondiscrimination provisions. In exercising its responsibility, HHS works cooperatively with the State for the purpose of addressing the State's concerns and avoiding conflicts with the exercise of State authority. HHS has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. HHS' procedures address the handling of reports that States may not be enforcing HIPAA's requirements, and the mechanism for allocating enforcement responsibility between the States and HHS. In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Department of Labor and HHS have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials. It is expected that the Departments will act in a similar fashion in enforcing the GINA requirements.

In addition, the Departments specifically consulted with the National Association of Insurance Commissioners (NAIC) in developing these interim final regulations. Through the NAIC, the Departments sought and received the input of State insurance departments regarding certain insurance rating practices. The Departments have also cooperated with the States in several ongoing outreach initiatives, through which information on GINA is shared among federal regulators, State regulators, and the regulated community.

Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to GINA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress's intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached interim final regulations in a meaningful and timely manner.

V. Statutory Authority

The Department of the Treasury temporary and final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 USC 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec.101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 USC 651 note); sec. 101(f), Public Law 110–233, 122 Stat. 881; Secretary of Labor's Order 1–2003, 68 FR 5374 (Feb. 3, 2003).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as added by Public Law 104–191, and amended by Public Law 104–204, Public Law 105–277, and Public Law 110–233.

* * * * *

Amendments to the Regulations

Internal Revenue Service
26 CFR Chapter 1

Accordingly, 26 CFR Part 54 is amended as follows:

PART 54 — PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by adding an entry for §54.9802–3T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9802–3T also issued under 26 U.S.C. 9833. * * *

Par. 2. Section 54.9801–1 is amended by revising paragraph (a) and adding paragraph (b)(6) to read as follows:

§54.9801–1 Basis and scope.

(a) *Statutory basis*. This section and sections 54.9801–2 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9802–3T, 54.9811–1, 54.9812–1T, 54.9831–1, and 54.9833–1 (portability sections) implement Chapter 100 of Subtitle K of the Internal Revenue Code of 1986.

(b) * * *

(6) Additional requirements prohibiting discrimination based on genetic information.

* * * * *

Par 3. Section 54.9801–2 is amended by revising the text in the first sentence and revising the entry for Genetic information to read as follows:

§54.9801–2 Definitions.

Unless otherwise provided, the definitions in this section govern in applying the provisions of §54.9801–1, this section, §§54.9801–3 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9802–3T, 54.9811–1, 54.9812–1T, 54.9831–1, and 54.9833–1.

* * * * *

Genetic information has the meaning given the term in §54.9802–3T(a)(3).

* * * * *

Par 4. Section 54.9802–1 is amended by revising paragraphs (a)(1)(vi), (c)(2)(i), (c)(2)(iii), and the introductory text and paragraph (c)(2)(iii) *Example 1* to read as follows:

§54.9802–1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) * * * (1) * * *

(vi) Genetic information, as defined in §54.9802–3T.

* * * * *

(c) * * *

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section*. Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But see §54.9802–3T(b), which prohibits adjustments in group premium or contribution rates based on genetic information.

* * * * *

(iii) *Examples*. The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts*. An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual F had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of F's claims experience.

(ii) *Conclusion*. See *Example 1* in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer does not violate the provisions of 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) similar to the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for F than for a similarly situated individual based on F's claims experience. (However, those examples conclude that if the issuer used genetic information in computing the group rate, it would violate 29 CFR 2590.702–1(b) or 45 CFR 146.122(b).)

* * * * *

Par. 5. Section 54.9831–1 is amended by revising paragraph (b) to read as follows:

§54.9831–1 Special rules relating to group health plans.

* * * * *

(b) *General exception for certain small group health plans*. (1) Subject to paragraph (b)(2) of this section, the requirements of §§54.9801–1 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9811–1, 54.9812–1T, and 54.9833–1 do not apply to any group health plan for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) The exception of paragraph (b)(1) of this section does not apply with respect to the following requirements:

(i) Section 54.9801–3(b)(6).

(ii) Section 54.9802–1(b), as such paragraph applies with respect to genetic information as a health factor.

(iii) Section 54.9802–1(c), as such paragraph applies with respect to genetic information as a health factor.

(iv) Section 54.9802–1(e), as such paragraph applies with respect to genetic information as a health factor.

(v) Section 54.9802–3T(b).

(vi) Section 54.9802–3T(c).

(vii) Section 54.9802–3T(d).

(viii) Section 54.9802–3T(e).

* * * * *

Par. 6. Section 54.9802–3T is added to read as follows:

§54.9802–3T Additional requirements prohibiting discrimination based on genetic information (temporary).

(a) *Definitions*. Unless otherwise provided, the definitions in this paragraph (a) govern in applying the provisions of this section.

(1) *Collect* means, with respect to information, to request, require, or purchase such information.

(2) *Family member* means, with respect to an individual —

(i) A dependent (as defined for purposes of §54.9801–2) of the individual; or

(ii) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(A) First-degree relatives include parents, spouses, siblings, and children.

(B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

(3) *Genetic information* means—

(i) Subject to paragraphs (a)(3)(ii) and (a)(3)(iii) of this section, with respect to an individual, information about—

(A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);

(B) The genetic tests of family members of the individual;

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or

(D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(ii) The term *genetic information* does not include information about the sex or age of any individual.

(iii) The term *genetic information* includes—

(A) With respect to a pregnant woman (or a family member of the pregnant woman), genetic information of any fetus carried by the pregnant woman; and

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member.

(4) *Genetic services* means—

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a BRCA1 or BRCA2 variant is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts*. Individual A is a newborn covered under a group health plan. A undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in A's blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion*. In this *Example*, the PKU screening is a genetic test with respect to A because the screening is an analysis of metabolites that detects a genetic mutation.

(6)(i) *Manifestation* or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this section, a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts*. Individual A has a family medical history of diabetes. A begins to experience excessive sweating, thirst, and fatigue. A's physician examines A and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, A's symptoms, and test results that show elevated levels of blood glucose, A's physician diagnoses A as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion*. In this *Example 1*, A has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to A.

Example 2. (i) *Facts*. Individual B has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). B's physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that B undergo a targeted genetic test to look for the specific mutation found in B's relative to determine if B has an elevated risk for cancer. The genetic test with respect to B showed that B also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. B has a colonoscopy which indicates no signs of disease, and B has no symptoms.

(ii) *Conclusion*. In this *Example 2*, because B has no signs or symptoms of colorectal cancer, B has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to B.

Example 3. (i) *Facts*. Same facts as *Example 2*, except that B's colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, B's physician makes a diagnosis of HNPCC.

(ii) Conclusion. In this *Example 3*, HNPCC is manifested with respect to B because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts*. Individual C has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that C has the Huntington's Disease gene variant. At age 42, C begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. C is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion*. In this *Example 4*, C is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to C.

Example 5. (i) *Facts*. Same facts as *Example 4*, except that C exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to C.

(ii) *Conclusion*. In this *Example 5*, C could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to C.

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general*. For purposes of this section, a group health plan must not adjust premium or contribution amounts for any employer, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, "similarly situated individuals" are those described in §54.9802–1(d).

(2) *Rule of construction*. Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a group health plan to

increase the premium for an employer or for a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for an employer or a group of similarly situated individuals under the plan.

(3) *Examples*. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts*. An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that three individuals covered under the plan had unusually high claims experience. In addition, the issuer finds that the genetic information of two other individuals indicates the individuals have a higher probability of developing certain illnesses although the illnesses are not manifested at this time. The issuer quotes the plan a higher per-participant rate because of both the genetic information and the higher claims experience.

(ii) *Conclusion*. See *Example 1* in 29 CFR 2590.702–1(b)(3) or 45 CFR 146.122(b)(3) for a conclusion that the issuer violates the provisions of 29 CFR 2590.702–1(b) or 45 CFR 146.122(b) similar to the requirements of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of 29 CFR 2590.702–1 or 45 CFR 146.122 similar to the requirements of this section (nor would it violate the requirements of paragraph (c) of 29 CFR 2590.702 or 45 CFR 146.121 similar to the requirements of paragraph (c) of §54.9802–1, which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

Example 2. (i) *Facts*. An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that Employee A has made claims for treatment of polycystic kidney disease. A also has two dependent children covered under the plan. The issuer quotes the plan a higher per-participant rate because of both A's claims experience and the family medical history of A's children (that is, the fact that A has the disease).

(ii) *Conclusion*. See *Example 2* in 29 CFR 2590.702–1(b)(3) or 45 CFR 146.122(b)(3) for a conclusion that the issuer violates the provisions of 29 CFR 2590.702–1(b) or 45 CFR 146.122(b) similar to the requirements of this paragraph (b) because, by taking the likelihood that A's children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in A's children. However, the issuer does not violate the requirements of 29 CFR 2590.702–1(b) or 45 CFR 146.122(b) similar to the requirements of this paragraph (b) by increasing the premium based on A's claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule*. Except as otherwise provided in this paragraph (c), a group health plan must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test*. Nothing in paragraph (c)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples*. The rules of paragraphs (c)(1) and (c)(2) of this section are illustrated by the following examples:

Example 1. (i) *Facts*. Individual A goes to a physician for a routine physical examination. The physician reviews A's family medical history and A informs the physician that A's mother has been diagnosed with Huntington's Disease. The physician advises A that Huntington's Disease is hereditary and recommends that A undergo a genetic test.

(ii) *Conclusion*. In this *Example 1*, the physician is a health care professional who is providing health care services to A. Therefore, the physician's recommendation that A undergo the genetic test does not violate this paragraph (c).

Example 2. (i) *Facts*. Individual B is covered by a health maintenance organization (HMO). *B* is a child being treated for leukemia. B's physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. B's physician recommends that B undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion*. In this *Example 2*, even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to B. Therefore, the physician's recommendation that B undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment*—(i) *In general*. As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, "payment" has the meaning given such term in 45 CFR 164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan is permitted to condition payment for the item or service on the outcome of a genetic test. The plan may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation*. A plan is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in 45 CFR 164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples*. See paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception*. Notwithstanding paragraph (c)(1) of this section, a plan may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations*. The plan makes the request pursuant to research, as defined in 45 CFR 46.102(d), that complies with 45 CFR Part 46 or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research*. The plan makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in §54.9802–1(b)(1)) or premium or contribution amounts.

(iii) *Prohibition on underwriting*. No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies*. The plan completes a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information*—(1) *For underwriting purposes*—(i) *General rule*. A group health plan must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. See paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined*. Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in §54.9802–1(b)(1)(ii) (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(iii) *Medical appropriateness*. If an individual seeks a benefit under a group health plan, the plan may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan is permitted to condition the benefit on the genetic information. A plan is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. See paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment*—(i) *In general.* A group health plan must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan, nor in connection with the rules for eligibility (as defined in §54.9802–1(b)(1)(ii)) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception*—(A) *In general*. If a group health plan obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation*. The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples*. The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts*. A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion*. In this *Example 1*, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

Example 2. (i) *Facts*. The same facts as *Example 1*, except there is no premium reduction or any other reward for completing the health risk assessment.

(ii) *Conclusion*. In this *Example 2*, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 3. (i) *Facts*. A group health plan requests that enrollees complete a health risk assessment prior to enrollment, and includes questions about the individual's family medical history. There is no reward or penalty for completing the health risk assessment.

(ii) *Conclusion*. In this *Example 3*, because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

Example 4. (i) *Facts*. The facts are the same as in *Example 1,* except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

(ii) *Conclusion*. In this *Example 4*, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited under this paragraph (d). Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.

Example 5. (i) *Facts*. A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the

results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion*. In this *Example 5*, no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 6. (i) *Facts*. A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, "Is there anything else relevant to your health that you would like us to know or discuss with you?"

(ii) *Conclusion*. In this *Example 6*, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts*. Same facts as *Example 6*, except that the last question goes on to state, "In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk."

(ii) *Conclusion*. In this *Example 7*, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

Example 8. (i) *Facts*. Issuer M acquires Issuer N. M requests N's records, stating that N should not provide genetic information and should review the records to excise any genetic information. N assembles the data requested by M and, although N reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, M receives genetic information about some of N's covered individuals.

(ii) *Conclusion*. In this *Example 8*, M's request for health information explicitly stated that genetic information should not be provided. See *Example 8* in 29 CFR 2590.702–1(d)(3) or 45 CFR 146.122(d)(3) for a conclusion that the collection of genetic information was within the incidental collection exception of 29 CFR 2590.702–1(d)(2)(ii) or 45 CFR 146.122(d)(ii) similar to the incidental exception of paragraph (d)(2)(ii) of this section. See *Example 8* in 29 CFR 2590.702–1(d)(3) or 45 CFR 146.122(d)(3) also for a caveat that M may not use the genetic information it obtained incidentally for underwriting purposes.

(e) *Examples regarding determinations of medical appropriateness*. The application of the rules of paragraphs (c) and (d) of this section to plan determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts*. Individual A's group health plan covers genetic testing for celiac disease for individuals who have family members with this condition. After A's son is diagnosed with celiac disease, A undergoes a genetic test and promptly submits a claim for the test to A's issuer for reimbursement. The issuer asks A to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion*. See *Example 1* in 29 CFR 2590.702–1(e) or 45 CFR 146.122(e) for a conclusion under the rules of paragraph (c)(4) of 29 CFR 2590.702–1 or 45 CFR 146.122 similar to the rules of paragraph (c)(4) of this section that the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of A's claim, the conclusion in *Example 1* in 29 CFR 2590.702–1(e) or 45 CFR 146.122(e) concludes that the issuer's request for the results of the genetic test violates paragraph (c) of 29 CFR 2590.702–1 or 45 CFR 146.122 similar to paragraph (c) of this section.

Example 2. (i) *Facts*. Individual B's group health plan covers a yearly mammogram for participants and beneficiaries starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. B is 33 years old and has the BRCA2 mutation. B undergoes a mammogram and promptly submits a claim to B's plan for reimbursement. Following an established policy, the plan asks B for evidence of increased risk of breast cancer, such as the results of a genetic test or a family history of breast cancer, before the claim for the mammogram is paid. This policy is applied uniformly to all similarly situated individuals and is not directed at individuals based on any genetic information.

(ii) *Conclusion*. In this *Example 2*, the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts*. Individual C was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of C's physician, C has been taking a regular dose of tamoxifen to help prevent a recurrence. C's group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion*. In this *Example 3*, the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on C's undergoing a genetic test to determine what genetic markers C has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for C.

Example 4. (i) *Facts*. A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion*. In this *Example 4*, the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts*. Same facts as *Example 4*, except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion*. In this *Example 5*, the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts*. Same facts as *Example 4*, except the disease management program provides an enhanced benefit in the form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion*. In this *Example 6*, because the enhanced benefits include benefits not related to the

determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Effective/applicability date*. This section applies for plan years beginning on or after December 7, 2009.

(g) *Expiration date*. This section expires on or before October 1, 2012.

Linda E. Stiff,
Deputy Commissioner for Services and Enforcement.

Approved September 11, 2009.

Michael Mundaca,
Acting Assistant Secretary of the Treasury (Tax Policy).

(Filed by the Office of the Federal Register on October 1, 2009, 11:15 a.m., and published in the issue of the Federal Register for October 7, 2009, 74 F.R. 51663)

Part III. Administrative, Procedural, and Miscellaneous

New Qualified Plug-in Electric Drive Motor Vehicle Credit

Notice 2009–89

Section 1. PURPOSE

This notice sets forth interim guidance, pending the issuance of regulations, relating to the new qualified plug-in electric drive motor vehicle credit under § 30D of the Internal Revenue Code, as in effect for vehicles acquired after December 31, 2009. Specifically, this notice provides procedures for a vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) to certify to the Internal Revenue Service ("Service") both:

(1) That a motor vehicle of a particular make, model, and model year meets certain requirements that must be satisfied to claim the new qualified plug-in electric drive motor vehicle credit under § 30D; and

(2) The amount of the credit allowable with respect to that motor vehicle.

This notice also provides guidance to taxpayers who purchase motor vehicles regarding the conditions under which they may rely on the vehicle manufacturer's (or, in the case of a foreign vehicle manufacturer, its domestic distributor's) certification in determining whether a credit is allowable with respect to the vehicle and the amount of the credit. The Service and the Treasury Department expect that the regulations will incorporate the rules set forth in this notice.

Section 30D originally was enacted in the Energy Improvement and Extension Act of 2008, Pub. L. 110–343, 122 Stat. 3765. The American Recovery and Reinvestment Act of 2009, Pub. L. 111–5, 123 Stat. 115 ("the Act"), amended § 30D in certain material respects, effective for vehicles acquired after December 31, 2009. This notice provides guidance regarding the credit under § 30D for qualified plug-in electric drive motor vehicles acquired after December 31, 2009. All references to § 30D in subsequent sections of this notice are to the provision as amended by the Act. Guidance regarding the credit under § 30D for qualified plug-in electric drive motor vehicles acquired before January 1, 2010, is provided in Notice 2009–54, 2009–26 I.R.B. 1124. This notice also amplifies Notice 2009–54 and Notice 2009–58, 2009–30 I.R.B. 163 (relating to the plug-in electric vehicle credit under § 30) to provide that a vehicle is considered "acquired" when title to that vehicle passes under state law.

Section 2. BACKGROUND

Section 30D provides for a credit for certain new qualified plug-in electric drive motor vehicles. The credit is equal to the sum of: (1) $2,500, plus (2) for a vehicle which draws propulsion energy from a battery with at least 5 kilowatt hours of capacity, $417, plus an additional $417 for each kilowatt hour of battery capacity in excess of 5 kilowatt hours. Under § 30D(b)(3), that portion of the credit determined by battery capacity cannot exceed $5,000. Therefore, the total amount of the credit allowed for a vehicle is limited to $7,500. The new qualified plug-in electric drive motor vehicle credit phases out for a manufacturer's vehicles over the one-year period beginning with the second calendar quarter after the calendar quarter in which at least 200,000 qualifying vehicles manufactured by that manufacturer have been sold for use in the United States (determined on a cumulative basis for sales after December 31, 2009) ("phase-out period"). Qualifying vehicles manufactured by that manufacturer are eligible for 50 percent of the credit if acquired in the first two quarters of the phase-out period and 25 percent of the credit if acquired in the third or fourth quarter of the phase-out period. Vehicles manufactured by that manufacturer are not eligible for a credit if acquired after the phase-out period. After December 31, 2009, a vehicle that qualifies for a credit under § 30 does not qualify for the credit under § 30D.

Section 3. SCOPE OF NOTICE

The new qualified plug-in electric drive motor vehicle credit determined under this notice applies to plug-in electric drive motor vehicles that—

(1) Are placed in service by the taxpayer in a taxable year beginning after December 31, 2009;

(2) Are acquired by the taxpayer after December 31, 2009; and

(3) Otherwise meet the requirements of § 30D.

Section 4. MEANING OF TERMS

The following definitions apply for purposes of this notice:

.01 *In General*. Terms used in this notice and not defined in this section 4 have the same meaning as when used in § 30D.

.02 *Clean Air Act Regulations*. The Clean Air Act regulations are the regulations prescribed by the Administrator of the Environmental Protection Agency for purposes of the administration of Title II of the Clean Air Act (42 U.S.C. §§ 7521, *et. seq.*).

.03 *Battery Capacity*. Battery capacity is the quantity of electricity that a battery is capable of storing, expressed in kilowatt hours, as measured from a 100 percent state of charge to a zero percent state of charge.

.04 *Motor Vehicle*. The term "motor vehicle" means any vehicle that is manufactured primarily for use on public streets, roads, and highways (not including a vehicle operated exclusively on a rail or rails) and which has at least 4 wheels. For purposes of this notice, the term "motor vehicle" does not include a low-speed vehicle within the meaning of section 571.3 of Title 49 of the Code of Federal Regulations, or a vehicle that is manufactured primarily for off-road use, such as primarily for use on a golf course.

.05 *Manufacturer*. The term "manufacturer" has the meaning given that term in the Clean Air Act regulations.

.06 *Model Year*. The term "model year" means the model year determined under the Clean Air Act regulations (see 40 CFR § 86–082–2).

.07 *Acquired*. A vehicle is not "acquired" before the date on which title to that vehicle passes under state law.

Section 5. MANUFACTURER'S CERTIFICATION AND QUARTERLY REPORTS

.01 *When Certification Permitted*. A vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domes-

tic distributor) may certify to purchasers that a motor vehicle of a particular make, model, and model year meets all requirements (other than those listed in section 5.02 of this notice) that must be satisfied to claim the new qualified plug-in electric drive motor vehicle credit allowable under § 30D with respect to the vehicle, if the following requirements are met:

(1) The manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) has submitted to the Service, in accordance with this section 5, a certification with respect to the vehicle and the certification satisfies the requirements of section 5.03 of this notice; and

(2) The manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) has received an acknowledgment of the certification from the Service and the acknowledgment states that purchasers may rely on the certification.

.02 *Purchaser's Reliance*. Except as provided in section 5.07 of this notice, a purchaser of a motor vehicle may rely on the manufacturer's (or, in the case of a foreign vehicle manufacturer, its domestic distributor's) certification concerning the vehicle and the amount of the credit allowable with respect to the vehicle (including in cases in which the certification is received after the purchase of the vehicle). The purchaser may claim a credit in the certified amount with respect to the vehicle if the following requirements are satisfied:

(1) The vehicle is placed in service by the taxpayer in a taxable year beginning after December 31, 2009, and is acquired by the taxpayer after December 31, 2009;

(2) The original use of the vehicle commences with the taxpayer;

(3) The vehicle is acquired for use or lease by the taxpayer, and not for resale; and

(4) The vehicle is used predominantly in the United States.

.03 *Content of Certification*. The certification must contain the following:

(1) The name, address, and taxpayer identification number of the certifying entity.

(2) The make, model, model year, and any other appropriate identifiers of the motor vehicle.

(3) A statement that the vehicle is made by a manufacturer.

(4) A statement that the vehicle is treated as a motor vehicle for purposes of Title II of the Clean Air Act.

(5) The amount of the credit for the vehicle (showing computations).

(6) The gross vehicle weight rating of the vehicle.

(7) A statement that the motor vehicle is propelled to a significant extent by an electric motor that draws electricity from a battery that has a capacity of not less than 4 kilowatt hours.

(8) The number of kilowatt hours if any, in excess of 4 kilowatt hours.

(9) A statement that the battery is capable of being recharged from an external source of electricity.

(10) A statement that the vehicle has at least four wheels.

(11) A statement that the vehicle is not a low-speed vehicle within the meaning of section 571.3 of Title 49 of the Code of Federal Regulations.

(12) A statement that the vehicle is manufactured primarily for use on public streets, roads and highways.

(13) A statement that the vehicle is not manufactured primarily for off-road use, such as primarily for use on a golf course.

(14) A statement that the vehicle complies with the applicable provisions of the Clean Air Act.

(15) A statement that the vehicle complies with the applicable air quality provisions of state law of each state that has adopted the provisions under a waiver under § 209(b) of the Clean Air Act or a list identifying each state that has adopted applicable air quality provisions with which the vehicle does not comply.

(16) A description of the motor vehicle safety provisions of 49 U.S.C. §§ 30101 through 30169 applicable to the vehicle and a statement that the vehicle complies with those provisions.

(17) A declaration, applicable to the certification, statements, and any accompanying documents, signed by a person currently authorized to bind the manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) in these matters, in the following form: "Under penalties of perjury, I declare that I have examined this certification, including accompanying documents, and to the best of my knowledge and belief, the facts presented in support of this certification are true, correct, and complete."

.04 *Acknowledgement of Certification*. The Service will review the original signed certification and issue an acknowledgment letter to the vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) within 30 days of receipt of the request for certification. This acknowledgment letter will state whether purchasers may rely on the certification.

.05 *Quarterly Reporting of Sales of Qualified Vehicles*. A manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) that has received an acknowledgment of its certification from the Service must submit to the Service, in accordance with section 6 of this notice, a report of the number of qualified plug-in electric drive motor vehicles sold by the manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) to consumers or retail dealers during the calendar quarter. The quarterly report must contain the following:

(1) The name, address, and taxpayer identification number of the reporting entity.

(2) The number of qualified vehicles sold by the reporting entity to consumers or retail dealers during the calendar quarter.

(3) The make, model, model year, and any other appropriate identifiers of the qualified vehicles sold during the calendar quarter.

(4) A declaration, applicable to the quarterly report and any accompanying documents, signed by a person currently authorized to bind the manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) in these matters, in the following form: "Under penalties of perjury, I declare that I have examined this report, including accompanying documents, and to the best of my knowledge and belief, the facts presented in support of this report are true, correct, and complete."

.06 *Acknowledgment of Quarterly Report*. The Service will review the original signed quarterly report and issue an acknowledgment letter to the vehicle manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) within 30 days of receipt of the report. This acknowledgment letter will state whether purchasers may continue to rely on the certification.

.07 *Effect of Erroneous Certification, Erroneous Quarterly Reports, or Failure to Make Timely Quarterly Reports*.

(1) *Erroneous Certification or Quarterly Report*. The acknowledgment that the Service provides for a certification is not a determination that a vehicle qualifies for the credit, or that the amount of the credit is correct. The Service may, upon examination (and after any appropriate consultation with the Department of Transportation or the Environmental Protection Agency), determine that the vehicle is not a new qualified plug-in electric drive motor vehicle or that the amount of the credit determined by the manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) to be allowable with respect to the vehicle is incorrect. In either event, or in the event that the manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) makes an erroneous quarterly report, the manufacturer's (or, in the case of a foreign vehicle manufacturer, its domestic distributor's) right to provide a certification to future purchasers of the new qualified plug-in electric drive motor vehicles will be withdrawn, and purchasers who acquire a vehicle after the date on which the Service publishes an announcement of the withdrawal may not rely on the certification. Purchasers may continue to rely on the certification for vehicles they acquired on or before the date on which the announcement of the withdrawal is published (including in cases in which the vehicle is not placed in service and the credit is not claimed until after that date), and the Service will not attempt to collect any understatement of tax liability attributable to such reliance. Manufacturers (or, in the case of foreign vehicle manufacturers, their domestic distributors) are reminded that an erroneous certification or an erroneous quarterly report may result in the imposition of penalties, including, but not limited to, the penalties:

(a) Under § 7206 for fraud and making false statements; and

(b) Under § 6701 for aiding and abetting an understatement of tax liability in the amount of $1,000 ($10,000 in the case of understatements by corporations) per return on which a credit is claimed in reliance on the certification.

(2) *Failure to Make Timely Quarterly Report*. If a manufacturer (or, in the case of a foreign vehicle manufacturer, its domestic distributor) fails to make a quarterly report in accordance with section 5.05 of this notice and at the time specified in section 6.02 of this notice, the acknowledgment letter issued under section 5.04 of this notice may be withdrawn, and purchasers will not be entitled to rely on the related certification for quarters beginning after the date on which the Service publishes an announcement of the withdrawal (generally, quarters beginning after the due date of the report). If the quarterly report is filed subsequently, the Service may reissue the acknowledgment letter and retract the withdrawal announcement.

Section 6. TIME AND ADDRESS FOR FILING CERTIFICATION AND QUARTERLY REPORTS

.01 *Time for Filing Certification*. In order for a certification under section 5 of this notice to be effective for new qualified plug-in electric drive motor vehicles placed in service during a calendar year, the certification must be received by the Service not later than December 31 of that calendar year.

.02 *Time for Filing Quarterly Reports*. A report of sales of qualified vehicles during a quarter must be filed with the Service at the address specified in section 6.03 of this notice not later than the last day of the first calendar month following the quarter to which the report relates.

.03 *Address for Filing*. Certifications and quarterly reports under section 5 of this notice must be sent to:

Internal Revenue Service
Industry Director, LMSB, Heavy Manufacturing & Transportation
Metro Park Office Complex — LMSB
111 Wood Avenue, South
Iselin, New Jersey 08830

Section 7. PAPERWORK REDUCTION ACT

The collection of information contained in this notice has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–2137.

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 and 6. This information is collected and retained in order to ensure that vehicles meet the requirements for the new qualified plug-in electric drive motor vehicle credit under § 30D. This information will be used to determine whether the vehicle for which the credit is claimed by a taxpayer is property that qualifies for the credit. The collection of information is voluntary to obtain a benefit. The likely respondents are corporations and partnerships.

The estimated total annual reporting burden is 280 hours.

The estimated annual burden per respondent varies from 20 hours to 35 hours, depending on individual circumstances, with an estimated average burden of 24 hours to complete the certification required under this notice. The estimated number of respondents is 12.

The estimated annual frequency of responses is on occasion.

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

Section 8. DATE OF APPLICABILITY

This notice is applicable to plug-in electric drive motor vehicles acquired (within the meaning of section 4.07 of this notice) after December 31, 2009.

Section 9. EFFECT ON OTHER DOCUMENTS

Notice 2009–54, 2009–26 I.R.B. 1124, is amplified by adding the following sentence to section 4:

.09 *Acquired*. A vehicle is not "acquired" before the date on which title to that vehicle passes under state law.

Notice 2009–58, 2009–30 I.R.B. 163, is amplified by adding the following sentence to section 4:

.06 *Acquired*. A vehicle is not "acquired" before the date on which title to that vehicle passes under state law.

Notice 2009–54 is superseded, effective for plug-in electric drive motor vehicles acquired after December 31, 2009.

Section 10. DRAFTING INFORMATION

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).

Withholding on Wages of Nonresident Alien Employees Performing Services Within the United States

Notice 2009–91

I. PURPOSE

This notice modifies the rules in Notice 2005–76, 2005–2 C.B. 947, for determining the amount of income tax employers must withhold under section 3402 of the Internal Revenue Code (Code) from wages paid for services performed by nonresident alien employees within the United States. The modification is effective with respect to wages paid on or after January 1, 2010.

Notice 2005–76 provides rules for determining the amount of withholding on wages paid to nonresident alien employees. These rules need to be modified to reflect changes made in the withholding tables as a result of the enactment of section 36A of the Code (the "Making Work Pay Tax Credit") in the American Recovery and Reinvestment Act of 2009 (Public Law No. 111–5) (ARRA). Nonresident alien individuals are not eligible for the Making Work Pay Tax Credit under section 36A. The modified rules provide for withholding on the wages of nonresident alien employees that more closely approximates their income tax liability.

II. BACKGROUND

A. Income Tax Withholding on Wages of Nonresident Alien Employees

Generally, employers are liable for the withholding of income tax on remuneration for services performed within the United States by a nonresident alien employee. Section 3402(a)(1) of the Code provides that, except as otherwise provided in section 3402, every employer making a payment of wages shall deduct and withhold from such wages a tax determined in accordance with tables or computational procedures prescribed by the Secretary. Section 3402(a)(1) further provides that any tables or procedures prescribed under section 3402(a)(1) shall be in such form, and provide for such amounts to be deducted and withheld, as the Secretary determines to be appropriate to carry out the purposes of chapter 1 (imposition of individual income tax).

Income tax withholding tables in Publication 15, *(Circular E) Employer's Tax Guide*, for use with the percentage and wage bracket methods of withholding, are based on the assumption that the employee receiving the wages is entitled to a standard deduction in determining his or her income tax liability. However, in the case of a nonresident alien individual, section 63(c)(6)(B) provides that the standard deduction shall be zero. Notice 2005–76 addresses this difference in treatment by directing an employer to add an amount to the wages of a nonresident alien employee solely for purposes of calculating the income tax withholding for each payroll period.

B. Making Work Pay Tax Credit

Section 36A, which was added to the Code by the ARRA, provides a credit against income tax to an eligible individual in an amount equal to the lesser of (1) 6.2 percent of earned income, or (2) $400 ($800 in the case of a joint return). The credit is reduced or completely eliminated for individuals with modified adjusted gross income exceeding threshold amounts. Section 36A(d)(1)(A)(i) provides that an eligible individual for purposes of section 36A does not include a nonresident alien individual. As currently enacted, the Making Work Pay Tax Credit does not apply to taxable years beginning after December 31, 2010. *See* section 36A(e). Under the ARRA, taxpayers' reduced tax liability under the provision is expeditiously implemented through revised income tax withholding. *See* H.R. Conf. Rep. 111–16, 111th Cong., 1st Sess. (2009) at 517. Accordingly, the income tax withholding tables have been revised to take the Making Work Pay Tax Credit into account in determining the amount of income tax to be withheld.

C. Reason for Change to Withholding Procedures for Nonresident Alien Employees

The income tax withholding tables reflect two tax benefits for which nonresident alien employees are not eligible: (1) the standard deduction; and (2) the Making Work Pay Tax Credit. If adjustments from the generally applicable procedures for using the income tax withholding tables are not made in determining income tax withholding for nonresident alien employees, the withholding on the wages of such employees will generally be less than their tax liability. This notice modifies the rules for employers to use in calculating income tax withholding on nonresident alien employees to offset the effects of both the standard deduction and Making Work Pay Tax Credit as assumed under the withholding tables.

The modification applies only to the procedure used by employers in calculating income tax withholding on wages paid to nonresident alien employees as set forth in part III.B. of Notice 2005–76. The requirements in Notice 2005–76 (part III.A.) relating to the completion of Form W–4, *Employee's Withholding Allowance Certificate*, by nonresident alien employees, continue in effect.

III. WITHHOLDING RULES THAT WILL BE IN EFFECT FOR NONRESIDENT ALIEN EMPLOYEES ON OR AFTER JANUARY 1, 2010

Beginning with wages paid on or after January 1, 2010, employers are required to calculate income tax withholding under section 3402 of the Code on wages of nonresident alien employees by making two modifications rather than the one modification described in Notice 2005–76 (part III.B). First, employers need to add an amount to wages before determining withholding under the wage bracket or percentage method in order to offset the standard deduction built into the withholding tables. Second, employers need to determine an additional amount of withholding from a separate table applicable only to nonresident alien employees to offset the effect of

the Making Work Pay Tax Credit built into the withholding tables. The specific steps to be followed for each of these two modifications will be set forth in Publication 15 and other IRS forms or publications.

IV. EFFECT ON OTHER DOCUMENTS

Notice 2005–76 is modified for wages paid after December 31, 2009, during any period when the Making Work Pay Tax Credit provided under section 36A is in effect.

V. DRAFTING INFORMATION

The principal author of this notice is Alfred G. Kelley of the Office of Associate Chief Counsel (Tax Exempt & Government Entities). For further information regarding this notice, contact Alfred G. Kelley at (202) 622–6040 (not a toll-free call).

Part IV. Items of General Interest

Notice of Proposed Rulemaking by Cross-Reference to Temporary Regulations

Genetic Information Nondiscrimination Act

REG–123829–08

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: Elsewhere in this issue of the Bulletin, the IRS is issuing temporary and final regulations governing the provisions of the Genetic Information Nondiscrimination Act (GINA) prohibiting discrimination based on genetic information for group health plans. The IRS is issuing the temporary and final regulations at the same time that the Employee Benefits Security Administration of the U.S. Department of Labor and the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services are issuing substantially similar interim final regulations with respect to GINA for group health plans and issuers of health insurance coverage offered in connection with a group health plan under the Employee Retirement Income Security Act of 1974 and the Public Health Service Act. The temporary regulations provide guidance to employers and group health plans relating to the group health plan genetic nondiscrimination requirements. The text of those temporary regulations (T.D. 9464) also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by January 5, 2010. ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–123829–08), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered to: CC:PA:LPD:PR (REG–123829–08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224. Alternatively, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–123829–08).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Russ Weinheimer at 202–622–6080; concerning submissions of comments, Oluwafumilayo Taylor at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information referenced in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the **Office of Management and Budget**, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the **Internal Revenue Service**, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by December 7, 2010. Comments are specifically requested concerning:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the proposed collection of information (see the preamble to the temporary regulations published elsewhere in this issue of the Bulletin);
- How to enhance the quality, utility, and clarity of the information to be collected;
- How to minimize the burden of complying with the proposed collection of information, including the application of automated collection techniques or other forms of information technology; and
- Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information is in §54.9802–3 (see the temporary regulations published elsewhere in this issue of the Bulletin). The collection of information is required so that the IRS can be apprised when a group health plan is conducting research with respect to genetic information of plan participants or beneficiaries to ensure that all the requirements of the research exception to GINA are being complied with. The likely respondents are business or other for-profit institutions, and nonprofit institutions. Responses to this collection of information are required if a plan wishes to conduct genetic research with respect to participants or beneficiaries of the plan.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

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

Background

The temporary regulations published elsewhere in this issue of the Bulletin add a new §54.9802–3T to the Miscellaneous Excise Tax Regulations. In the same document, certain conforming changes are also being made to the final regulations under §§54.9801–1, 54.9801–2, 54.9802–1, and 54.9831–1. The proposed, temporary, and final regulations are being published as part of a joint rulemaking with the Department of Labor and the Department of Health and Human Services (the joint rulemaking). The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this proposed regulation. It is hereby certified that the collection of information contained in this notice of proposed rulemaking will not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. GINA requires group health plans claiming the research exception to GINA to notify the Secretary of the Treasury when the exception is being claimed. This notice of proposed rulemaking does not add to the reporting requirement imposed by the statute. Moreover, it is anticipated that very few and only the largest group health plans are likely to claim the research exception to GINA and thus be subject to the reporting requirement. For this reason, the burden imposed by the reporting requirement of the statute and this notice of proposed rulemaking on small entities is expected to be near zero. For further information and for analyses relating to the joint rulemaking, see the preamble to the joint rulemaking. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. Comments are specifically requested on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Russ Weinheimer, Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), IRS. The proposed regulations, as well as the temporary and final regulations, have been developed in coordination with personnel from the U.S. Department of Labor and the U.S. Department of Health and Human Services.

* * * * *

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 54.9802–3 also issued under 26 U.S.C. 9833. * * *

Par. 2. Section 54.9802–3 is added to read as follows:

§54.9802–3 Additional requirements prohibiting discrimination based on genetic information.

[The text of proposed §54.9802–3 is the same as the text of §54.9802–3T published elsewhere in this issue of the Bulletin].

Linda E. Stiff,
Deputy Commissioner for Services and Enforcement.

(Filed by the Office of the Federal Register on October 1, 2009, 11:15 a.m., and published in the issue of the Federal Register for October 7, 2009, 74 F.R. 51710)

Effective Date of Regulations Under § 411(b)(5)(B)(i); Relief Under § 411(d)(6); and Notice to Pension Plan Participants

Announcement 2009–82

The Treasury Department and the Internal Revenue Service are announcing relief for sponsors of statutory hybrid plans that must amend the interest crediting rate in those plans. Plan sponsors may rely on this announcement pending publication of the anticipated additional guidance described below.

Treasury and the Service expect to issue in the near future final regulations and proposed regulations relating to statutory hybrid plans. The regulations will include rules interpreting the requirement in § 411(b)(5)(B)(i) of the Internal Revenue Code that such plans not have an interest crediting rate in excess of a market rate of return. The rules in the regulations specifying permissible market rates of return are not expected to go into effect before the first plan year that begins on or after January 1, 2011.

In addition, it is anticipated that Treasury and the Service will exercise the authority under § 1.411(d)–4, A–2(b)(2)(i) of the Treasury regulations to provide that, once final regulations regarding the market rate of return requirements are issued, an amendment to a statutory hybrid plan with an interest crediting rate that is in excess of a market rate of return under those final regulations that is adopted prior to the effective date of those final regulations will not violate § 411(d)(6) merely because it reduces the future interest crediting rate on participants' account balances to the extent necessary to constitute a permissible rate under those final regulations. Under this anticipated guidance, § 411(d)(6) will not operate to bar such an amendment, even if the amendment is adopted after the last day of the first plan year that begins on or after January 1, 2009, and therefore is not an amendment described in section 1107 of the Pension Protection Act of 2006 (PPA '06), Pub. L. 109–280. Section 1107 of PPA '06 provides, in general, that a plan will not fail to satisfy § 411(d)(6) as a result of amendments that are adopted pursuant to PPA '06 or regulations thereunder by the last day of the first plan year that begins on or after January 1, 2009.

Finally, it is anticipated that future guidance will include a special timing rule for providing section 204(h) notice, as defined in § 54.4980F–1, Q&A–4, to participants and other applicable individuals with respect to an amendment that changes a statutory hybrid plan's interest crediting rate that is adopted by the last day of the first plan year that begins on or after January 1, 2009 (that is, by the

end of the period described in section 1107 of PPA '06) and after November 10, 2009. Under this special timing rule, any required section 204(h) notice relating to such an amendment will be permitted to be provided as late as 30 days after the effective date of the amendment. It is expected that this relief will apply to an amendment only if the amendment is effective not later than the first day of the first plan year that begins on or after January 1, 2010.

For further information regarding this announcement, please email *RetirementPlanQuestions@irs.gov*.

Definition of Terms

Revenue rulings and revenue procedures (hereinafter referred to as "rulings") that have an effect on previous rulings use the following defined terms to describe the effect:

Amplified describes a situation where no change is being made in a prior published position, but the prior position is being extended to apply to a variation of the fact situation set forth therein. Thus, if an earlier ruling held that a principle applied to A, and the new ruling holds that the same principle also applies to B, the earlier ruling is amplified. (Compare with *modified*, below).

Clarified is used in those instances where the language in a prior ruling is being made clear because the language has caused, or may cause, some confusion. It is not used where a position in a prior ruling is being changed.

Distinguished describes a situation where a ruling mentions a previously published ruling and points out an essential difference between them.

Modified is used where the substance of a previously published position is being changed. Thus, if a prior ruling held that a principle applied to A but not to B, and the new ruling holds that it applies to both A and B, the prior ruling is modified because it corrects a published position. (Compare with *amplified* and *clarified*, above).

Obsoleted describes a previously published ruling that is not considered determinative with respect to future transactions. This term is most commonly used in a ruling that lists previously published rulings that are obsoleted because of changes in laws or regulations. A ruling may also be obsoleted because the substance has been included in regulations subsequently adopted.

Revoked describes situations where the position in the previously published ruling is not correct and the correct position is being stated in a new ruling.

Superseded describes a situation where the new ruling does nothing more than restate the substance and situation of a previously published ruling (or rulings). Thus, the term is used to republish under the 1986 Code and regulations the same position published under the 1939 Code and regulations. The term is also used when it is desired to republish in a single ruling a series of situations, names, etc., that were previously published over a period of time in separate rulings. If the new ruling does more than restate the substance of a prior ruling, a combination of terms is used. For example, *modified* and *superseded* describes a situation where the substance of a previously published ruling is being changed in part and is continued without change in part and it is desired to restate the valid portion of the previously published ruling in a new ruling that is self contained. In this case, the previously published ruling is first modified and then, as modified, is superseded.

Supplemented is used in situations in which a list, such as a list of the names of countries, is published in a ruling and that list is expanded by adding further names in subsequent rulings. After the original ruling has been supplemented several times, a new ruling may be published that includes the list in the original ruling and the additions, and supersedes all prior rulings in the series.

Suspended is used in rare situations to show that the previous published rulings will not be applied pending some future action such as the issuance of new or amended regulations, the outcome of cases in litigation, or the outcome of a Service study.

Abbreviations

The following abbreviations in current use and formerly used will appear in material published in the Bulletin.

A—Individual.
Acq.—Acquiescence.
B—Individual.
BE—Beneficiary.
BK—Bank.
B.T.A.—Board of Tax Appeals.
C—Individual.
C.B.—Cumulative Bulletin.
CFR—Code of Federal Regulations.
CI—City.
COOP—Cooperative.
Ct.D.—Court Decision.
CY—County.
D—Decedent.
DC—Dummy Corporation.
DE—Donee.
Del. Order—Delegation Order.
DISC—Domestic International Sales Corporation.
DR—Donor.
E—Estate.
EE—Employee.
E.O.—Executive Order.
ER—Employer.
ERISA—Employee Retirement Income Security Act.
EX—Executor.
F—Fiduciary.
FC—Foreign Country.
FICA—Federal Insurance Contributions Act.
FISC—Foreign International Sales Company.
FPH—Foreign Personal Holding Company.
F.R.—Federal Register.
FUTA—Federal Unemployment Tax Act.
FX—Foreign corporation.
G.C.M.—Chief Counsel's Memorandum.
GE—Grantee.
GP—General Partner.
GR—Grantor.
IC—Insurance Company.
I.R.B.—Internal Revenue Bulletin.
LE—Lessee.
LP—Limited Partner.
LR—Lessor.
M—Minor.
Nonacq.—Nonacquiescence.
O—Organization.
P—Parent Corporation.
PHC—Personal Holding Company.
PO—Possession of the U.S.
PR—Partner.
PRS—Partnership.
PTE—Prohibited Transaction Exemption.
Pub. L.—Public Law.
REIT—Real Estate Investment Trust.
Rev. Proc.—Revenue Procedure.
Rev. Rul.—Revenue Ruling.
S—Subsidiary.
S.P.R.—Statement of Procedural Rules.
Stat.—Statutes at Large.
T—Target Corporation.
T.C.—Tax Court.
T.D. —Treasury Decision.
TFE—Transferee.
TFR—Transferor.
T.I.R.—Technical Information Release.
TP—Taxpayer.
TR—Trust.
TT—Trustee.
U.S.C.—United States Code.
X—Corporation.
Y—Corporation.
Z —Corporation.

Numerical Finding List[1]

Bulletins 2009–27 through 2009–48

Announcements:

Notices:

Notices— Continued:

Proposed Regulations:

Revenue Procedures:

Revenue Rulings:

Tax Conventions:

Treasury Decisions:

[1] A cumulative list of all revenue rulings, revenue procedures, Treasury decisions, etc., published in Internal Revenue Bulletins 2009–1 through 2009–26 is in Internal Revenue Bulletin 2009–26, dated June 29, 2009.

Finding List of Current Actions on Previously Published Items[1]

Bulletins 2009–27 through 2009–48

Announcements:

2006-93
Superseded by
Ann. 2009-62, 2009-33 I.R.B. *247*

Notices:

2002-3
Modified and superseded by
Notice 2009-68, 2009-39 I.R.B. *423*

2004-67
Supplemented and superseded by
Notice 2009-59, 2009-31 I.R.B. *170*

2005-76
Modified by
Notice 2009-91, 2009-48 I.R.B. *717*

2006-70
Obsoleted by
T.D. 9453, 2009-28 I.R.B. *114*

2006-109
Superseded in part by
Rev. Proc. 2009-32, 2009-28 I.R.B. *142*

2007-7
Modified by
Notice 2009-82, 2009-41 I.R.B. *491*

2008-30
Amplified and clarified by
Notice 2009-75, 2009-39 I.R.B. *436*

2008-43
Obsoleted by
REG-113289-08, 2009-33 I.R.B. *244*

2009-28
Clarified by
Notice 2009-69, 2009-35 I.R.B. *261*

2009-31
Amplified by
Rev. Proc. 2009-43, 2009-40 I.R.B. *460*

2009-42
Amplified by
Rev. Proc. 2009-43, 2009-40 I.R.B. *460*

2009-54
Amplified by
Notice 2009-89, 2009-48 I.R.B. *714*

2009-58
Amplified by
Notice 2009-89, 2009-48 I.R.B. *714*

Proposed Regulations:

REG-130200-08
Hearing cancelled by
Ann. 2009-81, 2009-46 I.R.B. *647*

Revenue Procedures:

97-27
Clarified and modified by
Rev. Proc. 2009-39, 2009-38 I.R.B. *371*

97-49
Modified and superseded by
Rev. Proc. 2009-31, 2009-27 I.R.B. *107*

2002-44
Superseded by
Rev. Proc. 2009-44, 2009-40 I.R.B. *462*

2002-59
Superseded by
Rev. Proc. 2009-41, 2009-39 I.R.B. *439*

2005-63
Modified by
Rev. Proc. 2009-39, 2009-38 I.R.B. *371*

2007-44
Modified by
Rev. Proc. 2009-36, 2009-35 I.R.B. *304*

2007-65
Modified by
Ann. 2009-69, 2009-40 I.R.B. *475*

2008-34
Superseded by
Rev. Proc. 2009-46, 2009-42 I.R.B. *507*

2008-38
Superseded by
Rev. Proc. 2009-30, 2009-27 I.R.B. *27*

2008-44
Superseded by
Rev. Proc. 2009-35, 2009-35 I.R.B. *265*

2008-52
Amplified, clarified, and modified by
Rev. Proc. 2009-39, 2009-38 I.R.B. *371*

2008-59
Superseded by
Rev. Proc. 2009-47, 2009-42 I.R.B. *524*

2008-65
Modified by
Rev. Proc. 2009-33, 2009-29 I.R.B. *150*

2009-16
Modified by
Rev. Proc. 2009-33, 2009-29 I.R.B. *150*

2009-39
Modified by
Ann. 2009-67, 2009-38 I.R.B. *388*

Revenue Rulings:

74-346
Superseded by
Rev. Rul. 2009-34, 2009-42 I.R.B. *502*

75-190
Superseded by
Rev. Rul. 2009-34, 2009-42 I.R.B. *502*

75-398
Superseded by
Rev. Rul. 2009-34, 2009-42 I.R.B. *502*

75-526
Superseded by
Rev. Rul. 2009-34, 2009-42 I.R.B. *502*

2009-22
Corrected by
Ann. 2009-74, 2009-42 I.R.B. *537*

2009-29
Corrected by
Ann. 2009-74, 2009-42 I.R.B. *537*

Treasury Decisions:

9456
Corrected by
Ann. 2009-73, 2009-41 I.R.B. *500*

[1] A cumulative list of current actions on previously published items in Internal Revenue Bulletins 2009–1 through 2009–26 is in Internal Revenue Bulletin 2009–26, dated June 29, 2009.

INDEX

Internal Revenue Bulletin 2009–27 through 2009–48

The abbreviation and number in parenthesis following the index entry refer to the specific item; numbers in roman and italic type following the parenthesis refers to the Internal Revenue Bulletin in which the item may be found and the page number on which it appears.

Key to Abbreviations:

Ann	Announcement
CD	Court Decision
DO	Delegation Order
EO	Executive Order
PL	Public Law
PTE	Prohibited Transaction Exemption
RP	Revenue Procedure
RR	Revenue Ruling
SPR	Statement of Procedural Rules
TC	Tax Convention
TD	Treasury Decision
TDO	Treasury Department Order

EMPLOYEE PLANS

EMPLOYEE PLANS—Cont.

EMPLOYMENT TAX

ESTATE TAX

INCOME TAX—Cont.

INCOME TAX—Cont.

INCOME TAX—Cont.

U.S. GOVERNMENT PRINTING OFFICE
KEEPING AMERICA INFORMED

Order Processing Code: 3465

Easy Secure Internet: bookstore.gpo.gov

Internal Revenue Cumulative Bulletins Publications and Subscription Order Form

Toll Free: 866 512-1800
DC Area: 202 512-2800
Fax: 202 512-2250

Mail: Superintendent of Documents
P.O. Box 371954
Pittsburgh, PA 15250-7954

Publications

Qty.	Stock Number	Title	Price Each	Total Price
	048–004–02467–5	Cum. Bulletin 1999–3	20.40	
	048–004–02462–4	Cum. Bulletin 2001–2 (Jul-Dec)	24.00	
	048–004–02480–2	Cum. Bulletin 2001–3	71.00	
	048–004–02470–5	Cum. Bulletin 2002–2 (Jul-Dec)	28.80	
	048–004–02486–1	Cum. Bulletin 2002–3	54.00	
	048–004–02483–7	Cum. Bulletin 2004–2 (July–Dec)	54.00	
	048–004–02488–8	Cum. Bulletin 2005–2	56.00	
			Total for Publications	

Subscriptions

Qty.	List ID	Title	Price Each	Total Price
	IRS	Internal Revenue Bulletin	$247	
		Optional – Add $50 to open Deposit Account		
			Total for Subscriptions	
			Total for Publications and Subscriptions	

NOTE: Price includes regular shipping and handling and is subject to change. International customers please add 40 percent.

Standing Order Service*

To automatically receive future editions of *Internal Revenue Cumulative Bulletins* without having to initiate a new purchase order, sign below for Standing Order Service.

Qty.	Standing Order	Title
	ZIRSC	Internal Revenue Cumulative Bulletins

Authorization

I hereby authorize the Superintendent of Documents to charge my account for Standing Order Service:
(enter account information at right)

❑ VISA ❑ MasterCard ❑ Discover/NOVUS ❑ American Express

❑ Superintendent of Documents (SOD) Deposit Account

Authorizing signature (Standing orders not valid unless signed.)

_____

Please print or type your name.

Daytime phone number (_____) _____

SuDocs Deposit Account

A Deposit Account will enable you to use Standing Order Service to receive subsequent volumes quickly and automatically. For an initial deposit of $50 you can establish your Superintendent of Documents Deposit Account.

❑ **YES!** Open a SOD Deposit Account for me so I can order future publications quickly and easily.
I am enclosing the $50 initial deposit.

Check method of payment:

❑ Check payable to Superintendent of Documents

❑ SOD Deposit Account ☐☐☐☐☐☐☐ – ☐

❑ VISA ❑ MasterCard ❑ Discover/Novus ❑ American Express

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

☐☐☐☐ (expiration date)

Thank you for your Order!

Authorizing signature 06/06

Company or personal name (Please type or print)

Additional address/attention line

Street address

City, State, Zip Code

E-mail address

Daytime phone including area code

Purchase order number (optional)

*Standing Order Service

Just sign the authorization above to charge selected items to your existing Deposit Account, VISA or MasterCard, Discover/NOVUS, or American Express account. Or open a Deposit Account with an initial deposit of $50 or more. Your account will be charged only as each volume is issued and mailed. Sufficient money must be kept in your account to insure that items are shipped. Service begins with the next issue released of each item you select.

You will receive written acknowledgement for each item you choose to receive by Standing Order Service.

If you wish to cancel your Standing Order Service, please notify the Superintendent of Documents in writing (telephone cancellations are accepted, but must be followed up with a written cancellation within 10 days).

Important: Please include this completed order form with your payment.

INTERNAL REVENUE BULLETIN

The Introduction at the beginning of this issue describes the purpose and content of this publication. The weekly Internal Revenue Bulletin is sold on a yearly subscription basis by the Superintendent of Documents. Current subscribers are notified by the Superintendent of Documents when their subscriptions must be renewed.

CUMULATIVE BULLETINS

The contents of this weekly Bulletin are consolidated semiannually into a permanent, indexed, Cumulative Bulletin. These are sold on a single copy basis and *are not* included as part of the subscription to the Internal Revenue Bulletin. Subscribers to the weekly Bulletin are notified when copies of the Cumulative Bulletin are available. Certain issues of Cumulative Bulletins are out of print and are not available. Persons desiring available Cumulative Bulletins, which are listed on the reverse, may purchase them from the Superintendent of Documents.

ACCESS THE INTERNAL REVENUE BULLETIN ON THE INTERNET

You may view the Internal Revenue Bulletin on the Internet at www.irs.gov. Select Businesses. Under Businesses Topics, select More Topics. Then select Internal Revenue Bulletins.

INTERNAL REVENUE BULLETINS ON CD-ROM

Internal Revenue Bulletins are available annually as part of Publication 1796 (Tax Products CD-ROM). The CD-ROM can be purchased from National Technical Information Service (NTIS) on the Internet at www.irs.gov/cdorders (discount for online orders) or by calling 1-877-233-6767. The first release is available in mid-December and the final release is available in late January.

HOW TO ORDER

Check the publications and/or subscription(s) desired on the reverse, complete the order blank, enclose the proper remittance, detach entire page, and mail to the Superintendent of Documents, P.O. Box 371954, Pittsburgh PA, 15250–7954. Please allow two to six weeks, plus mailing time, for delivery.

WE WELCOME COMMENTS ABOUT THE INTERNAL REVENUE BULLETIN

If you have comments concerning the format or production of the Internal Revenue Bulletin or suggestions for improving it, we would be pleased to hear from you. You can email us your suggestions or comments through the IRS Internet Home Page (www.irs.gov) or write to the IRS Bulletin Unit, SE:W:CAR:MP:T:T:SP, Washington, DC 20224.

Internal Revenue Service
Washington, DC 20224

Official Business
Penalty for Private Use, $300