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January 31, 2011

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9998-IFC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Interim Final Rule – Medical Loss Ratio Requirements (OCIIO-9998-IFC)
Submitted via www.regulations.gov

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) to offer comments in response to the interim final rule ("IFR") relating to the *Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Interim Final Rule* published in the *Federal Register* on December 1, 2010. The IFR implements Section 2718 of the Public Health Service Act, as enacted in the Patient Protection and Affordable Care Act (PPACA), which was signed into law March 23, 2010.[1]

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs.

We appreciate the opportunity to comment on Medical Loss Ratio (MLR) requirements of the IFR. Since the IFR was published on December 1, 2010, and has an effective date of January 1, 2011, we urge that the Department act as quickly as possible to take additional regulatory action to address the concerns and comments raised as part of the regulatory process.

This letter highlights our general concerns about the IFR while the Attachment sets out more specific concerns related to the *Federal Register* notice and the regulatory text.

While we focus our comments on the MLR regulation, we are also mindful of the substantial concerns policy experts have voiced for years about the unintended consequences of using MLRs

[1] Pub. L. No. 111-148, as amended by Pub. L. No. 111-152.

for purposes other than monitoring health plan solvency – the purpose for which these measures were originally meant to serve.

Key Concerns Related to Disruption for Consumers, Impact on Quality Investments, and Increased Administrative Costs

Recognizing that the Department of Health and Human Services (HHS) has an obligation to implement the MLR provision, our comments focus on concerns relating to how the specific implementation path established in the IFR should be changed in order to:

- Minimize disruption in the marketplace for consumers and promote competition;
- Avoid raising administrative costs throughout the health care system;
- Avoid crowding out innovations and investments in health care quality and limiting consumer choices; and
- Provide for an adequate "credibility adjustment" to address volatility and avoid solvency issues caused by statistical "false positives."

Overall, our comments focus on alternative approaches to mitigate potential coverage disruptions and other unintended consequences, and that avoid disturbing or impairing continued private sector efforts that are helping lead the nation toward a 21st century health care system.

It is important to keep in mind that health plan administrative costs have been declining as a percentage of total national health expenditures (NHE) and private health insurance (PHI) premiums for seven years in a row. Private health insurance administrative costs now constitute 3.5 percent of total NHE, reflecting market incentives that encourage efficiency in health care administrative cost spending. This helps demonstrate why by focusing only on health plans, the MLR risks drawing attention and energy away from efforts to address true cost drivers in the health care system such as the continued growth in underlying medical costs.

Meanwhile, new studies and research continue to demonstrate that health plan quality programs and innovations in payment and delivery system reform are helping to ensure greater coordination and less fragmentation in the health care system. For example, a recent article concluded that health plans improve the quality of care through tools, such as disease management, provider education efforts, patient education efforts, the development of reminder systems, and the use of financial incentives and other activities.[2]

[2] Laurence C. Baker and David S.P. Hopkins, International Journal for Quality in Health Care, "The Contribution of Health Plans and Provider Organizations to Variations in Measured Plan Quality," (March 18, 2010).

These tools, as well as other health plan activities, not only produce better clinical outcomes, but also result in significant cost savings. Many health plans, for example, are seeking to reduce preventable hospital admissions, readmissions, and emergency room use through a wide range of patient-centered initiatives that focus on rebuilding primary care efforts, engaging patients, and recognizing the important role of pharmacists. A recent AHIP survey indicates that these programs are reducing costs, improving quality, and positively impacting patient satisfaction.[3]

I. Minimize Marketplace Disruption For Consumers and Promote Competition: The Essential Need for an Effective Transition to a 2014 Post-Reform Market

Two issues are paramount to our concerns over the potential for marketplace disruption and the impairment of competition: (1) the need for an effective transition to the 2014 reforms for all markets; and (2) modification or supplementation of the credibility adjustment to more adequately address random year-to-year statistical volatility in MLR measures.

Need for a Transition – Differences Between Current Market and MLR Rules

We urge HHS to place a high priority on minimizing disruption and preserving consumer choices in the marketplace during the 2011-2014 period leading up to the implementation of PPACA's major insurance market reforms. PPACA established the new minimum loss ratio standards of 80 percent (individual and small group markets) and 85 percent (large group market). Recognizing that the standards for loss ratios were significantly lower or did not exist in some states prior to the PPACA, we urge HHS to adopt a predictable and effective transition plan designed to reach all three market segments.

From now until 2014, it is vitally important to minimize disruption in the pre-reform marketplace. Four-fifths of the individual market will remain medically underwritten, guided by the rules and regulations in each state. A transition policy is needed to move from the current system to the new system that will be created in 2014 and to allow individuals and those receiving coverage through employer group health plans to maintain their coverage. In addition, a smooth transition and preservation of the marketplace leading up to 2014 will provide consumers with continued choices and stability until the Exchanges are operational and the rest of the market reforms become effective. Until that time, consumers in the individual and small group markets will rely on brokers to review their insurance options and consider which ones best suit their needs. Thereafter, brokers will continue to have an important role to play, but will

[3] AHIP Center for Policy and Research, "Innovations in Reducing Preventable Hospital Admissions, Readmissions, and Emergency Room Use: An Update on Health Plan Initiatives to Address National Health Care Priorities" (June 2010) accessed at: http://www.ahipresearch.org/pdfs/innovations2010.pdf

operate in the context of new systems for making coverage available to consumers and employers.

Similarly, the large group market typically has not been subject to loss ratio requirements. This reflects the sophistication of large group purchasers and the custom element of benefit packages and associated cost and quality programs often demanded by large group purchasers. For many carriers, large group pricing is not developed on a state-by-state basis, such that the imposition of a MLR counted state-by-state will constitute a major change to existing business practices. This will cause some large groups to incur significant new administrative costs they do not incur today, and will require a substantial period of adjustment to promote stability.

Policies for 2011 Were Filed Well Before Publication of the MLR Regulation and Reflect Solvency Assumptions & State Regulatory Requirements in Place At That Time

Supporting the case for an effective transition, rates that are in effect in today's 2011 market were filed and approved many months before the components of the MLR standards were known. This regulation was published on December 1 2010, with an effective date of January 1, 2011. Rates were filed with states in some instances, in February and March of 2010, even before the legislation itself was signed into law. Failing to include some form of transition, or some safe harbor for health plans whose rates were appropriately based on their states' existing MLR requirements, damages the solvency assumptions those health plans – and their state regulators – made at the time the rates were developed and approved. HHS should provide specific transition guidance leading to 2014 to ensure that these solvency assumptions are not ignored.

Structural Issues Driving Need for Transition Concept

To be effective, a transition should recognize structural issues associated with each of the individual, small group, and large group markets now and in 2014. Key among these are issues concerning current market cost structures and operating models, which when understood make the case and need for transition clear.

In particular, health plans have developed cost structures and operating models to meet the needs of consumers and employers across different insurance markets. These structures also reflect existing regulatory requirements and market rules that remain substantially unchanged for most types of coverage prior to 2014.

Below is a chart showing why the pre-2014 market is structurally different from the 2014+ market:

2011-2013 Marketplace	2014+ Market
Volatility in MLR calculation • Annual, state specific MLR calculations, creating significant issues in volatility in MLRs across states year by year • No risk adjustment	***Mechanisms introduced to provide less volatility in MLR calculation*** • 3-year averaging to smooth the volatility of results • Introduction of risk adjustment, and transitional reinsurance and risk corridors
Higher costs relating to underwritten individual markets in most states • "Durational" issues meaning MLRs rise with the passage of time • Administrative costs relating to underwriting	***New rating rule and guarantee issue reduce administrative costs*** • Durational issues minimized because market is no longer underwritten • No underwriting costs
Distribution channel through agents and brokers • Principal distribution channel for individual and small group coverage • Source of human resources type functions for individuals and employer groups	***Exchanges established and functional*** • Alternative distribution mechanism • Possible assistance of brokers, ombudsman, and others with human resources type functions
Administrative spending higher as a percentage of premium • Benefit packages designed for affordability, especially in individual and small group market, have a higher percentage of overall premium expended on administrative costs.	***Administrative spending lower as a percentage of premium*** • New essential benefit packages and actuarial value requirements will result in lower percentage of overall premium being expended on administrative costs

The fact that the MLR rules are in effect prior to the creation of the new rules and infrastructure planned for the 2014 and beyond environment creates a mismatch giving rise to the need for an effective transition.

Recognizing these facts, numerous experts, including the American Academy of Actuaries (AAA), have urged that a transition plan be included as part of MLR implementation. The National Association of Insurance Commissioners (NAIC) similarly urged for a transition

although they did not include one in their regulation, based on the perceived scope of authority and mandate for making recommendations.

While the IFR proposes the potential for a transition for the individual market, it makes no such proposal for the small group or large group markets. In addition, even with respect to the individual market, the approach laid out in the IFR is unnecessarily burdensome requiring very detailed data submissions and speculative calculations, and provides little of the deference requested by state regulators in their October 13, 2010 recommendations for transition.[4] Moreover, despite the fact that the MLR became effective January 1 2011, the application process outlined in the IFR provides little in the way of certainty with respect to timing as exemplified by a provision that keeps the "clock" on review from even starting until after HHS determines in its discretion that the application is "complete."

Essential Elements for an Effective Transition

The policy goal should be to create a transition that works. Three elements in this regard are essential:

1. Recognize that the basic structure of the market is unchanged in 2011, 2012, and 2013 as illustrated above.

2. Use an application process that minimizes the burden on states and encourages rather than discourages them to apply for a transition in each of the individual, small group, and large group market segments as necessary.

3. Provide adequate flexibility to ensure that transition plans can address key fundamental differences between the current market and the reformed market, especially as they relate to cost structure and volatility.

In addition, an effective transition would also take the form of a bridge, at least allowing states adequate time to evaluate and put together an appropriate transition plan that meets their citizens' needs. In this regard, the need for a bridge is present across all market segments, including in the large group market where time is needed to restructure existing contractual arrangements with employers. As an example from the large group segment, one complexity that arises and requires time to address involves multiple contracts between a carrier and a single employer, but where the arrangements are structured to ensure that the employer is treated consistently across its enterprise, even where the employer operates in multiple states.

[4] *See NAIC Letter to Secretary Sebelius* (October 13, 2010), "We urge HHS to give deference to the analysis and recommendations of state regulators when determining how the new requirements will be phased-in."

A bridge would help guard against disrupting or impairing these existing contractual obligations and related arrangements, reducing the risk that MLR implementation becomes a source of inefficiency and concern in the workplace, and could provide time for a state-based application process to be put into place and made effective.

II. Avoiding Increases in Administrative Costs Across the System

We are concerned that the IFR reflects an approach to regulation that will have the unintended consequence of increasing administrative costs across the health care system rather than decreasing them. This runs counter to the spirit and words of the recent Executive Order on regulatory streamlining which recognizes the fact that "regulations have costs."[5]

As examples of our concerns, we highlight three areas where the IFR overreaches, imposing requirements not required by statute or the NAIC, and lacks any significant consideration of less complex alternatives.

These examples illustrate how the IFR will require the creation of whole new information technology (IT) systems, contracts, and administrative compliance centers to address and manage the complexity of the proposed requirements, and the unprecedented involvement of government into the records of private entities, including entities other than health plans that are not, by Congressional design, even subject to the MLR regulation.

Treatment of Rebates Paid to Employers on Behalf of Their Employees

The IFR holds health plans responsible for multiple payments based on the actions of employers they do not control, while at the same time recognizing that health plans do not have the information to provide specific rebates to all individual enrollees, especially those who are members of employer group health plans. Our concern is that the unintended consequence of this policy will be a significant increase in administrative costs tied to whole new audit processes and procedures designed to assess compliance, which ultimately will lead to higher costs for consumers and employers.

An alternative to the approach outlined in the IFR would ensure that, health plans can rely upon the appropriate actions of the employer/policyholder. To accomplish this, the regulation should include a specific safe harbor permitting health plans to rely upon the accuracy of their employer-clients' representations.

[5] Executive Order 13563, "Improving Regulation and Regulatory Review," (January 18, 2011).

Artificial Deconstruction of Payments to Vendors and Providers and the Risk of Increased Health System Costs

The IFR contains language and examples suggesting that when a health plan pays a vendor or provider on a fee for service or medical/quality capitation claim, those parties may be required to itemize and deconstruct payments they receive in order to break out any administrative component embedded within the claim.

By injecting this burdensome and wasteful administrative requirement, this provision risks creating an extremely difficult system to administer that will significantly increase costs for the nation's health delivery system without adding any value to consumers. In *every* claim for health care, overhead must be built into the fee. Even non-profit and government-run providers must include these amounts in order for the entity to continue functioning efficiently and effectively. It would be especially burdensome if this provision were to be interpreted as requiring that every claim for services or contract for payment be accompanied by a detailed breakdown of all intermediary or provider's costs built into the claim.

Moreover, by potentially discouraging a range of models that rely on more aggregated payments, this provision seems at odds with the wide range of public policy efforts designed to encourage a movement away from fee-for-service payments toward a more value based payment system. In addition, it may also discourage competition by unintentionally impeding certain alternative network models.

If implemented without attention to the concerns articulated above, it is difficult to see how this provision will advance any positive goal. Moreover, it will again have the effect of increasing, rather than reducing, administrative costs.

Unprecedented Demands of Access to Premises and Records of Entities Not Subject to the MLR Regulation

The IFR demands that health plans permit, or by contract require, access for HHS audits of parent organizations, related entities, contractors, subcontractors, agents or transferees that "pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part."[6] According to the plain language of this section, every provider who submits a claim, and every network participant whose costs are somehow included in the calculation of a MLR will need, as a result of providing health care to employer groups or individuals, to agree to make its books, records, physical facilities, computers, and all other data and records open to HHS inspection and audit. Even businesses and other entities that merely provide services to

[6] 45 CFR §158.501(b).

those who may submit claims to health plans would be subject to a potential audit under these provisions.

This reflects a substantial – perhaps unparalleled – expansion of federal government activity into the daily operation of participants in the commercial health care system, substantially implicating a range of entities and individuals whose businesses are not, by Congressional design, subject to HHS authority under the MLR.

Attempting to regulate these entities through health plans will have the effect of raising health care administrative costs rather than lowering them to the detriment of consumers. In particular, a more cost effective, and less intrusive and disruptive approach, would be for HHS to simply leverage the existing information already available to it. In this regard, health plans must have internal financial controls in place, they have risk management reports, financial examinations from their state regulators, reports to the Securities and Exchange Commission (SEC) and other federal agencies if they are publicly traded, and myriad other control reports and audits that will provide sufficient information for HHS to determine that charges made to and expenses incurred by the entity are accurate and necessary.

III. Avoid Crowding Out Innovations and Investments in Quality and Limiting Consumer Choices

In numerous places the IFR sets out an approach that threatens innovation in quality and in the design of benefit plans and delivery system payment models.

Threat to Innovations in Quality

The concept of using regulation to define what constitutes innovation or "quality" in health care often invites public suspicion as it gives to regulators the power and burden of effectively deciding what technologies and methods of organizational innovation will be experimented with and where investments will be made. In other sectors, such as technology, it is unlikely that such an approach would be attempted, recognizing the speed with which information moves and change occurs and because of the intrinsically dynamic nature of innovation itself.

Yet, with its specific exclusions and categorical approach to classifying "quality activities," and its drawing of artificial divisions between activities that contain costs and those that improve quality that is exactly the path the IFR takes. In adopting this approach, the IFR defies vast tomes of research on the problems of variation in care relating to underuse, misuse, and overuse that lie at the heart of both cost and quality issues in our health care system.

Thus, while the IFR acknowledges many existing efforts to improve quality, it overlooks and effectively discourages other more dynamic alternatives such as more generally requiring a

relationship between qualifying activities and the widely recognized principles of quality such as those espoused in the Institute of Medicine's classic report, "*Crossing the Quality Chasm*."[7] Moreover, in two specific areas – ICD-10 implementation and fraud prevention – the IFR does not even recognize current and well-established efforts to improve quality. In this regard, it is essential that activities in this area be properly recognized as quality improvement activities under the MLR rule.

Recognizing ICD-10 Implementation as a Quality Improvement Activity

We strongly believe that the definition of health care quality initiatives should include the startup costs that health plans incur in meeting the October 1, 2013 compliance deadline for ICD-10 implementation. The primary reason for the required adoption of the ICD-10 codes is to enhance the ability of the health care community to exchange and use detailed clinical data to deliver higher quality care to consumers.

ICD-10 is not a claims payment system – all health plans have existing capabilities to pay claims. Rather, implementation of ICD-10 will provide health plans and health care providers an expanded understanding of diagnoses and procedures at institutional settings of care, thereby enhancing the ability of providers and plans to categorize disease states, document medical complications, and track care outcomes. These advances, in turn, will support efforts to gain a deeper understanding of disease, causes of death, and ways to make significant improvements in health care quality.

The ICD-10 conversion, which was mandated by the federal government, was not undertaken in order to enhance claims payment capabilities. In fact, HHS has publicly recognized that implementation of ICD-10 represents "a giant step forward toward developing a health care system that focuses on quality" and is one that will "enable HHS to fully support quality reporting bio-surveillance, and other critical activities."[8]

The IFR specifically requested comments regarding the inclusion of ICD-10 costs, noting that there is "general recognition that the conversion to ICD-10 will enhance the provision of quality care through the collection of better and more refined data."[9] In this regard, we strongly urge HHS to recognize that ICD-10 implementation is a major quality improvement initiative and not merely an administrative task surrounding the payment of claims. The ongoing maintenance of

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[7] Institute of Medicine, "Crossing the Quality Chasm: A New Health System for the 21st Century," (2001). The IOM in this report stated that enhancing quality in our health care system requires a focus on six core aims: (1) safety; (2) effective; (3) patient-centered; (4) timely; (5) efficient (including avoiding waste); and (6) equitable.

[8] CMS News Release, "Proposed Changes Would Improve Disease Tracking and Speed Transition to an Electronic Health Care Environment," (August 15, 2008), accessed at: http://www.hhs.gov/news/press/2008pres/08/20080815a.html

[9] 75 Fed. Reg. 74877.

the system, once it is built and operational in 2013, may legitimately be deemed an administrative cost. The "conversion" or investment costs to build the system, however, are clearly being undertaken in order to improve the quality of our nation's health care system and should be included in the quality portion of the MLR.

Additionally, the preamble notes perceived difficulties in "parsing expenses associated with ICD-10 conversions" in the implementation costs of putting in place the ICD-10 codes.[10] Toward this end, an AHIP study[11], published September 2010, focused on those very issues and was able to collect significant data from health plans showing the costs of implementing the conversion from ICD-9 code sets to ICD-10 codes. The study outlines findings, based on a survey of 20 health insurance plans, which indicate an average implementation cost for ICD-10 implementation of about $12 per member, ranging from $38 per member for small health plans (less than one million members) to $11 per member for large plans (more than 5 million members). The overall incremental cost for ICD-10 implementation for all responding plans is estimated to be $1.7 billion. Since the 20 responding health plans do not comprise the entire U.S. health insurance market, the estimated total system-wide cost for insurers is likely to be in the range of $2-3 billion.

By demonstrating that conversion and investment costs can be tracked and distinguished from operating or routine maintenance costs associated with adjudicating claims, the report should help put to rest concerns that these expenses cannot be "parsed." It should also help clear the path to account for these investment costs as quality activities – perhaps on an amortized basis spread over some reasonable period of years.

Recognizing the Role of Fraud Prevention Activities in Quality Improvement

The MLR rule threatens to substantially hinder health plan fraud prevention initiatives, exactly at a time when the government is seeking to emulate these successful programs in other areas such as traditional fee-for-service Medicare. It similarly contradicts the broader universal recognition by the Administration, the HHS Office of the Inspector General, and other leaders in the public and private sectors, that there is a direct link between fraud prevention activities and improved health care quality and outcomes.

The basic problem is that the IFR only provides a credit for fraud "recoveries" – i.e., money that was paid out to providers, then recovered. It does not include the cost of developing and administering anti-fraud programs. This creates a negative incentive, as the primary goal of health plan anti-fraud initiatives is to identify fraudulent claims and prevent payment of those

[10] 75 Fed. Reg. 74876.
[11] AHIP Center for Policy and Research, "Health Plans' Estimated Costs of Implementing ICD-10 Diagnosis Coding," (September 2010) accessed at: http://www.ahipresearch.org/pdfs/SurveyICD-10CostsSept2010.pdf

fraudulent claims in the first place. Therefore, the MLR regulation provides an incentive to pay out more claims initially – the so-called "pay and chase" scenario – to get credit for their fraud detection and recovery activities, rather than try to manage robust fraud prevention efforts on administrative budgets that are now being capped as a result of the MLR and specific IFR implementation.

This is exactly the wrong kind of incentive, especially given the increased priority of fraud prevention and detection in other places in the health care reform law. A new AHIP report, "*Research Brief: Insurers' Efforts to Prevent Health Care Fraud*," bears this out.[12] It highlights how health plans' programs operate to prevent and detect fraud, and how these programs are focused primarily on preventing fraud from occurring in the first place rather than only recouping funds retroactively after fraud occurs. As the report points out, "The knowledge that health plans have robust anti-fraud measures and controls likely prevents inappropriate billings or claims in the first place." The direct relationship between these programs and health care quality is clear, and the IFR should encourage, not discourage, these patient-centered quality and safety initiatives.

Threatening Consumer Choice

Section 2718 directs that the circumstances of small and "different types" of plans when crafting the rules for the MLR be taken into account. The IFR ignores this directive in many instances and will have the unintended consequence of discouraging the availability of certain types of benefit plans. The link between the MLR IFR and consumer choice is extremely important and should not be overlooked. Nor should it become a source of proactive government activity to choose which products consumers should have access to. Other implementation efforts, such as those relating to "Essential Benefits," contain specific provisions related to benefit design – and the public is better served from the standpoint of public debate and a transparent regulatory process if issues related to benefit design are considered in that context.

As an example of our concern, the MLR will make it substantially more difficult for health plans to make high deductible health plans (HDHPs) available to consumers. By Congressional design, these plans are intended to provide consumers a highly affordable coverage option that gives them more control over their spending, allows for consumers to save for health care expenses through a Health Savings Account (HSA), and provides catastrophic coverage protection tied to a statutory out-of-pocket maximum. These consumer-driven HDHP/HSA policies were created in order to allow consumers to have a more direct stake in the cost of their health care. These plans are popular with consumers and employers – with 10 million enrollees

[12] AHIP Center for Policy and Research, "Insurers' Efforts to Prevent Health Care Fraud," (January 2011) accessed at: http://www.ahipresearch.org/pdfs/FraudPrevention2011.pdf.

as of January 2010[13]. This is a significant growth in enrollment from 2004 when HSAs were first authorized. By failing to recognize the unique nature of these policies, the IFR threatens to undermine Congress' intent, and could result in depriving consumers the opportunity to obtain or maintain what has become a very popular and affordable coverage option.

For this reason, HHS should include an exemption for HSA policies in the IFR that takes into account the potential volatility of MLR measurements for these products (which is increased by the larger deductible) and the fact that their low premium tends to make their administrative costs – which are often largely fixed – seem higher when looked at on a percentage basis.

IV. Provide for An Adequate "Credibility Adjustment" to Address Volatility and Avoid Solvency Issues Caused by Statistical "False Positives"

A critical concern across the individual, small group, and large group markets is whether the loss ratio for a small block of business in a state is based on enough experience to be "credible" such that if a health plan's experience is below the MLR it is clear that this result (and the requirement to pay a rebate) is not indicative of a "false positive," or put differently, the result of random statistical fluctuation.[14]

The handling of this issue is of vital importance because the structure of the MLR requires that health plans pay rebates in years when their performance is below the threshold but are not allowed to net these effects with experience that is above the thresholds. In practice, plans report high levels of variation from year-to-year that are inversely related to the size of the block of coverage (the smaller the block the greater the variation). In today's market, many health plans manage these effects by balancing the variation across a range of states in which they do business. However, because the MLR is to be calculated on a state-by-state legal entity basis, it is no longer possible to manage this variation through a portfolio approach that balances the effect of random, annual variation in MLR across states for small blocks of coverage (commonly reflecting the occurrence and impact of high cost claims). Likewise, it is not possible to manage this issue through reinsurance based on the expected rules because the cost of purchasing reinsurance is to be treated as an administrative cost under the MLR.

Importantly, the issue of volatility and credibility is not limited to the individual and small group markets, nor is it limited to smaller carriers – recognizing that even large carriers have small

[13] AHIP Center for Policy and Research, "2010 HSA Market Census," May 2010 accessed at http://www.ahipresearch.org/pdfs/HSA2010.pdf.

[14] The issue of credibility is a long-term issue, but it is especially acute for the 2011 to 2103 period, as the MLR rules do not include 3-year averaging until 2014 when such averaging might help to smooth the volatility of results. As a result, especially during the transition to 2014, health plans face the risk of paying rebates on blocks of business that were appropriately priced to achieve the required MLR level simply due to unavoidable, random statistical fluctuations in claim levels.

blocks of large group coverage when measured on a state-by-state basis as the MLR IFR requires.

The IFR acknowledges the issues and problems associated with credibility by including a credibility adjusted factor that appears to have been based on a confidence interval of 50 percent as opposed to 80 percent. This implies in any given year a 25 percent chance that the failure to achieve a MLR threshold is the result of random statistical variation, all other things equal. The problem presented by this significant risk of a "false positive" is magnified by the fact that, as noted, random statistical variation creating very high loss ratios in other states (creating financial losses and tapping reserves to pay claims) cannot be netted under the MLR rule with the statistical variation creating lower loss ratios in other states. The AAA has written regarding their concerns about the sufficiency of the credibility adjustment reflected in the IFR, raising issues of stability and potentially impairing smaller competitors in the market.[15] Similarly, the actuarial firm Milliman wrote in their report prepared for the NAIC that: *"[T]he use of a two-sided 50th percentile basis would likely be considered a very low confidence interval for a study concerned with plan solvency implications of the MLR refund requirement."*[16]

Adding to the problem, there is additional concern that the deductible related adjustments for credibility may pose specific problems for HDHPs that by Congressional design are lower cost and have higher deductibles, making them more susceptible to random statistical fluctuations in MLR measures.

Finally, amplifying our concern about the lack of an adequate credibility adjustment is a further and especially complex provision that denies *any* credibility adjustment at all in 2013 if the relevant block of coverage was under the MLR in each of 2011, 2012, and 2013 after the credibility adjustment in those years. This creates a further risk point for carriers, and penalizes those carriers that attempt to stay in the market and continue providing coverage and choice (even after paying rebates), and threatens to make it extremely difficult for a health plan to stay in the market over the long-term that is subject to this provision. Moreover, this provision is of special concern because, as noted above, 2011 pricing is and typically was set well before publication of the IFR, such that they will have only two years – 2012 and 2013 – to try and avert this increased risk. In sum, this provision by creating a 2013 cliff for plans subject to its effects threatens to lessen competition going into the 2014 market reforms and operation of the exchanges, again to the detriment of consumers and employers alike.

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[15] *See e.g., American Academy of Actuaries Letter to Steven B. Larsen (November 5, 2010), regarding "Regulatory Implementation of Section 2718 of the Public Health Service Act."*

[16] Milliman NAIC Report, "Credibility Adjustment Factors for Use in MLR Refund Calculations," (August 31, 2010), p. 12.

Not only does the IFR not provide a more appropriate credibility adjustment, through the preamble it also specifically rejects the potential use of other sensible and well tried mechanisms such as “high cost claims” pooling and stop-loss type reinsurance that could be employed to lessen volatility. Rather than seek to find ways for these mechanisms to be implemented, the IFR dispenses with this possibility without even requesting additional information from the public on whether these mechanisms could be used to complement the credibility adjustment, and denying consideration of all other potential alternative mitigations.

In addition to these comments, we’ve enclosed additional technical comments to the MLR in the attached enclosure. We appreciate the opportunity to comment on this important initiative. Please feel free to contact me should you have any questions.

Sincerely,
Daniel T. Durham
Executive Vice President
Policy and Regulatory Affairs

Appendix
Technical Comments to MLR IFR

The comments provided below supplement those provided in the letter submitted by America's Health Insurance Plans (AHIP), dated January 31, 2011. The AHIP letter focuses on issues and recommended changes associated with the IFR as it pertains to:

1. Minimizing Marketplace Disruption For Consumers and Promote Competition: The Essential Need for an Effective Transition to a 2014 Post-Reform Market;

2. Avoiding Increases in Administrative Costs Across the System;

3. Avoiding a Crowd Out of Innovations and Investments in Quality and Limiting Consumer Choices; and

4. Providing for An Adequate "Credibility Adjustment" to Address Volatility and Avoid Solvency Issues Caused by Statistical "False Positives."

This Appendix supplements the AHIP letter and addresses a range of technical issues raised by the IFR. It is arranged to follow the organization of the IFR regulation.

1. General Points and Definitions

A. Scope of MLR Regulation

The National Association of Insurance Commissioners (NAIC) recognized that the Medical Loss Ratio (MLR) filing requirements should be limited to the small group, large group and individual comprehensive major medical insurance market. The Patient Protection and Affordable Care Act (PPACA) sets MLR requirements only for these three markets. Although the IFR does not contain a specific scope limitation, the proper scope of the IFR should be read so as to exclude carve-out coverage, such as stand-alone pharmacy, behavioral health, and substance abuse. As they are only pieces of a larger whole, and do not generally control the benefits provided or negotiated by the larger group, such coverage should not be judged by the same standards. The NAIC did not make recommendations about these stand-alone products and carved them out of their proposed regulation. We urge the Department of Health and Human Services (HHS) to do the same, and make explicit in Section 158.102 that the regulation is applicable only to those policies that provide comprehensive medical, hospital, and surgical benefits and not carve-out coverage.

B. Definitions

The definition of "multi-state blended rate" does not track the final NAIC definition of blended rates. The NAIC recognizes that blended rates may apply to multi-state plans and multi-issuer plans within the same state. Its definition encompasses both and we suggest it is appropriate to track that definition closely. In addition, blended rates are recognized as a set of rates that are based on a consistent combined expectation from the results of multiple entities, rather than a

"single rate" as defined in the IFR. The set of rates would certainly recognize different rates for employee only coverage, as opposed to coverage for employee plus spouse, children or other dependents, and could recognize less than full actuarial difference in expected benefits.

C. No Application of Additional Obligations

The IFR does not address the ability of states to enact additional laws or promulgate regulations that provide for different definitions and methodologies than the ones provided for in the IFR. Congress expressed its clear desire that definitions be "uniform" and methodologies be "standardized." (*See* PPACA Section. 2718(c)). In order to ensure, for example, that conflicts do not arise between the Department's criteria for what qualifies as a quality activity and any other definition, the Secretary should clarify that the criteria it has established serve as a standard and not a floor above which states may impose additional obligations.

2. Section 158.120 – Aggregate Reporting

Subsection 158.120(c) discusses issues surrounding dual contracts in the group market. While we do not comment upon the IFR's treatment of the dual coverage itself, we note that this scenario can also arise in the individual market. Many individual managed care policies, for example, are required to provide the out-of-network component through an affiliate or even through a non-affiliated company that writes indemnity, rather than managed care coverage. We therefore suggest that the title of the subsection be amended to remove the word "group" and that the word "group" be removed from the first and seventh lines of substantive text.

Another issue arises under the aggregate reporting in paragraph 158.120 (d) (4), regarding health issuers offering expatriate coverage. As the preamble recognized, this coverage is offered under unique circumstances, and there are challenges presented to such plans which merit special consideration. For example, expatriate coverage generates substantially higher administrative costs than domestic coverage, since such expatriate coverage must provide customer support 24 hours a day, year round, and must engage in an exceedingly complex claims administration process involving non-standardized claims submission systems and multiple currencies and languages. Additionally, insurers offering expatriate coverage must establish global networks of contracted, qualified foreign health care providers, while maintaining online databases and customer service in many languages that allow members to understand, access, and navigate health care services in countries all over the world.

The language in paragraphs 158.120 (d) (4), and 158.221 (b) (4) seeks to address the reporting of this coverage, but fails to address the higher costs, and challenges of it raises. In addition, the "special circumstances adjustment" in paragraph 158.221(b)(4) is temporary; giving no insights into types of guidance or adjustments that can be counted on beyond 2011. This uncertainty has implications for both U.S. insurers and their customers.

The claims experience of expatriate coverage is likely to vary significantly based on the locations in which participants are living, and also tends to be significantly more volatile than the experience of similarly-sized groups in the U.S. Single large claims, e.g., for the evacuation of a critically ill worker in a remote location, can make a meaningful difference in the experience of

an expatriate group in a particular year. Other factors, such as the relocation of workers, local incidence of disease and changes in care access (particularly in remote locations) can also increase volatility. Many expatriate groups are also relatively small, increasing the difficulty of pricing to a predictable annual MLR. Additionally, expatriates by definition are not residents of any state, so that the concept of a state-based MLR has limited relevance for expatriate coverage.

An additional issue with this section arises with regard to the correction noted on page 74923 of the IFR correction issued December 2010. That correction noted:

> (I)n (§ 158.120(d)(4)), we are inserting the words "non-U.S." before "citizens working in their home country." The words "non-U.S." were inadvertently omitted and are necessary to make clear that this exception does not apply to U.S. citizens working in their home country. We have corrected the preamble section on page 74871 as well to reflect this revision to the text.

This change presents unintended challenges to an issuer offering expatriate coverage if the employer's policy includes dependent coverage, yet the employee's dependents remain in the U.S. while the employee works outside the U.S. The most common situation where this occurs is if the covered employee does not take their family, often for safety concerns. We note this situation is most likely to occur in defense industry. So while the policy may provide coverage for U.S. employees working outside their country of citizenship, it may also be covering dependents who do not meet the revised definition. Thus, there should be a clear exclusion to address this concern.

The IFR requirements also hold implications for U.S. insurers and their ability to compete on parity with foreign based insurers providing such coverage:

- The application of an 80 or 85 percent MLR to U.S. insurers offering expatriate coverage would put U.S. insurers at a disadvantage to foreign insurers, with the end result a loss of U.S. jobs at U.S. insurers - as this business would shift to overseas insurers and their foreign-based workers.
- The reporting mechanism requested under the IFR requires public disclosure of financial and MLR information (including very sensitive claims and expenses information) by U.S. insurers. This information would be very damaging in the hands of the foreign insurers who would have no obligation whatsoever to publish their claims expenses, and MLR results. This insight into U.S. insurers' cost structure would create a competitive advantage for the foreign insurers, one very difficult to overcome which could result in loss of jobs and opportunities for U.S. insurers and their employees.

Nothing in the PPACA or its legislative history suggests that Congress ever intended to reduce coverage offered by U.S. insurers by providing offshore health plans with a competitive advantage or that it intended to try to reach across the globe to apply U.S. laws to individuals living overseas. Thus, we strongly recommend that HHS exclude expatriate plans from the requirements of section 2718.

In addition, with respect to low-cost coverage addressed in section 158.120(d)(4), we urge that the definition of policies required to be reported separately under this be modified to recognize a broader range of policies that because of the low premium relative to the level of fixed costs are at significant risk of disruption to the detriment of consumers covered by these policies. In this regard, many low-cost policies may have an annual limit that is greater than $250,000 but may have internal limits that raise the same issues and policy concerns with respect to calculating an MLR.

3. Section 158.121 – Newer Experience

This section is intended to carry out the directive in section 2718 that the MLR calculation take into account "the special circumstances of smaller plans, different types of plans, and newer plans." Again, the language in the IFR appears to miss the mark. It appropriately recognizes that new business, whether written by a new health plan or one that is well established, will by definition have a lower loss ratio than older, more well-developed blocks of business, and excludes premiums attributable to that new business from the MLR calculation. It inappropriately sets the threshold, however, for this to occur at 50 percent or more of the health plan's total earned premium for the calendar year. As a result, a health plan, with one large older block of premium-generating policies and a number of smaller blocks of new business that total 49 percent of the total earned premium will be significantly disadvantaged. A bright-line percentage-of-business test cannot level the playing field for a health plan with a significant amount of new business, and will create precisely the disincentives to innovation and new market creation that Congress intended this rule to avoid. A better rule would recognize that all new business should be treated similarly, and would exclude all premiums attributable to policies with less than 12 months' experience from the calculation. This would encourage the market to continue to robustly write new policies and will enhance the competitive environment sought by the drafters. Alternatively, a graduated scale leading up to the 50 percent mark, or a deferral of all premiums on new business written in the last half of a calendar year, would similarly recognize the universal issues surrounding the claims development for new business.

4. Section 158.140 – Reimbursement for Clinical Services Provided to Enrollees

This section raises a number of issues that are of particular concern. We urge HHS to revise the IFR to more closely follow the NAIC model. Section 158.140 defines those elements that must be included in the category of "claims" for the purpose of the MLR. Subsection (a) generally defines "incurred claims," and subsection (b) outlines the adjustments to those claims that will be both permitted and prohibited.

a. Subsection 158.140(a).

We note that the NAIC model regulation regarding direct claims incurred defines the term as including all medical claims, including capitation payments to physicians or any other health care providers.[1] Subsection 158.140(a), by contrast, references capitation payments only to

[1] *See* NAIC Model Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years, 2011, 2012 and 2013 ("NAIC Model MLR Regulation"), pp. 190-39, 190-40.

physicians. We suggest that capitation payments can, and often are, paid to health care providers other than physicians, including medical risk sharing arrangements with physician hospital organizations, chiropractic practices, laboratories, and other entities that traditionally enter into these types of arrangements. We suggest that in order to capture these claims the first sentence of the subsection should be amended to read:

> The report required in § 158.110 of this subpart must include direct claims paid to or received by providers, including under those medical risk sharing or capitation agreements, whose services are covered by the policy for clinical services or supplies covered by the policy.

In addition to the above, we note that subsection (a) does not include a run-out period for determining direct claims incurred. We believe section 158.103 is instructive in the importance of considering a run-out-period. The definition of *Unpaid Claim Reserves* recognizes a run-out of claims for three months beyond the end of the calendar year. This is the minimum amount of time that should be defined as a run-out period in order to allow for a truly accurate estimate of the claims that a health plan incurs for a year's worth of coverage. It recognizes that services provided to members close to the end of the calendar year may not be submitted for payment before December 31 of that year, but instead, may be sent to a health plan much later. Ensuring that the appropriate claims are matched to the appropriate premium is critical to an accurate MLR calculation.

We note, however, that there is no discussion of "claims run-out" in section 158.140, despite the fact that this is the method adopted by the NAIC and despite the fact that the IFR preamble clearly indicates that HHS has adopted the NAIC's methodology. We urge that, subsection 158.140(a) be amended to include the three-month time period after the close of the calendar year for claims incurred to ensure accuracy and clarity, and consistent with the NAIC methodology..

b. Adjustments to incurred claims in section 158.140(b).

Although the IFR claims to have adopted the NAIC approach and recommendations in regards to section 158.140,[2] it does not, and we suggest it should.

i. Paragraph 158.140(b) (2) – Adjustments That Must Be Included in Incurred Claims

The technical correction published on December 29, 2010 moved the costs plans incur for fraud reduction efforts (not to exceed the amount of claims payments recovered) from the section on activities that improve health care quality into this incurred claims provision. As we note more fully below, we suggest this is incorrect as a matter of policy. By prohibiting plans from including the costs they incur for fraud prevention activities in the numerator of the MLR, it appears that HHS takes the position that *preventing* fraudulent medical claims or *preventing*

[2] *See, e.g.,* 75 Fed. Reg. at 74874 ("The NAIC defines reimbursement for clinical services as direct claims paid and incurred claims during the applicable MLR reporting year. In this interim final regulation, HHS is adopting this NAIC approach, at Sec 158.140.")

providers from fraudulently prescribing medication or intentionally providing care they know is unnecessary is an inappropriate activity for health plans. The impact of classifying those costs as "administrative" and therefore outside the numerator of the MLR likens those costs to salaries, overhead and advertising expenses. The message to consumers – and providers – is that health plans should not engage in robust fraud prevention programs. This is the wrong message to send.

Instead, HHS should be encouraging health plans to join even more actively in the fight against health care fraud. The PPACA has given HHS an additional $350 million over the next 10 years to fight fraud in the Medicare program, an activity fully supported by the Administration. This significant expenditure is being made in recognition of the fact that combating fraud is a top priority of the Medicare program, and of the Administration. It indicates a realization that people who receive medication or treatments that they do not need are being harmed, and that fraud prevention is the first line of defense against this harm.

Recognizing that the Administration is seeking to step up efforts in combating fraud within government programs, a more consistent policy would be to encourage plans to continue their own efforts rather than penalizing plans for doing so. As HHS itself recognizes, "investments in anti-fraud detection and enforcement pay for themselves many times over."[3] The IFR's language should be revised to reincorporate fraud prevention and detection in Section 158.150, "Activities that improve health care quality," and as more fully discussed below, the full amount that plans use to combat fraud should be included in the numerator of the MLR.

ii. Paragraph 158.140(b) (3) – Adjustments That Must Not Be Included in Incurred Claims

The IFR contains language and examples suggesting that when a health plan pays a vendor or provider on a fee for service or medical/quality capitation claim, those parties may be required to itemize and deconstruct payments they receive in order to break out any administrative component embedded within the claim.

By injecting this burdensome and wasteful administrative requirement, this provision risks creating an extremely difficult system to administer that will significantly increase costs for the nation's health delivery system without adding any value to consumers. In *every* claim for health care, overhead must be built into the fee. Even non-profit and government-run provider must include these amounts in order for the entity to continue functioning efficiently and effectively. It would be especially burdensome if this provision were to be interpreted as requiring that every claim for services or contract for payment be accompanied by a detailed breakdown of all intermediary or provider's costs built into the claim.

Moreover, by potentially discouraging a range of models that rely on more aggregated payments, this provision seems at odds with the wide range of public policy efforts designed to encourage a movement away from fee-for-service payments toward a more value based payment

[3] *See:* http://www.hhs.gov/news/press/2010pres/07/20100716a.html

system. In addition, it may also discourage competition by unintentionally impeding certain alternative network models.

If implemented without attention to the concerns articulated above, it is difficult to see how this provision will advance any positive goal. Moreover, it will again have the effect of increasing, rather than reducing, administrative costs.

We would similarly request confirmation that the reference to "third party vendors" in Paragraph 158.140(b)(3) shall apply equally to all vendors, regardless of whether the vendor is an affiliated or non-affiliated vendor with the health plan."

5. Section 158.150 – Activities that Improve Health Care Quality

a. ICD-10

The IFR specifically requests comments regarding the inclusion of ICD-10 costs, noting that there is "general recognition that the conversion to ICD-10 will enhance the provision of quality care through the collection of better and more refined data."[4] The NAIC inappropriately excluded these costs from the definition of quality activities. HHS should not follow this recommendation, which we believe resulted from a misconception about the ICD-10 program and its goals.

ICD-10 is not a claims payment system. All health plans have existing abilities to pay claims. The ICD-10 conversion, which was mandated by the federal government, was not undertaken in order to enhance claims payment capabilities. As HHS has publicly recognized, implementation of ICD-10 represents "a giant step forward toward developing a health care system that focuses on quality" and is one that will "enable HHS to fully support quality reporting…bio-surveillance, and other critical activities."[5] It is difficult to understand why HHS would now fail to recognize this immense undertaking as a quality activity. Its recognition of use of ICD-10 as a quality initiative was, and remains, correct.

The preamble notes perceived difficulties in "parsing the expenses associated with ICD-10 conversions" (IFR Preamble 74876) in the implementation costs of the ICD-10 codes. To address that concern, we reference an AHIP study[6], published September 2010, which focused on those very issues. The AHIP Research Brief: Estimated Costs of Implementing ICD-10 Diagnosis Coding collected significant data from insurers on their costs of implementing the conversion from ICD-9 code sets to ICD-10 codes.

The AHIP survey was designed to specifically identify conversion costs. "*AHIP's survey of ICD-10 implementation costs was designed to separate the incremental, extra costs of implementing the new coding system from routine information technology (IT) or business costs (e.g., costs for maintenance or upgrades to existing IT systems) that would occur even in the absence of ICD-10*

[4] 45 CFR at 74877.
[5] http://www.hhs.gov/news/press/2008pres/08/20080815a.html
[6] http://www.ahipresearch.org/pdfs/SurveyICD-10CostsSept2010.pdf

implementation." Thus, focusing on the add on cost of implementing the ICD-10 code sets, the findings "*revealed an average per-member implementation cost of about $12, ranging from $38 for small health plans (less than one million members) to $11 for large plans (more than 5 million members).*" These numbers indicate an administrative cost resulting from a mandate on the system which should be recognized in the MLR methodology for special consideration.

The ICD-10 project is intended to be a leap forward from the ICD-9 codes currently in place. The ICD codes, which stand for "International Classification of Diseases," were created in recognition that only through the development of an internationally understood common language could the world describe, and therefore combat, common diseases.

The World Health Organization (WHO) developed a monograph entitled "History of the development of the ICD," which traces the development of this standard nomenclature for disease reporting from its earliest attempts in 1777, to its adoption by the American Public Health Association in 1898, to an earlier expansion from mortality to morbidity reporting after the Crimean War to its standardized adoption in the U.S. in 1944. In 1946, the WHO was charged by the International Health Conference to maintain *and update* the standardized nomenclatures. It was then titled the "International Classification of Diseases, Injuries, and Causes of Death" and was in the sixth iteration of what would become ICD-10. Revision seven was undertaken by the International Conference for the Seventh Revision of the International Classification of Diseases in 1955. The conference to begin the tenth revision was called in 1989. Countries continue to implement its provisions, including the U.S., which is one of the last of the developed countries to do so.

None of these countries have undertaken the massive overhaul of their insurance industry coding systems that ICD-10 requires to improve claims payments. To the contrary, they have done so specifically so that they may participate in the global conversation to prevent and combat death and disease world-wide. ICD is a century-old nomenclature to classify, understand, and therefore eradicate diseases around the globe. To categorize it as "administrative" or "claims-payment" is to fail to understand the gravity of this undertaking, and to discount the value of world-wide health care and disease eradication.

The World Health Organization explains ICD as follows:

> The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use. These include the analysis of the general health situation of population groups and monitoring of the incidence and prevalence of diseases and other health problems in relation to other variables such as the characteristics and circumstances of the individuals affected, reimbursement, resource allocation, quality and guidelines.
>
> It is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records. In addition to enabling the storage and retrieval of diagnostic information for clinical, epidemiological and quality purposes, these records also provide the

basis for the compilation of national mortality and morbidity statistics by WHO Member States.

See: http://www.who.int/classifications/icd/en/

At least 25 countries already use ICD-10. The U.S. is not yet among these countries, but will join them officially on October 1, 2013. This is a national quality initiative. There is nothing in the ICD-10 project that is intended to develop a claims payment system. Health plans have undertaken this massive realignment of their data collection systems to permit the U.S. to join the rest of the world in developing a deeper collective understanding of disease, causes of death and the way to combat both. We are one of the few remaining countries not already using this system.[7]

HHS has publicly recognized this as an international quality initiative. The HHS final rule (*see, 74 FR 3328-3362)* states:

> ICD-10…provide[s] specific diagnosis and treatment information that can *improve quality measurements and patient safety, and the evaluation of medical processes and outcomes.*…ICD-10-PCS is sufficiently detailed to describe complex medical procedures. *This becomes increasingly important when assessing and tracking the quality of medical processes and outcomes and compiling statistics that are valuable tools for research (*emphasis supplied).

We have located no source or commentator who has described this massive overhaul of the U.S. healthcare reporting system as one designed to improve claims payments. If the system is also used for payments, it is only because it is the only internationally recognized system of describing processes, procedures, diagnoses, outcomes and all other metrics that can be collected and analyzed through the medical community. Claims, however, may be paid without ICD-10. This is not its purpose. Its purpose is to bring the U.S. into compliance with the standards for international nomenclature of diseases and to add our knowledge and information into the international conversation and mission to eradicate preventable illness and death. Health plans must not be penalized for undertaking this years-long project, and for bearing the brunt of the financial burden of bringing the U.S. into the international mission to combat disease.

The ongoing maintenance of the system, once it is built and operational in 2013, may legitimately be deemed an administrative cost, much as is the maintenance of any system. The costs to build the system, however, are clearly being undertaken in order to improve the quality of the U.S. health care system and should be included in the quality portion of the MLR.

b. Fraud

We urge HHS to define the expenses health plans incur for fraud prevention activities as an activity that improves health care quality. Excluding these expenses is contrary to the very goals of the PPACA: developing a system to deliver consistently high quality care; optimizing the use

[7] *See: http://www.cdc.gov.nchs/data/dvs/icd10fct.pdf*

of health care resources; and advancing the federal policy to enhance anti-fraud cooperation between private and public entities. Excluding these expenses also contradicts the universal recognition by the Administration, the HHS Office of the Inspector General, and other leaders in both the public and private sectors, that there is a direct link between fraud prevention activities and improved health care quality and outcomes.

As noted above, we do not agree that fraud reduction efforts should be accounted for as an adjustment to incurred claims and we reincorporate those comments here. In addition, the costs health plans incur for fraud *prevention*, as opposed to recoupment, are critical in ensuring high quality health care and should, as a matter of federal policy, be encouraged. Health plans that implement programs to prevent unnecessary services or care, or that prevent, detect and remedy fraudulent and abusive conduct must not be penalized when they commit appropriate resources to these tasks. Classifying them as administrative costs does just that. The public is not well served when health plans are forced to choose between robust fraud prevention programs and other significant programs, such as the mandatory ICD-10 program discussed above.

Health plans devote substantial resources to programs to identify individuals who provide care under false credentials, who line their pockets by delivering medically unnecessary services, or who make treatment decisions based on illegal referral relationships. The direct relationship between these programs and health care quality is unassailable. As noted by the Coalition Against Insurance Fraud, in November 2006, nearly one half of at least one health plan's active pharmacy investigations involved prescription forgery and overprescribing.[8] The federal government should encourage, not discourage, these patient-centered quality and safety initiatives.

AHIP's recently released *AHIP Research Brief: Insurers' Efforts to Prevent Health Care Fraud*[9] addresses the very concern noted above. The cost savings to the system are primarily due to the *prevention* of false claims or fraudulent activity, rather than paying such claims and then recovering them. The MLR IFR does not, however, recognize the value of the savings to the system by preventing fraudulent claims from occurring.

The findings of the cited research brief indicate significant savings result from identifying and not paying submitted fraudulent claims, the very anti-fraud activities not recognized in the MLR IFR. Survey respondents included a cross-section of health plans ranging from small, regional companies, to large, multi-state commercial carriers. In total, responding companies had 95 million enrollees. Companies were asked to estimate only costs and savings directly attributable to their antifraud efforts, the costs of special programs or employees dedicated to fraud prevention or detection, as well as savings from improper payments recouped or prevented.

Among the large companies in the survey, estimated net savings from anti-fraud operations (savings less costs) were over $3 per enrollee, resulting in an estimated total net savings of nearly $300 million in 2008. For the medium-sized companies reporting, estimated net savings were about $1 per enrollee and 2008 total net savings were about $10 million. For smaller

[8] *Prescription for Peril,* Coalition Against Insurance Fraud, December 2007, at 34.
[9] http://www.ahipresearch.org/pdfs/FraudPrevention2011.pdf

companies, estimated net savings were about $2.70 per enrollee, and total net savings reported were approximately $5 million in 2008.

The value of these fraud detection and prevention programs is clearly demonstrated, and the costs per enrollee are low compared to the savings. Thus, if administrative expense cost cutting related to MLRs cuts into the efforts that support anti-fraud programs, the expected result would be loss of such potential savings and higher claims costs. Neither are optimal outcomes for consumers or the costs of health insurers.

c. Health Care Professional Hotlines

We continue to urge recognition of the important work that nurses and other providers do every day as they provide advice and information to consumers who call professional hotlines. A health care professional hotline is not a customer service dial-in, where individuals receive information about benefits or administrative issues about coverage. These hotlines are for emergencies, for medical questions, for coaching, and for wellness and care management to facilitate member access to quality care and care management. It has long been recognized that professionally staffed hotlines, after-hours emergency service number and similar services are truly "quality" improvement activities. The IFR should be clear that all professional hotline services are considered quality improvement and not imply that there are portions that are not. If HHS requires information about the elements of a specific program for a specific health plan, then it has the ability to gather that information during the course of its audits. It should not promote the misconception that there are professional hotlines that are not staffed by medical professionals, and that do not give individuals access to high quality care for emergency, wellness or other health-care related activities.

d. Subsection 158.150(c) (14)

The language of paragraph (c) (14), that excludes from the definition of quality activities "any function or activity not expressly included…" remains overly narrow and prescriptive. As we noted in early comments on this issue, the list of programs that provide direct benefits to health plan members and to the population as a whole is long and continues to evolve rapidly. Creating a static list of "quality" programs, as this IFR does, freezes the ability of health plans to innovate and develop new and better programs for the populations they serve. Giving the Secretary the discretion to add specific programs for specific issuers does not save this IFR from being overly rigid and likely to stifle innovation and improved quality.

A workable system would ensure that investments in quality activities are recognized before they are made. If HHS believes that improving the quality of care that people in this country receive is an important goal, then it should join with the plans that have led the way in quality improvement, rather than stifle their ability to grow this important function. An after-the-fact review, after staff time and, energy and funding have already been expended, is not an appropriate commitment to improving quality of care. Instead, HHS should draw broad, identifiable parameters, and permit health plans to innovate to find appropriate ways to improve health care quality and hold down health care costs within those borders.

A decade ago, provider credentialing efforts were in their infancy. Then, the concept of quality standards was only randomly adopted. Today, it is axiomatic that plans will credential their provider networks, and that they will do so under standards significantly more uniform than they were at the outset. Today, quality review by credentialing organizations such as URAC and the National Committee for Quality Assurance (NCQA) are commonly accepted and, in many states, required. Reviewing these kinds of quality improvement activities after the fact, on a health plan–by-health plan basis, rather than drawing the broad parameters within which quality design and activities can be developed, effectively prevents the creation of these nationally recognized programs in the future. This is counterproductive and harmful to the health care delivery system as a whole.

6. Section 158.161 – Reporting of Federal and State Licensing and Regulatory Fees

Section 2718 describes the denominator of the MLR as:

> The total amount of premium revenue (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 the Patient Protection and Affordable Care Act) for such plan year.

Where the language of the statute is clear and reasonable, legislative intent should be carried out. Here, the statute very clearly excludes "licensing or regulatory fees." It does not exclude only those fees that defray insurance department operating expenses, or examination fees in lieu of premium taxes. The appropriate reading of this clear legislative language includes all examination fees, such as financial and market conduct examinations, fees for the audits that HHS will be conducting based on Subpart D of the IFR, all licensing fees imposed by state insurance departments, and all other fees imposed by the states or federal government that health plans must pay to maintain the privilege of doing the business of insurance. Health plans are not given a choice or opportunity to avoid these charges, and should not be penalized by having them included in premium revenue for the MLR. HHS similarly should not attempt to undermine clear congressional language by placing restrictive parameters around the fees that may be deducted from the denominator of the MLR equation.

7. Section 158.162 – Reporting of Federal and State Taxes

As we discussed above, section 2718 describes the denominator of the MLR as including premium revenue, and deducting from that revenue "Federal and State taxes and licensing or regulatory fees…"

Congress was very clear when it spelled out the categories of fixed expenses that were to be deducted from premium. It used plain language to require the calculation to remove "Federal and State taxes" from the denominator. It neither said "certain Federal and State taxes" nor specified that only some taxes, but not others were to be deducted.

Where the language of the statute is clear and reasonable, legislative intent should be carried out. Here, it is more than reasonable to assume that taxes, which are a non-discretionary cost to health

plans and to their members, should be removed from the calculation. Based on that clear and reasonable language, there is no rational basis for HHS to refuse to carry out this legislative intent, or to mandate that certain taxes be included in the MLR calculation. The appropriate reading of this language mandates that all taxes that health plans are required to pay to maintain their corporate status or to maintain the privilege of doing the business of insurance should be excluded from the calculation.

8. Section 158.170 – Allocation of Expenses

This section requires that health plans include in their report to HHS:

> A detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

We understand the need for allocation given the structure of the MLR calculation. However, we are concerned about the public disclosure of potentially sensitive internal financial information that would result. Providing this detail to HHS or to a state insurance department during the course of an audit or examination, where the department's work papers remain out of the public domain, would be preferable, and would not diminish the regulatory objective of ensuring that there is a reasonable and rational allocation taking place. Health plans' internal methodologies are not needed to achieve this objective, and, should under no circumstances be made public.

Additionally, we note that the level of detail, including a narrative description of allocation for each expense required in this section is overly broad and will simply add to the administrative costs that health plans must bear. Given the stated purpose of section 2718, to bring down the cost of health care, it is not appropriate for the agency to add to the cost of the system. Health plans' annual statements are audited annually. The vast majority of the information included in this "Supplemental Health Care Exhibit" is included in that document, and will therefore be audited, directly or indirectly, for reasonableness. Requiring a narrative description, in a public document explaining the rationales for these allocations is duplicative, and therefore unnecessary. HHS should leverage the work already being done by the states before layering on additional reporting requirements.

9. Sections §158.230 to 158. 232: Credibility Adjustments

HHS recognized the need for a credibility adjustment to be used in the MLR calculation. It is indisputable that small blocks of business cannot withstand or absorb purely random variations in claims frequency or severity, and that, without a credibility adjustment, health plans' ability to maintain the solvency of those blocks would be severely compromised. However, as both we and the American Academy of Actuaries (AAA) noted, using a confidence interval of 50 percent as opposed to 80 percent significantly decreases the value of that credibility adjustment and

leaves all health plans with small blocks of business susceptible to those random variations. This likely results in rebate payments even when the products are appropriately priced, leading to potential adverse solvency implications. An appropriate credibility adjustment will, to a great extent, eliminate the random fluctuation and give a more accurate picture of the actual loss ratio at which the health plan operates.

The AAA, in its letters of May 20 and November 5, 2010 to the NAIC's Accident and Health Working Group,[10] and the HHS Office of Consumer Information and Insurance Oversight (OCIIO) respectively, compared the results of using a 50 percent and an 80 percent confidence interval factor. The comparison resulted in their concluding that "applying adjustments with a confidence interval of 80 percent or 90 percent results in expected post-rebate MLRs that are relatively close to the pricing target MLR of 80 percent. However, a confidence interval of 50 percent results in an expected post-rebate MLR in excess of 81 percent for the smaller market sizes."[11] In other words, health plans with smaller blocks are significantly disadvantaged by the failure to use an appropriate credibility adjustment to protect them from the impact of random statistical variations in claims. These health plans with small blocks of business will effectively produce loss ratios significantly higher than their competitors with large blocks of business. This is an inappropriate result.

The PPACA was clear that the special circumstances of smaller plans should be taken into account when designing the loss ratio calculations. (*See*, Section 2718 (c), *"Such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.")* HHS recognized this as well, when it required states wishing to increase their MLR requirement above the PPACA standards to take the same issues into account:

> In adopting a higher minimum loss ratio than that set forth in Sec 158.210, a State must seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State and value for consumers so that premiums are used for clinical services and quality improvements. (158.211 (b))

A market that does not ensure a level playing field for health plans with small blocks of business ultimately may see those health plans exit the markets, thereby crippling competition. The IFR recognizes this on one hand, but then ignores it on the other. In the area of credibility it ignores the pricing and solvency issues facing the smaller plans and hinders their ability to compete with health plans with large blocks of business. We urge HHS to adopt the rationale described in the AAA's May 20 letter and move the credibility adjustments to 80 percent.

In addition to ensuring that the credibility adjustment provides that, to the extent possible, small blocks of business are not disadvantaged in the MLR environment, it is critical to recognize that these small blocks even with those adjustments will remain disproportionately volatile.

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[10] *See,* http://www.actuary.org/pdf/health/aaa_statistical_credibility_response_100520_final.pdf and http://www.actuary.org/pdf/AAA%20to%20HHS%20on%20MLR%20100510.pdf

[11] *Id.*

Extremely large single-occurrence claims, often called "shock claims" in the industry, are singularly unpredictable and will seriously distort the experience for small to mid-sized blocks of business. Spreading these catastrophic costs over the broadest possible risk pool is one of the fundamental purposes of insurance. Appropriately spreading "shock claims" across a health plan's entire block of business strengthens the MLR system by increasing the credibility of the reported loss ratios and encouraging broad pooling of catastrophic claims. Failing to spread these claims undermines the very foundations and principles of insurance and can threaten the stability of the market. HHS should not create rules that may destabilize, rather than strengthen the insurance marketplace.

To ensure that market stability and strengthening are achieved to the greatest extent possible, we recommend pooling claims over a specified attachment point, and then allocating them as a percentage of earned premiums. For example, to determine the attachment point the health plan's total enrollment could be divided by the number of states in which it has active blocks of business. The resulting average state enrollment would be used to determine the attachment point. The attachment point would increase as the average state enrollment increased, rising to an attachment point that would limit pooling to truly catastrophic claims for fully credible plans.

Then, at the end of each reporting period, claims over the specified attachment point would be subtracted from the incurred claims for each state. The aggregate amount of the pooled claims would then be divided by the aggregate earned premium for the health plan and the resulting percentage of premium allocated back to each state.

This approach is designed to tie the level of pooling allowed to the average size of each health plan's book of business in any given state, and ensure that all claims are allocated back to and fully reflected in the health plan's various state MLR calculations. We believe that this method appropriately avoids the distortion of the experience of small and mid-sized blocks of business discussed above.

In addition to the issues above, we note that paragraph 158.232(c) (1) contains the following language:

> (i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be calculated as follows: The lesser of the sum of the individual family members' deductibles or the overall family deductible for the subscriber and subscriber's family, shall be divided by the total number of individuals covered through the subscriber (including the subscriber).

This directive for the derivation of average deductible amounts is not actuarially sound and is not internally consistent with the underlying manner in which the Table 2 values were determined by the NAIC. It is also unnecessarily complex. We understand that the AAA will similarly address this issue.

The concept of a "family deductible" was developed as a way to deal with the relatively few situations in which multiple family members exceeded their individual deductible in the same policy year. It is generally recognized that the probability of more than two members of the

same family incurring substantial medical expenses, unless caused by the same accident, is small enough that a family deductible maximum of two times the individual deductible does not add significantly to the overall benefits paid under a policy. Therefore, actuarially sound principles generally and historically have set a family deductible at twice the individual deductible, not at an amount equal to the individual deductible times the number of people covered. Indeed, the calculation described in the IFR has never been used anywhere in calculating deductibles.

Because of this, health plans as a rule do not request or maintain information to match family deductibles with the *total* number of family members covered during each year. Families, for example, with more than two or three children are not necessarily required to report the total number of family members covered by the policy, and beyond the base number of children – generally two or three – health plans cover the entire family without an increase in premium. Consequently, the requirement to divide the family deductible by the total number of individuals covered will not be a calculation readily available without significant additional administrative costs being incurred by not only for health plans, but also for the employers for collecting the data for the employees being covered. Since this calculation also produces an actuarially unsound answer, we urge HHS to revise this language to base the average deductible solely upon the individual deductible.

10. Section 158.240 – Rebating Premium if the Applicable Medical Loss Ratio Standard is not Met

Subsection 158.240(d) requires rebates to be provided no later than August 1 following the end of the MLR reporting year. We suggest that September 1 is a more realistic date, and that September 15 would best ensure that the data used is complete and accurate.

The section 158.110 report is due no later than June 1 of the calendar year. This is an adequate time after the final calculation of the three-month run-out to ensure that the majority of claims for services are appropriately matched against premium received. By June 1, a health plan can determine which "cell" or line of business it believes may cause a rebate payment. Because of the unnecessarily complex manner of rebate payments outlined in the IFR, health plans will then need to approach each policyholder in the impacted "cell" and gather not only the names and address of each individual covered by that policy, but also the names (and addresses if applicable) of all covered dependents. In addition, it will need to then gather information from each policyholder regarding the portion of the premium paid by each individual covered under the policy in that prior year. This will require employers to provide data not only on current, but also on former employees. It is highly unlikely that every employer with a large or small group policy will – or can - immediately provide this information within the month of June.

During the month of July, the health plan will be required to process the payments to meet the requirement that they be provided no later than August 1. To the extent that a policyholder receives a credit against premiums due, this calculation will need to be made and a premium notice must be sent. To the extent a policyholder or a former policyholder will receive a check or a credit against a debit card, the health plan will need appropriate time to make the payments. This is a tremendous undertaking, parts of which will entail manual calculations. The effort necessary to ensure this will all be done on a timely and accurate basis, significantly increases

administrative operations and costs. The purpose of section 2718 is to bring down the cost of health care. We should, therefore, be working together to streamline the system, not create unnecessary complexities.

If the insurer's report is approved as submitted, then a period of at least 60 days following the June 1 date is appropriate for providing rebates. The rebate due date should be delayed whenever HHS requires a recasting of the insurer's report. There should also be a provision for a waiver, or appropriate adjustment of the rebate due date for insurers under circumstances where an employer fails to provide, or timely provide, the necessary information upon request.

11. Section 158.241 – Form of Rebates

We request clarification with respect to paragraph (a) (2) of this section. If a health plan provides a rebate in the form of a premium credit and the rebate exceeds the premium due for the first month billed after the rebate due date, the IFR should make clear that the health plan is not subject to a late payment penalty if the premium credit is extended to the premium due the following month.

12. Section 158.242 – Recipients of Rebates

HHS recognized that health plans are unable to provide specific rebates to every individual enrollee in all its health plans, particularly those who are members of large or small employer groups. Drafting the IFR to have the health plan remit the rebate to the party that has submitted the premium in the first instance is a reasonable, rational policy position. Health plans writing group contracts will rarely have a census of members of the group. Those members are not static, as employment status or insured status changes during the course of a calendar year. Remitting the rebate to the policyholder, which in the group setting is the employer, is the only truly effective way to ensure that the rebates are appropriately returned to the entity that paid the premium to the health plan.

It is reasonable to require that health plans, by contract, obligate the employer to return to its employees that portion of the rebate that is attributable to their contributions. But it is not reasonable to hold health plans responsible for potentially multiple payments based on actions of entities they do not control. A health plan has a responsibility to demand that the employer take appropriate actions. The health plan, however, cannot be ultimately responsible for those actions. If an employer, for example, refuses to provide rebates to its employees individually, and instead uses them for some other purpose, the health plan will have no means to know, or to prevent that from occurring. If the employer returns the rebates to some, but not all of its employees, the health plan will again have no means to know or to prevent that from occurring.

Similarly, if the health plan demands a census and the employer provides one that is less than totally accurate or complete, the health plan has no means of knowing that has occurred. The IFR sets up a system of strict liability, in which the health plan must somehow ensure that employers take specific actions with regard to their employees or face the possibility of double payments. The health plan can include those requirements in its contract of insurance, but without a full and complete audit of the employer's actions after a rebate is delivered, it will have

no means to determine to whom the employer provided rebates, or if those remittances were correct. The level of detail that would need to be audited and the level of intrusion into the daily operations of the employer are unjustified. Health plans should be able to rely upon the appropriate actions of the employer/policyholder, and should not be held responsible for the actions or misdeeds of others outside its sphere of control, and the IFR should include a specific safe harbor permitting health plans to rely upon the accuracy of their employer-clients' representations.

In addition, the language of the IFR makes it impossible for a health plan to timely provide a rebate in situations where the employer provides no census or proportional payment information. The health plan in those instances will be in a position of being forced to choose which provisions of the IFR to violate – the timely rebate payment requirements, or the data collection requirements. It is important to give health plans the appropriate tools to ensure that rebates get credited to the employer's contract or are remitted back to the employer at the right time. Forcing the employer and health plan to undertake onerous reporting and data collection exercises in order to do so creates the wrong environment for this to take place smoothly. Health plans should be specifically permitted to remit the entire rebate to the employer in instances in which the health plans asks for, but does not receive timely information from the employer, without violating the IFR's data collection requirements.

13. Section 158.260 – Reporting of Rebates

Again, we recognize the necessity of a report of rebates paid. The focus of the report should be to ensure that health plans have taken the steps necessary to provide rebates to the policyholder who remitted the premium. The reporting requirements of this section, however, go well beyond that and create significant administrative burdens, not only for the health plans, but also for the policyholders. As an example, paragraph 158.260(c) (3) requires a report on the

> [a]mount of rebates that were provided to enrollees, including a breakdown of the amounts provided based upon the portion of premiums paid by group policyholders and amounts provided based upon the portion of premium paid by subscribers.

As we noted in our comments above, this level of individual reporting would require significant intrusion into the operations of each employer group that receives a rebate – the only way a health plan could obtain this information would be to require that the employer provide detailed and burdensome amounts of employee-specific reporting. An employer whose group receives a rebate would be burdened with many hours of unnecessary paperwork. The alternative to requiring this detailed up front reporting from employers would be for the health plan to audit the employer every time a rebate is provided. This is similarly an intrusive and burdensome requirement that will negatively impact the very individuals and employer groups the MLR is intended to benefit. HHS should not create a rule that will add more costs and administrative responsibilities to the health care financing and delivery system, when no good purpose is served by the additional information gathered.

In addition, we note that the report required by section 158.260 is due at the same time as the report for premiums and expenses required by section 158.110, which is due on June 1 of each calendar year. The concurrent reporting date means that health plans will have to report on the rebates provided and, in the case of employer group business, how they are allocated among employees, before the report on which they would be based has been approved by HHS, before rebates have been completely calculated and before the insurers would have collected any necessary information from the employers as noted in our comments above. We suggest that the reports required by section 158.260 should be submitted after the rebates are calculated and delivered, and in any event, not before October 1 of each calendar year.

In addition, we note the current open question of whether health plans must also issue 1099s for the rebates, and if so, to whom. To avoid duplicate and burdensome reporting requirements we suggest that if 1099s must be issued, then this section would not apply.

14. Section 158.403 – Circumstances in Which a State is Conducting Audits of Issuers

We agree that, if a state conducts an audit of one of its regulated health plans, HHS should accept and adopt the findings of that audit. However, we have significant concerns about the requirements that HHS would place upon the state in order to accept its audit.

Initially, we request clarification regarding the provisions of paragraph (a) (1) of this section. The requirement is that the "laws of the State permit public release of the findings of audits of issuers." We question whether this is intended to mean that states will release the findings of the audits during the pendency of the audit, or, as is the case today, not until after the audit is finalized and the health plan has exhausted its due process rights to review and respond. If it is the latter, then we have no objection to the provisions. If the former, then we point out that significant harm, both to health plans and to the state process itself, will occur if preliminary audit findings are made public. We suggest HHS amend this section to indicate that the laws of the state should permit public release of the final audit reports, rather than the "findings" of audits.

Similarly, there is no provision for the confidential treatment of preliminary audit reports in paragraph (a) (5), which requires the state to submit "preliminary or draft audit reports to HHS within 6 months of the completion of audit field work…" The IFR should clearly state that HHS will maintain as confidential any preliminary or draft audit report. Release of preliminary, potentially incorrect or incomplete data by the federal government is inappropriate and can cause significant harm not only to health plans but also to their policyholders.

15. Subsection 158.501 –Access to Facilities and Records.

Our concern in this area reflects a perspective that the degree of access HHS demands of subcontractors and other entities not directly subject to this IFR is unprecedented and disproportionate to the goal of encouraging and verifying compliance inasmuch as it lacks consideration of viable, less onerous alternatives. In particular, the IFR demands that health plans permit or by contract require access for HHS audits of parent organizations, related entities, contractors, subcontractors, agents or transferees that "pertain to any aspect of the data

reported to HHS or to rebate payments calculated and made under this part." (*See,* §*158.501(b)).* According to the plain language of this section, every provider who submits a claim, and every network participant whose costs are somehow included in the calculation of a MLR will need, as a result of providing health care to employer groups or individuals, to agree to make its books, records, physical facilities, computers and all other data and records open to HHS inspection and audit. Even businesses and other entities that merely provide services to those who may submit claims to health plans would be subject to a potential audit under these provisions.

This is a substantial – perhaps unparalleled -- expansion of the federal government into the commercial health care system, and deeply implicates a number of entities and individuals whose businesses are not, by Congressional design, subject to HHS authority under the MLR. Attempting, effectively, to regulate these entities through health plans will have the effect of raising health care administrative costs rather than lowering them. A more cost effective, and less intrusive and disruptive approach, would be for HHS to leverage the existing information already available to it. Health plans must have internal financial controls in place; in preparation for financial examinations from their state regulators or to comply with the requirements for risk management reports, reports to the Securities and Exchange Commission (SEC) and other federal agencies if they are publicly traded, and myriad other control reports and audits that will provide sufficient information for HHS to determine whether charges made to and expenses incurred by the entity are accurate and necessary. Demands for audits of individuals and entities with only tangential relationships to health plans, and whose information may "pertain to any aspect of the data" involved in calculating the MLR represents significant over-reaching by the federal agency, that is intrusive, burdensome and expensive to the system as a whole.

16. Subpart F – Federal Civil Penalties

Section 158.602 imposes a strict compliance standard to what are basically subjective and non-specific standards of performance, such as "substantially complete and accurate" reporting and "timely and accurately" payment of rebates. If strict compliance is required, than specific standards, such as exact timeframes for reporting, standards for financial accuracy of rebate calculation and timeframes for providing rebates should be set forth.

Section 158.606 sets very high penalty amounts, based on calculation standards that may be irrelevant to the alleged non-compliant activity. For example, it is improbable that specific individuals will suffer any identifiable injury by a failure to allow access and entry to an insurer's premises, yet the penalty is calculated as if they were. We recommend penalties more directly relate to the specific harm caused by an alleged, specific violation. For a failure to file reports or allow access, the penalty should be a flat amount per business day of delay. In the case of untimely payment of rebates under section 158.602(c), an appropriate penalty could be the assessment of interest on the amount of rebates paid late. Otherwise, an insurer who miscalculates a rebate amount by pennies would pay the same fine as a miscalculation by hundreds of dollars. In each case, the remedy or penalty should address the specific harm.

Neither section 158.606 nor section 158.608 provides for an offset against or mitigation of the penalty amount by any amount paid to a state regulatory authority for a state penalty arising from the same act or omission giving rise to the federal violation. The regulatory entity with primary

jurisdiction, whether it be the state or federal agency, should collect any penalty for non-compliance. To the extent that the non-primary agency assesses a greater penalty, that penalty amount should at least be reduced by the primary agency's penalty. If the two agencies' penalties are not somehow coordinated, the total amount assessed, especially if unrelated to the actual dollar harm of the violation, could result in an unintended but adverse impact on the solvency of an insurer.

17. Underestimated Costs of Implementation in the IFR Regulatory Impact Analysis

Health plans have significant concerns with the cost of implementing systems changes and protocols to address the requirements of the IFR, and the additional, unanticipated administrative and staffing costs related to the new elements in the IFR that were not included in the NAIC recommendations. Key concerns are related to disaggregation of data, need for new methods of allocations (and system updates or upgrades and storage), reporting, auditing, and compliance costs. No one anticipated, nor do the costs in the Regulatory Impact Analysis (the "RIA") anticipate the larger cost this IFR will impose on the health insurance industry.

The RIA appropriately noted in the technical appendix:

> The Department anticipates that the level of effort relating to these activities will vary depending on the scope of an issuer's operations. Specifically, each issuer's estimated reporting burden is likely to be affected by a variety of factors that will affect the level of complexity of its filing – including the number of markets in which it operates (e.g., individual, small group, large group), the number of States and licensed entities through which it offers coverage, the degree to which it currently captures relevant data at the State / company / market level, number of enrollees, whether it offers other types of A&H coverage, whether it is a Health Blank or Life Blank filer, and whether it is a subsidiary of a larger carrier.

However, the remainder of the analysis fails to take into account key concerns which we outline below. This leads to a significant underestimation of the administrative costs imposed on an industry already working to reduce such administrative expenses in keeping with the stated intent of the PPACA's promise of providing value.

Concerns:

- One of the key assumptions in the RIA is that "companies already collect this data." In fact, that is not always the case, and, especially in the context of employee premium sharing in employer groups, plans have never collected that data. Even data that companies may have collected was often on an aggregated basis, and allocated at a corporate level, not at a per state, per segment, per product level. The RIA thus underestimates the significant impact on accounting systems, allocation processes and procedures, and auditing.
- The RIA assumes certain economies of scale, yet as noted above the disaggregation required, and in the case of multi-state plans, the differences in state-by-state regulations,

and data gathering down to an employer group level drives out any possible economies of scale.

- ***Section 158.140 (b) 3 (ii) and (iii)*** in particular pose significant and new cost implications to insurers that reflect data not gathered, and the disaggregation of data that does not drive savings nor economies of scale. Worse yet, the unintended consequences of such requirements might be to see increased administrative expenses *and* increased claims expenses if providers move from more effective capitation and global reimbursements to instead seek a per service fee that is increased to cover more administrative load placed on them as a result of these new requirements.
- The implementation costs do not anticipate the challenges imposed on both insurers and employer groups in ***section 158.242 (b) 1*** to obtain prior year enrolled employee's portion of premiums paid, by product. Additionally, the costs do not appear to reflect the challenges health plans will face in gaining the information needed, and the amount of paperwork for employer groups to maintain records of all that data to provide to insurers. Even if the employer group chooses not to issue the rebates, the employer group is obliged, under this IFR, to provide needed information to the insurer. Yet employers are not liable for any civil penalties under this IFR, only insurers would be penalized. This liability on insurers, if employers do not – or cannot – provide the necessary employee cost sharing information on a timely basis, or at all, does not appear to be included in the costs of the RIA, either.
- The complexities of administering ***section 158.242 (b) 1*** which insurers have identified include: employer groups with renewal dates off calendar cycle, so that they may have employees change between programs, at renewal, doubling the amount of information that must be collected, and the number of rebate allocations and checks.
- In an AHIP survey of insurers, ranging from small insurers (enrollment less than 100,000) to very large insurers (greater than 5 million), 18 of the 25 insurers surveyed had cost estimates in excess of the total cost estimates in the RIA, with some estimates above $25 million. These estimates are preliminary and may not cover some significant aspects of compliance with the rule. In any event, even these limited estimates are considerably higher than the RIA low range estimate of over $100 thousand, and high range of over $200 thousand per health plan. For example, one responding health plan – a large plan with enrollment of between 1 million and 5 million in the survey – noted that it covered tens of thousands of small groups. If rebates were involved, the mailing costs alone of communicating with those small businesses would likely far exceed the RIA estimate.

These concerns reflect the serious unanticipated effects and cost of the MLR IFR on the regulated industry, and which will likely have deleterious impact on insurers, consumers and providers as a result. We thus strongly urge reconsideration of those elements in the IFR that we've identified as creating these unintended consequences.

We thank you for the opportunity to provide our input and concerns.