August 27, 2010

Office of Consumer Information and Insurance Oversight
Department of Health & Human Services
Attention: OCIIO-9994-IFC
P.O. Box 8016
Baltimore, MD 21244-1850


RE: Request for Comments Regarding the Interim Final Rules for Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act Relating to Pre-Existing Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections

Dear Sir or Madam:

UnitedHealth Group is pleased to provide the Departments of Health and Human Services, Labor and Treasury (the “Agencies”) our comments regarding the Interim Final Rules (the "IFR" or the “Rule”) relating to Pre-Existing Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections under the Patient Protection and Affordable Care Act (“PPACA” or the "Act"), 75 Fed. Reg. 37188 (June 28, 2010). We applaud the efforts of the Agencies to publish this important regulatory guidance in such a timely manner.

UnitedHealth Group is dedicated to making our nation’s health care system work better. UnitedHealth Group's 78,000 employees serve the health care needs of more than 70 million Americans, funding and arranging health care on behalf of individuals, employers and government, in partnership with more than 5,000 hospitals and 650,000 physicians, nurses and other health professionals. It is this experience upon which we rely in offering the following comments.

We welcome the opportunity for constructive dialogue regarding the pre-existing condition exclusions, lifetime and annual limits, rescissions and patient protection provisions, and their impact on the health care system. We would be pleased to provide additional data and information supporting the comments set forth in this letter.
Summary of Recommendations

The recommendations offered below stem from our evaluation of the practical implications of implementing the IFR’s requirements across diverse health care offerings. To support our recommendations, we provide specific examples and data based on our experience. We believe these recommended changes are appropriate to best serve consumers and reduce unintended consequences associated with the rules in their current form.

Accordingly, we recommend the following for the Final Rule for pre-existing condition exclusions, lifetime and annual limits, rescissions and patient protections:

Pre-Existing Condition Exclusions

- Incorporate provisions related to annual open enrollment periods, as outlined in the Agency’s July 27, 2010 “Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions.”

Annual and Lifetime Limits

- Provide clarification that plans and issuers may treat out-of-network benefits differently, consistent with the Agencies’ Interim Final Rule on preventive care services.
- Specify, in the text of the regulation, that a policy or plan’s exclusion of benefits for a condition is not considered an annual or lifetime limit.
- Develop a model notice for required notice to enrollees who have exceeded their lifetime limit.
- Provide clarification that the re-enrollment right does not apply to former enrollees no longer covered by the plan.
- Provide an exemption from annual limit restrictions for stand-alone health reimbursement accounts (“HRAs”).

Rescissions

- Provide clarification that the Rule's rescission requirements do not apply to retroactive terminations of coverage.

Emergency Services and Primary Care Provider Designations

- Ensure patient protection by prohibiting providers delivering emergency room services from balance billing consumers.
- Provide guidance on the application of the Rule’s provisions in an Accountable Care Organization (“ACO”) setting.
- Provide guidance on the application of the Rule’s provisions in a capitated network setting.

Waiver Process

- Establish and provide guidance on the waiver process, including factors for consideration in granting waivers and the method for application and approval.
• Expand the Secretary’s waiver authority to include consideration of lifetime limit provision waivers.

Highlighted below are the primary concerns that drive these recommendations, focusing on potential unintended consequences to consumers, as well as specific detailed recommendations for the modification of the IFR. We also include commentary on items that were specifically noted for comment in the IFR or where the Agencies solicited feedback.

I. Pre-Existing Condition Exclusions

(1) Incorporate provisions related to annual open enrollment periods, as outlined in the Agency’s July 27, 2010 “Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions.”

On July 27, 2010, HHS released “Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions.” This guidance indicated that the IFR does not preclude plans and issuers from restricting open enrollment for children under 19, whether in family or individual coverage, if permitted under existing state law. The guidance further indicated that issuers in the individual market may determine the length and frequency of open enrollment periods for children under 19, families and adults, subject to state law. We urge the Agencies to include these open enrollment provisions in the Final Rule, in order to provide appropriate clarity around these new pre-existing condition exclusion requirements.

Recommendation: We request that the Agencies codify the guidance in the “Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions” by amending the Rule to include the provisions related to open enrollment periods, including allowing plans and issuers to determine frequency and duration of the open enrollment and include guidance on the plan’s rights and obligations outside of the open enrollment period.

II. Annual and Lifetime Limits

(1) Provide clarification that plans and issuers may treat out-of-network benefits differently, consistent with the Agencies’ Interim Final Rule on preventive care services.

The IFR does not address whether the prohibition on annual and lifetime limits applies to out-of-network benefits. Such limits are important plan design features that ensure quality of care and assist in controlling health care costs. UnitedHealth Group, like the vast majority of health plans and issuers, utilizes networks of credentialed providers that have a contractual relationship with the plan or issuer to deliver health benefits to covered members. Our experience has shown that the use of network providers enhances the quality, coordination, and efficiency of health care services. We believe it is important to allow continued use of annual or lifetime limits on non-network services, which provide an additional tool to encourage the use of in-network providers by covered members.
We believe this approach is consistent with policies encouraged in the Act. For example, Congress took into account a provider’s status as an out-of-network provider when it defined cost-sharing in Section 1302(c)(3) of the Act. That section makes clear that balance billing amounts for non-network providers should not be considered cost-sharing for purposes of essential benefits. We also note the recently released Interim Final Rule on preventive care services specifies that coverage requirements do not apply to services received out-of-network for reasons that are also applicable to the provision of essential benefits by non-network providers (and which are described in the preceding paragraph).

**Recommendation:** We recommend revising the Rule to allow the continued use of annual and lifetime limits in the case of non-network services. Such a change would be consistent with the Act’s regulatory framework and allow continued use of plan design tools to encourage the provision of coordinated care through in-network providers.

(2) **Specify, in the text of the regulation, that a policy or plan’s exclusion of benefits for a condition is not considered an annual or lifetime limit.**

The Preamble to the IFR provides that an exclusion of benefits for a condition will not be treated as an annual or lifetime limit, but this is not specified in the text of the IFR itself. We request that the text of the IFR be clarified to reflect this guidance.

(3) **Develop a model notice for required notice to enrollees who have exceeded their lifetime limit.**

Section (e) of the IFR contains the transitional rules for those individuals whose coverage or benefits have ended due to a lifetime limit, including a requirement that plans issue a notice to individuals when a lifetime limit will no longer apply and that the individual, if covered, is eligible for benefits under the plan. The notice must also advise certain individuals of their right to enroll in the plan. We request that the Agencies issue a model notice to facilitate compliance with this requirement.

(4) **Provide clarification that the re-enrollment right does not apply to former enrollees no longer covered by the plan.**

The IFR does not specify that notice of re-enrollment rights, for those individuals who have reached the lifetime maximum, applies only to those individuals who are otherwise eligible for the plan, and not to former enrollees who are no longer eligible or covered by the plan due to reasons other than meeting the lifetime maximum. We request that the Agencies clarify that the notice of re-enrollment rights are required only for those enrollees who are otherwise eligible for the group plan and eligible and still covered under an individual plan.

(5) **Provide an exemption from annual limit restrictions for stand-alone HRAs.**

The IFR exempts from the annual limit restrictions certain types of health coverage, including health flexible spending accounts, medical savings accounts, health savings accounts, retiree-only HRAs and HRAs integrated with group health coverage that otherwise complies with the annual and lifetime limit restrictions. The Agencies requested comments on non-retiree, stand-alone HRAs and whether the annual limits should apply. We recommend that the Final Rule
exempt stand-alone HRAs from the annual limit restrictions, in order to offer flexibility in plan design and because it may offer consumers lower premiums.

III. **Rescissions**

(1) **Provide clarification that the Rule’s rescission requirements do not apply to retroactive terminations of coverage.**

The prohibition on rescissions in Section 2712 of the Act only refers to rescissions of coverage and not retroactive terminations of coverage. Rescission of coverage is to rescind the contract of insurance such that a person never had such coverage. By contrast, retroactive termination is to terminate the coverage retroactively, wherein the contract of insurance is cancelled back to a point in time, and the enrollee retains coverage prior to that point in time. For example, if an employer informs a plan that one of its employees left the company two months ago and requests that the plan retroactively terminate that employee’s coverage, that termination should not be affected by the Rule’s rescission provisions. Rescission has specific legal meaning that is not applicable to the retroactive termination of coverage of employees or dependents in a group insurance plan.

We are concerned that the Rule’s definition of rescission, which requires fraud or an intentional misrepresentation of material fact for a plan to retroactively cancel or discontinue any coverage, is overly broad and could be read to prohibit routine changes to group eligibility rolls made in the ordinary course of business. For example, the Rule’s Example 2 outlines a case of a retroactive termination – not rescission – wherein the employee retains his insurance coverage, prior to the point the employee becomes a part-time employee. Since the employee retained coverage the entire time the employee worked full-time, there was no rescission. However, the inclusion of this example in the Rule wrongly implies that the rescission provisions apply in this situation.

**Recommendation:** We request that the Agencies confirm that the Act’s rescission provisions do not apply to retroactive terminations of coverage as described above. We also request that the Rule either eliminate Example 2 or revise the example to describe a true rescission of coverage.

IV. **Emergency Services and Primary Care Provider Designations**

(1) **Ensure patient protection by prohibiting providers delivering emergency room services from balance billing consumers.**

The IFR sets forth a federal standard for reimbursement for out-of-network emergency room services and, when the formula is applied, the reimbursement is considered "reasonable." If reimbursement by plans to providers is "reasonable," then providers should be required to accept such payment in full and prohibited from balance billing. Consumers are subject to unknown financial risk if providers can determine when and for how much they want to seek additional reimbursement from patients. Additionally, the ability to balance bill may create an incentive for providers to terminate their contracts with plans. This will destabilize networks and ultimately result in higher costs for services for consumers.
**Recommendation:** The Final Rule should clarify that emergency room providers must accept payment from plans as payment in full and are prohibited from balance billing consumers for emergency room services. If HHS determines that it does not have the authority to impose such a prohibition, we recommend that the Final Rule provide additional guidance to states to address this important consumer protection issue through state legislation by confirming that PPACA does not preempt states from regulating this issue.

(2) **Provide guidance on the application of the Rule’s provisions in an Accountable Care Organization (“ACO”) setting.**

The IFR requires that plans or issuers allow: (i) enrollees to designate any available participating primary care provider (“PCP”) as their PCP; (ii) parents to designate any available participating physician who specializes in pediatrics as their children’s PCP; and (iii) enrollees to directly access in-network OB/GYNs without a prior authorization or referral. We request that the Agencies consider how these provisions would work in an Accountable Care Organization (“ACO”) setting, and whether the provisions would support the Act’s objectives for these new delivery models.

ACOs are commonly defined as a group of providers associated with a defined population of patients, accountable for the quality and cost of care delivered to that patient population. ACOs may include a hospital, a group of primary care physicians, and specialists who share accountability for the coordination and quality of care, including meeting specific outcomes measures. The Act establishes an ACO pilot program that permits these entities to share in Medicare savings generated through their initiatives. As the ACO framework is based on extensive care coordination, we believe it is important to carefully consider whether the Rule’s access provisions should apply to ACOs.

**Recommendation:** We request that the Agencies review the Rule’s access provisions and provide guidance to clarify how these provisions would apply to an ACO framework.

(3) **Provide guidance on the application of the Rule’s provisions in a capitated network setting.**

The Rule’s access provisions, as described above in Section IV(2), could have unintended consequences if applied in a capitated network setting where providers receive a specified payment per enrollee for managing and delivering health care services. Capitated provider groups negotiate these specified payments based on a coordinated care model, with services delivered by providers within their group. Enrollees typically select a capitated provider group and that group receives a capitated payment to deliver services to that enrollee. However, an enrollee who is permitted to access any participating OB/GYN without an authorization, including an OB/GYN who participates in the plan’s network but is not part of the capitated group, would undermine the group’s ability to manage that enrollee’s care and their negotiated payment arrangements.
**Recommendation:** We request that the Agencies review the Rule’s access provisions and consider whether they should apply in a capitated network setting. We also recommend a clarification that, in a capitated network setting, OB/GYN direct access provisions apply only to OB/GYNs who belong to the enrollee’s selected medical group.

V. **Waiver Process**

(1) **Establish and provide guidance on the waiver process, including factors for consideration in granting waivers and the method for application and approval.**

The IFR provides that the HHS Secretary may establish a program to waive the annual limit restrictions, if compliance would result in: (1) a significant decrease in access to benefits under the policy or plan; or (2) significantly increased premiums for policy or plan coverage. We support the Secretary’s authority to establish a waiver program and request that the Final Rule provide specific details on the process.

**Recommendation:** We request that the Agencies provide guidance in the Final Rule outlining the Secretary’s waiver program, including application method, timeframes for Agency review and decision-making, and factors that the Secretary will consider when evaluating waiver applications. We also suggest that existing plans be provided grandfathered status through 2011, as the waiver process is not yet established and open enrollment materials are being produced now.

(2) **Expand the Secretary’s waiver authority to include consideration of lifetime limit provision waivers.**

We strongly support the authority granted to the HHS Secretary to waive the annual maximum provisions in the case of coverage where compliance with the Rule would cause a significant increase in premiums or decrease access to plan benefits. We believe that the lifetime maximum provisions may have the same impact on certain plans, resulting in significant premium increases or decreased access to benefits. Therefore, we urge the Agencies to expand the Secretary’s waiver authority to include both annual maximums and lifetime dollar maximums.

**Summary of Recommendations & Conclusion**

We believe the recommendations highlighted in this letter support the goals of the Act and the IFR to balance protections for consumers with continued access to affordable and high quality coverage. On behalf of the 70 million consumers served by UnitedHealth Group, we thank you for your thoughtful consideration of these recommendations and the discussion of the issues and concerns underlying them.

UnitedHealth Group appreciates the opportunity to provide you with our comments on the IFR for Group Health Plans and Health Insurance Issuers under PPACA. Should you have any questions regarding the information set forth in these comments please do not hesitate to contact me.
Thank you again for your time and thoughtful consideration of the enclosed comments.

Sincerely,

Gail K. Boudreaux
Executive Vice President
and President,
UnitedHealthcare