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

Office of the Secretary

45 CFR Parts 146 and 148

Medical Loss Ratios; Request for Comments Regarding Section 2718 of the Public Health Service Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This document is a request for comments regarding Section 2718 of the Public Health Service Act (PHS Act), which was added by Sections 1001 and 10101 of the Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, enacted on March 23, 2010. Section 2718 of the PHS Act, among other provisions, requires health insurance issuers offering individual or group coverage to submit annual reports to the Secretary on the percentages of premiums that

the coverage spends on reimbursement for clinical services and activities that improve health care quality, and to provide rebates to enrollees if this spending does not meet minimum standards for a given plan year. Section 1562 of PPACA also added section 715 of the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815 of the Internal Revenue Code of 1986 (the Code). These two sections effectively incorporate by reference section 2718 and other amendments to title XXVII of the PHS Act. The Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) invite public comments in advance of future rulemaking.

DATES: Submit written or electronic comments by **[OFR: insert date 30 days from date of publication in the Federal Register].**

ADDRESSES: Written or electronic comments should be submitted to the Department of HHS as directed below. Any comment that is submitted to the Department of HHS will be shared with the Departments of Labor and Treasury.

All comments will be made available to the public. Please do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed.

All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Comments, identified by DHHS–2010–MLR, may be submitted to the Department of HHS by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Written comments (one original and two copies) may be mailed to: Department of Health and Human Services, Attention: DHHS–2010–MLR, Hubert H. Humphrey Building, Room 445-G, 200 Independence Avenue, SW., Washington, DC 20201.
- Hand or courier delivery: Written comments (one original and two copies) may be delivered (by hand or courier) to Room 445-G, Department of Health and Human Services, Attention: DHHS–2010–MLR, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. 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 DHHS-2010-MLR drop box 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.

Inspection of Public Comments. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on the following public Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445-G, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1-800-743-3951.

FOR FURTHER INFORMATION CONTACT:

Sharon Arnold, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (202)690-5480; Amy Turner or Beth Baum, Employee Benefits Security

Administration, Department of Labor, at (202)693-8335; Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202)622-6080.

Customer Service Information: Individuals interested in obtaining information about the Patient Protection and Affordable Care Act may visit the Department of Health and Human Services' web site (http://www.healthreform.gov). In addition, information concerning employment-based health coverage laws is available by calling the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visiting the Department of Labor's Web site (http://www.dol.gov/ebsa).

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Section 1001 of the Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, enacted on March 23, 2010, amended the Public Health Service Act (PHS Act) to provide several individual and group market reforms. In 1996, Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which added title XXVII to the PHS Act, and parallel provisions to the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code of 1986 (the Code). The HIPAA amendments provided for, among other things, improved

portability and continuity of coverage with respect to health insurance coverage in the group and individual insurance markets, and group health plan coverage provided in connection with employment. Title XXVII of the PHS Act is codified at 42 U.S.C. 300gg, et seq. PPACA expanded Title XXVII of the PHS Act, redesignated several sections, and created new requirements affecting the individual and group markets. These amendments were incorporated by reference into ERISA and the Code by creating new sections 715 and 9815, respectively. The Secretaries of HHS, Labor, and the Treasury have shared interpretive and enforcement authority under Title XXVII of the PHS Act, Part 7 of ERISA, and Chapter 100 of the Code. See section 104 of HIPAA and Memorandum of Understanding applicable to Title XXVII of the PHS Act, Part 7 of ERISA, and Chapter 100 of the Code, published at 64 FR 70164, December 15, 1999.

B. Public Reporting of the Ratio of Incurred Claims to Earned Premiums (Medical Loss Ratio) for Individual and Group Coverage

PPACA sections 1001 and 10101 added Section 2718 of the PHS Act, which, among other provisions, requires health insurance issuers offering individual or group coverage to submit annual reports to the Secretary on the percentages of premiums that the coverage spends on reimbursement for

clinical services and activities that improve health care quality, and to provide rebates to enrollees if this spending does not meet minimum standards for a given plan year.

Specifically, Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual coverage to submit a report to the Secretary for each plan year, concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums (also known as the medical loss ratio (MLR)). Section 2718(a) requires that each report include the percentage of total premium revenue -- after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance -- that the coverage spends:

(1) on reimbursement for clinical services provided to enrollees;

(2) for activities that improve health care quality; and

(3) on all other non-claims costs, including an explanation of the nature of these costs, and excluding Federal and State taxes and licensing or regulatory fees.

Section 2718(a) also directs the Secretary to make these reports available to the public on the Internet

website of HHS.

C. Uniform Definitions

Section 2718(c) of the PHS Act directs the National Association of Insurance Commissioners (NAIC) to establish uniform definitions of the activities being reported to the Secretary under Section 2718(a), and standardized methodologies for calculating measures of these activities no later than December 31, 2010. Section 2718(c) specifies that NAIC's responsibilities relating to this provision are to include defining which activities constitute activities that improve quality (under Section 2718(a)(2)). Section 2718(c) also directs that the uniform methodologies that NAIC develops are to be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans. Finally, Section 2718(c) specifies that the uniform definitions and standardized methodologies that NAIC develops are to be subject to the certification of the Secretary.

D. Payment of Rebates to Enrollees if the Amount Spent on Clinical Services and Quality Improvement Does Not Meet Minimum Standards

Section 2718(b)(1)(A) of the PHS Act provides that, beginning not later than January 1, 2011, health insurance issuers offering group or individual health insurance

coverage must with respect to each plan year, provide an annual rebate to each enrollee under such coverage if the ratio of: (1) the amount of premium revenue the issuer spends on reimbursement for clinical services provided to enrollees and activities that improve health care quality to (2) the total amount of premium revenue for the plan year (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of PPACA) is less than the following percentages, referred to here as "the applicable minimum standards":

(1) 85 percent for coverage offered in the large group market (or a higher percentage that a given State may have determined by regulation); or

(2) 80 percent for coverage offered in the small group market or in the individual market (or a higher percentage that a given State may have determined by regulation), except that the Secretary may adjust this percentage for a State if the Secretary determines that the application of the 80 percent minimum standard may destabilize the individual market in that State).

Section 2718(b)(2) requires that in determining these minimum percentages, States shall seek to ensure adequate

participation by health insurance issuers, competition in the State's health insurance market, and value for consumers so that premiums are used for clinical services and quality improvements.

Additionally, Section 2718(d) provides that the Secretary may adjust the rates described in Section 2718(b)if the Secretary determines that it is appropriate to do so, on account of the volatility of the individual market due to the establishment of State Exchanges. (In this context, the terms "State Exchange" and "Exchange" refer to the State health insurance exchanges established under PPACA).

Section 2718(b)(1)(A) requires that the annual rebate be paid to each enrollee on a "pro rata basis". Section 2718(b)(1)(B)(i) specifies that the total amount of the annual rebate required under this provision shall be equal to the product of:

(1) The amount by which the applicable minimum standard exceeds the actual ratio of the issuer's expenditures to its premium revenue as described above; and

(2) The total amount of the premium revenue described above.

Section 2718(b)(1)(B)(ii) requires that beginning on January 1, 2014, the determination of whether the percentage

that the coverage spent on clinical services and quality improvement exceeds the applicable minimum standard (under Section 2718(b)(1)(A)) for the year involved shall be based on the average of the premiums expended on these costs and total premium revenue for each of the previous three years for the plan.

E. Enforcement

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations for enforcing the provisions of Section 2718, and specifies that the Secretary may provide for appropriate penalties.

F. Taxation of Certain Insurers

Section 9016 of the PPACA amends Section 833 of the Code to provide that Section 833 does not apply to any organization unless the organization's percentage of total premium revenue expended on reimbursement for clinical services (as reported under Section 2718 of the Public Health Service Act) is not less than 85 percent. In general, Section 833 provides a special deduction and a higher unearned premium reserve for certain Blue Cross or Blue Shield organizations that were in existence in 1986 and to other organizations that satisfy enumerated criteria. The amendment to Section 833 applies to taxable years beginning after December 31, 2009.

G. Effective Dates

Section 1004(a) of the PPACA provides that the provisions of Section 2718 of the PHS Act shall become effective for plan years beginning on or after the date that is 6 months after the date of enactment of PPACA. (The date of enactment of PPACA is March 23, 2010).

II. Solicitation of Comments

The Departments are inviting public comment to aid in the development of regulations regarding Section 2718 of the PHS Act. The Departments are interested in comments from all interested parties and are especially interested in the perspectives of health insurance issuers and States. To assist interested parties in responding, this request for comments describes specific areas in which the Departments are particularly interested.

This request for comments identifies a wide range of issues that are of interest to the Departments. Commenters should use the questions below to assist in providing the Departments with useful information relating to the development of regulations regarding Section 2718 of the PHS Act. However, it is not necessary for commenters to address every question below and commenters may also address additional issues under Section 2718. Individuals, groups, and organizations interested in providing comments may do so

at their discretion by following the above mentioned instructions.

Specific Areas in Which the Departments Are Particularly Interested Include the Following:

A. Actual MLR Experience and Minimum MLR Standards

The PPACA sets an 85 percent minimum standard for the percentage of premiums that coverage in the large group market spends on reimbursement for clinical services and activities that improve quality, and an 80 percent minimum standard for the small group and individual markets - allowing for higher State-level standards where appropriate (if they are specified in regulations). The PPACA allows the Secretary to adjust this percentage for the individual market in a given State: 1) if the Secretary determines that application of the 80 percent standard may destabilize the individual market in that State, and/or 2) on account of the volatility of the individual market due to the establishment of State Exchanges.

1. How do health insurance issuers' current medical loss ratios for the individual, small group, and large group markets compare to the minimum standards required in PPACA?

a. What factors contribute to annual fluctuations in issuers' medical loss ratios?

b. To what extent do States have different minimum MLR

requirements based on plan size, plan type, number of years of operation, or other factors?

2. What criteria do States and other entities consider when determining if a given minimum MLR standard would potentially destabilize the individual market? What other criteria could be considered?

B. Uniform Definitions and Calculation Methodologies

The statute requires health insurance issuers offering group or individual health insurance coverage to annually submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums – including the percentage of premiums spent on reimbursement for clinical services provided to enrollees, activities that improve health care quality, and on all other non-claims costs. PPACA also directs NAIC to develop uniform definitions and methodologies for calculating these statistics (subject to certification by the Secretary).

1. What definitions and methodologies do States and other entities currently require when calculating MLR-related statistics?

a. What assumptions and methodologies do issuers use when calculating MLR-related statistics? What are some of the major differences that exist, as well as pros and cons

of these various methods?

b. What kinds of assumptions and methodologies do issuers currently use for allocating administrative overhead by product, geographic area, etc.? What are the pros and cons of these various methods?

c. What kinds of assumptions and methodologies do issuers currently use when calculating the loss adjustment expense (or change in contract reserves)? What are the pros and cons of these various methods?

d. To what extent do States and other entities receive detailed information about the distribution of non-claims costs by function (for example, claims processing and marketing)? To what extent do they set standards as to which administrative overhead costs may be allocated to processing claims, or providing health improvements?

e. What kinds of criteria do States and other entities use in determining if a given company has credible experience for purposes of calculating MLR-related statistics?

f. What kinds of special considerations, definitions, and methodologies do States and other entities currently use relating to calculating MLR-related statistics for newer plans, smaller plans, different types of plans or coverage?

2. What are the similarities and differences between the

requirements in Section 2718 compared to current practices in States?

a. What MLR-related data elements that are required by PPACA do issuers currently capture in their financial accounting systems, and how are they defined? What elements are likely to require systems changes in order to be captured?

b. What MLR-related data elements that are required by PPACA do States or other entities currently require issuers to submit, and how are they defined? What elements are not currently submitted?

3. What definitions currently exist for identifying and defining activities that improve health care quality?

a. What criteria do States and other entities currently use in identifying activities that improve health care quality?

b. What, if any, lists of activities that improve health care quality currently exist? What are the pros and cons associated with including various kinds of activities on these lists (for example disease management and case management)?

c. To what extent do current calculations of medical loss ratios include the amount spent on improving health care quality? Is there any data available relating to how

much this amount is?

4. What other terms or provisions require additional clarification to facilitate implementation and compliance? What specific clarifications would be helpful?

C. Level of Aggregation

Depending on the context, insurance-related data may be aggregated at the policy form level, by plan type, by line of business, by company, by State.

1. What are the pros and cons associated with using various possible level(s) of aggregation for different contexts relating to implementation of the provisions in Section 2718 (that is, submitting medical loss ratio-related statistics to the Secretary, publicly reporting this information, determining if rebates are owed, and paying out rebates)?

2. What are the pros and cons associated with using various possible geographic level(s) of aggregation (e.g., State-level, national, etc.) for medical loss ratio-related statistics in these same contexts (i.e., submitting medical loss ratio-related statistics to the Secretary, publicly reporting this information, determining if rebates are owed, and paying out rebates)?

D. Data Submission and Public Reporting

PPACA requires health insurance issuers offering group or individual health insurance coverage to annually submit

data to the Secretary relating to several medical loss ratio-related statistics (including the percentage of premiums spent on reimbursement for clinical services provided to enrollees, activities that improve health care quality, and on all other non-claims costs) for posting on the Department's Internet web site.

1. To what extent do States or other entities currently require annual submission of actual medical loss ratio-related statistics for the individual, small group, and large group markets? How do these current requirements compare with the requirements in PPACA?

2. How soon after the end of the plan year do States and other entities typically require issuers to submit the required MLR-related statistics? What are the pros and cons associated with various timeframes?

3. What kinds of supporting documentation are necessary for interpreting these kinds of statistics? What data elements and format are typically used for submitting this information?

4. What methods do issuers use for purposes of submitting medical loss ratio-related data to these entities (for example, electronic filing and paper filing)?

5. To what extent is MLR-related information submitted to States or other entities currently made available to the

public, and how is it made available (for example, level of aggregation, and mechanism for public reporting)? What are the pros and cons associated with these various methods?

6. Are there any industry standards or best practices relating to submission, interpretation, and communication of MLR-related statistics?

7. What, if any, special considerations are needed for non-calendar year plans?

E. Rebates

PPACA requires health insurance issuers whose coverage does not meet the applicable minimum standard for a given plan year to provide rebates to enrollees on a pro rata or proportional basis. The rebate is to be calculated based on the product of: (1) the amount by which the applicable minimum standard exceeds the percentage that the coverage spent on clinical services and quality improvement for a given plan year; and (2) the total amount of premium revenue for that plan year (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of PPACA).

1. To what extent do States and other entities currently require MLR-related rebates for the individual, small group,

large group, and/or other insurance markets, and how are these rebates calculated and distributed?

2. How soon after the end of the plan year do States and other entities currently require issuers to determine if rebates are owed?

3. What are the pros and cons of various timeframes and methodologies for calculating rebates?

4. How do States and other entities currently determine which enrollees should receive medical loss ratio-related rebates?[1] What are the pros and cons associated with these approaches?

5. What method(s) do States and other entities currently require issuers to use when notifying enrollees if rebates are owed, and paying the rebates? What are the pros and cons associated with these approaches?

6. Are there any important technical issues that may affect the processes for determining if rebates are owed, and calculating the amount of rebates to be paid to each enrollee?

F. Federal Income Tax

Under Section 9016 of the PPACA, the amendment to Section 833 of the Code applies to taxable years beginning

1 For example: current policyholders, current policyholders who were enrolled in the coverage during the applicable time period, or all policyholders who were enrolled in the coverage during the applicable time period (regardless of whether they are still active policyholders).

after December 31, 2009. Under Section 2718(c) of the PHS Act, the NAIC is directed to establish uniform definitions for purposes of the reporting required under Section 2718(a) not later than December 31, 2010.

What guidance, if any, is needed for purposes of applying Section 833 of the Code for the first taxable year beginning after December 31, 2009?

G. Enforcement

PPACA requires the Secretary to publish regulations for enforcing the provisions of this section, and specifies that the Secretary may provide for appropriate penalties.

1. What methods do States and other entities currently use in enforcing medical loss ratio-related requirements for the individual, small group, large group, and other insurance markets (for example, oversight and audit requirements)? What other methods could be used?

2. What, if any, penalties do these entities currently apply relating to noncompliance with medical loss ratio-related requirements? What, if any, related appeals processes are currently available to issuers?

H. Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

Executive Order 12866 requires an assessment of the anticipated costs and benefits of a significant rulemaking

action and the alternatives considered, using the guidance provided by the Office of Management and Budget. These costs and benefits are not limited to the Federal government, but pertain to the affected public as a whole. Under Executive Order 12866, a determination must be made whether implementation of Section 2718 of the PHS Act will be economically significant. A rule that has an annual effect on the economy of $100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act may require the preparation of an analysis of the economic impact on small entities of proposed rules and regulatory alternatives. An analysis under the Regulatory Flexibility Act must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and issuers and, in some contexts small governmental entities), the expense of the reporting, recordkeeping, and other compliance requirements (including the expense of using professional expertise), and a description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities.

The Paperwork Reduction Act requires an estimate of how

many "respondents" will be required to comply with any "collection of information" requirements contained in regulations and how much time and cost will be incurred as a result. A collection of information includes recordkeeping, reporting to governmental agencies, and third-party disclosures.

Furthermore, Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $135 million.

The Departments are requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and with respect to the following specific areas:

1. What policies, procedures, or practices of group health plans, health insurance issuers, and States may be impacted by Section 2718 of the PHS Act?

a. What direct or indirect costs and benefits would result?

b. Which stakeholders will be impacted by such benefits and costs?

c. Are these impacts likely to vary by insurance market, plan type, or geographic area?

2. Are there unique costs and benefits for small entities subject to Section 2718 of the PHS Act?

a. What special consideration, if any, is needed for these health insurance issuers or plans?

b. What costs and benefits have issuers experienced in implementing requirements relating to minimum medical loss ratio standards, reporting and rebates under State insurance laws or otherwise?

3. Are there additional paperwork burdens related to Section 2718 of the PHS Act, and, if so, what estimated hours and costs are associated with those additional burdens?

Signed at Washington, DC this 6th day of April, 2010.

_____

Clarissa C. Potter,
Deputy Chief Counsel, (Technical)
Internal Revenue Service
U.S. Department of the Treasury.

Signed at Washington, DC this 7th day of April, 2010.

_____

Michael F. Mundaca,
Assistant Secretary, (Tax Policy)
U.S. Department of the Treasury.

Signed at Washington, DC this 7th day of April, 2010.

_____

Phyllis C. Borzi,
Assistant Secretary,
Employee Benefits Security Administration
U.S. Department of Labor.

Signed at Washington, DC this 8th day of April, 2010.

_____

Donald B. Moulds,
Acting Assistant Secretary for Planning and Evaluation,
Office of the Secretary
Department of Health and Human Services.

BILLING CODE 4150-03

[FR Doc. 2010-8599 Filed 04/12/2010 at 10:15 am; Publication Date: 04/14/2010]