



UnitedHealth Group<sup>SM</sup>

Gail Boudreaux  
Executive Vice President  
President, UnitedHealthcare  
9900 Bren Road East  
Minnetonka, MN 55343

September 21, 2010

Office of Consumer Information and Insurance Oversight  
Department of Health & Human Services  
Attention: OCIO-9993-IFC  
P.O. Box 8016  
Baltimore, MD 21244-1850

*Submitted Via Federal Rulemaking Portal: <http://www.regulations.gov>*

**RE: Request for Comments Regarding the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act**

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 Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act ("PPACA" or the "Act"), 75 Fed. Reg. 43330 (July 23, 2010).

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.

We welcome the opportunity for constructive dialogue regarding the internal and external appeals 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.

Given the substantial changes required by the Rule, and the short timeframe within which to implement the changes, we respectfully request that the Agencies: (1) adopt a substantial compliance standard for enforcement; and (2) deem a plan's internal appeals and external review process compliant if the plan follows that substantial compliance standard.

In addition to the recommendation that the Agencies adopt a substantial compliance and deemer period, we address the following recommended changes:

- Protect enrollee privacy and minimize potential member confusion by eliminating some of the additional elements required in notices of adverse benefit determination;
- Consider reevaluating the language translation provisions for alternatives that may address enrollee needs and achieve the Agencies' objectives more effectively;
- Revise appeals timeframes to clarify the new requirements to provide enrollee notification of new and additional evidence;
- Retain a 72 hour notification requirement and emphasize that such is the outside limit, requiring early notification as warranted by the circumstances; and
- Clarify that external review for self-funded group health plans and health insurers in states that do not have an existing review process only applies to adverse benefit determinations based on medical necessity, appropriateness of care or settings of care, and experimental or investigational treatments.

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 Rule.

### **(1) A Substantial Compliance and Deemer Period Should Apply.**

September 23, 2010 is an extremely short timeframe to make the significant operational changes required by the Rule, which could subject group health plans and health insurance issuers (hereafter referred to as "plans") to legal or regulatory actions. Many of the new requirements will compel plans to make comprehensive changes in IT systems and business processes, which will take time to implement.

For example, notices of adverse benefit determinations, which include Explanations of Benefits ("EOBs"), must include diagnosis code(s) and treatment code(s) and their meanings; reference to both internal and any new external review rights; reference to reason codes; as well as information regarding the availability of any applicable offices of health insurance consumer assistance or ombudsman. EOBs currently do not include these data elements. The system changes needed, including reprogramming internal system formats, file structures and processing

logic to generate the codes, require more time than allotted under the Rule's current effective date.

Additionally, the Rule requires plans to respond to urgent claims within no more than 24 hours, which is currently not required by applicable regulatory or accreditation standards. As this is a hard-and-fast 24 hour rule that does not allow for weekends or holidays to be excluded from the calculation, plans will have to develop the capability to review such claims on a 24/7 basis. Hiring, equipping and training extra staff will take time that is not available under the current deadline. It is also unclear whether delegated medical groups, which contract with plans and have responsibility for urgent care claims, will be staffed with additional, trained personnel and ready to review such claims on this shorter timeframe.

“Substantial compliance” would refer to actions taken by plans to substantially comply with the Rule's requirements, as reflected by meeting the majority of the requirements, as well as planning for, analyzing, testing or implementing the systems and business process changes necessary to administer the remaining new requirements.

Since a non-enforcement policy for substantial compliance would extend only to the issuing Agency and does not affect other parties, we request that the Agencies also deem a plan's internal claims and appeals process, and its external review process, as being in compliance with the Rule's requirements for a transition period until September 23, 2011, if the plan meets a substantial compliance threshold.

This request allows for a phased-in approach, which is important to ensure a uniform transition period for the extensive outreach, data collection, staffing and system changes implicated by the new requirements. Substantial compliance, coupled with deeming, would not only remedy the short deadline, it would also make implementation processes more uniform during the transition period, thus increasing efficiency in operating employee benefit plans and health insurance.

**Recommendation:** We request that the Agencies mitigate the effects of the short compliance timeframe by: (1) adopting a substantial compliance standard for enforcement; and (2) deeming a plan's internal appeals and external review process as compliant if the plan is following that substantial compliance standard. We further request that the Agencies include a similar good faith standard as included in the Interim Final Rules for a Grandfathered Health Plan and in the Interim Final Rules for Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, e.g.: “[f]or purposes of enforcement, the Agencies will take into account good-faith efforts to comply with a reasonable interpretation of the Rules' requirements for a transition period until July 1, 2011 (thus affecting plan years beginning before July 1, 2011).”

**(2) Protect enrollee privacy and minimize potential member confusion by eliminating some of the additional elements required in notices of adverse benefit determination.**

The Rule requires that diagnoses and treatment codes and their corresponding descriptions be included on notices of adverse benefit determination. In addition to the concerns mentioned above and other technical implementation issues, including this private medical information in member mailings gives rise to privacy concerns. Diagnosis codes and treatment codes may

communicate extremely sensitive information that would not otherwise be communicated by listing the medical service delivered. For example, the new requirement could result in an EOB stating ICD-9 code and description 099.5/CHLAMYDIA TRACHOMATIS or ICD-9 code and description 079.53/HUMAN IMMUNODEFICIENCY VIRUS, TYPE 2 {HIV 2}. The addition of this detailed protected health information in member mailings goes beyond the minimum necessary amount of information needed to appeal a claim while unnecessarily risking unintended disclosure.

A specific example that raises a concern is where the subscriber would have access to EOBs that are issued to dependents under state law or HIPAA. Under the requirements of the Rule, EOBs would contain sensitive information as a result of the inclusion of diagnosis and treatment codes. Disclosure of this information, however, for a dependent on an EOB issued to a subscriber would potentially violate state laws that prohibit the sharing of information regarding sensitive conditions such as HIV/AIDS, drug and alcohol treatment, mental health treatment and sexually transmitted diseases unless specifically authorized by the recipient of those services. This conflict confronts plans with the possibility of noncompliance with federal or state law and the unintended disclosure to a subscriber of sensitive information that was not intended by a subscriber's dependent.

We also believe it is important to consider whether the addition of these coding elements to the notices would be easily understood by enrollees. EOBs and other notices of adverse benefit determination focus on the claims for medical services provided to the enrollee, not the medical condition or diagnosis that requires such services for treatment. The bills that enrollees receive from hospitals, physicians or other providers similarly outline charges for services provided, rather than the medical condition of diagnosis requiring treatment. Diagnosis codes sometimes do not correspond with information in the medical record – for example, physicians may label tests with the disease they hope to rule out – which may prove confusing or even cause alarm to enrollees.

The health care industry is working aggressively to implement the new ICD-10 coding system, which consists of over 140,000 codes and will replace the 17,000 codes in the current ICD-9 system. While we do not believe such coding should be in notices, as discussed above, if the requirement remains, we believe it would be more appropriate to phase in any changes over a reasonable time period to better gauge privacy concerns and mitigate member confusion during the transition to ICD-10.

**Recommendation:** We request that the Agencies reconsider the requirement to add diagnosis and treatment codes to EOBs and notices of adverse benefit determination. If the Agencies do not modify the Rule, we request that the Final Rule clarify that the plan will not be liable for unintended disclosures when someone other than the claimant opens the mail or reviews the EOB disclosing such sensitive or protected health information.

**(3) Consider reevaluating the language translation provisions for alternatives that may address enrollee needs and achieve the Agencies' objectives more effectively.**

The Rule requires plans to provide a notice to enrollees “in a culturally and linguistically appropriate manner” for both internal and external claims appeals processes. Plans are considered to provide relevant notices in a cultural and linguistic manner if notices are provided

in a non-English language, based on thresholds of the number of people who are literate in the same non-English language. UnitedHealth Group supports the provision of important health care information in a culturally and linguistically appropriate manner, as demonstrated by our longstanding use of telephonic oral interpretation services through our call centers as well as our plans and initiatives dedicated to serving the needs of our multicultural membership. However, we are concerned that the survey and data collection efforts required to implement these provisions, particularly for group plans, would require significant costs with potentially minimal enrollee response, and we request that the Agencies reevaluate these requirements and consider alternatives that may address enrollee needs and achieve the Agencies' objectives more effectively.

Recent legislation in California (effective in 2008) mandated that all plans and insurers implement a new Language Assistance Program ("LAP") that required: mailing surveys to all enrollees; collecting and storing all enrollee language preferences; determining languages that met threshold requirements; identifying and translating certain enrollee documents; and developing tracking and reporting mechanisms to report to state regulators and demonstrate compliance. UnitedHealth Group's total cost to implement LAP was approximately \$19 million, with a utilization rate in calendar year 2009 of 59 written translation requests, 538 plan-initiated written translations and zero complaints related to language translation. We also experienced no discernable increase in utilization of oral interpretation services due to LAP compared to prior use of such services. The state's health plan association estimates that the seven largest plans, including UnitedHealth Group, spent more than \$50 million to implement the LAP, with minimal enrollee response and utilization consistent with the data outlined above.

**Recommendation:** We recommend that the Agencies adopt a "translation upon request" standard for written or telephonic interpretation services, or work with stakeholders to consider alternatives that will reduce implementation costs and ensure that enrollees who require language translation or interpretation have access to those services. Given the very limited enrollee response to the LAP survey, we believe that a "translation upon request" approach would be an appropriate alternative to the broad survey and data collection requirements provided for in the Rule.

**(4) Revise appeals timeframes to accommodate the new requirement to provide enrollee notification of new and additional evidence.**

The Rule requires plans to provide claimants with any new or additional evidence considered in connection with their appeal and to provide the claimant with an opportunity to respond to this new information. While this requirement essentially creates an additional level of appeal, the Rule does not revise or extend any timeframes for resolving the appeal prior to external review. We request that the Agencies modify appeals timeframes to accommodate time for this new notification requirement.

The Rule does not indicate specific timeframes for plans to provide claimants with new or additional evidence or for claimants to provide a response. Because the existing timeframe for resolving appeals is already tight, adding this new appeal level will further strain compliance with turnaround times. As the Rule also provides enrollees with the right to go to external review immediately if issuers or plans fail to meet internal review requirements for any reason, it would be appropriate to modify the timeframes in light of this new appeal opportunity.

**Recommendation:** We recommend that the Agencies provide further guidance on the requirement to provide new and additional information and the opportunity to respond. We also suggest modifying the internal appeals timeframes to reflect the time required to implement this new requirement.

**(5) Retain a 72 hour notification requirement and emphasize that such is the outside limit, requiring early notification as warranted by the circumstances.**

The ERISA claims procedure rule and the Rule require urgent care claims to be made “as soon as possible, taking into account medical exigencies . . . .” The Rule modifies the current ERISA rule by changing the outside limit for urgent initial decisions to 24 hours. We agree that, due to the significant potential impact on the health and well-being of patients, urgent care claims should be handled as soon as possible based on a medical professional’s analysis of the individual’s condition, and we suggest that the 24 hour rule does not need to be applied in all cases. Appropriate handling (and enforcement of any violations) can be based upon exigencies of the situation, and does not necessitate a move to 24 hours for all urgent claims.

**Recommendation:** We suggest that the 72 hour outside time limit be retained, along with the requirement that faster action may be needed depending on the circumstances.

**(6) Clarify that external review for self-funded group health plans and health insurers in states that do not have an existing review process only applies to adverse benefit determinations based on medical necessity, appropriateness of care or settings of care, and experimental or investigational treatments.**

The Rule expands the scope of issues that are to be submitted to external review beyond what currently is required under state law, or as contemplated by the NAIC Model Act and PPACA. PPACA Section 10101(g) requires plans to comply with an external review process that, at a minimum, “includes the consumer protections set forth in the Uniform External Review Model Act” as promulgated by the National Association of Insurance Commissioners (“NAIC”). Section 3(A) of the NAIC Model Act states that “an adverse benefit determination” subject to external review is a denial based upon a determination that the service “does not meet the health carrier’s requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness. . . .” This is also the type of review that has been traditionally contemplated by the states.

The Rule appears to recognize this in its discussion of the application of external state review processes rather than the federal review process, if the state process meets the consumer protections of the NAIC Model Act, including providing for “external reviews of adverse benefit determinations (and final adverse benefit determinations) that are based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of covered benefit.”

By contrast, the Rule, in discussing the Federal external review process for self-funded group health plans and for health insurance issuers in states that do not currently have a review process, describes the scope as applying to “any adverse benefit determination or final internal adverse benefit determination” other than eligibility determinations. It is unclear why the Federal external review process would be different from that followed by the states, or that which

Independent Review Organizations (“IROs”) currently conduct. IROs perform reviews based on decisions involving medical necessity, appropriateness of care or settings of care, or experimental or investigational treatments and are intended to provide an additional, independent medical review of a claimant’s appeal of such an adverse benefit determination. They have not been involved in dispute resolution involving policy or coverage decisions. It is not clear how IROs, fulfilling their current role, can properly evaluate such decisions since the Rule does not set forth the criteria of the individuals who would be reviewing such adverse benefit determinations, nor the criteria to be utilized in undertaking such reviews.<sup>1</sup>

**Recommendation:** We request that the Agencies clarify that Federal external review only applies to adverse benefit determinations based on medical necessity, appropriateness of care or settings of care and experimental or investigational treatments. Such a change would be consistent with the Act, the NAIC Model Act and state external review laws.

On behalf of the 70 million consumers served by UnitedHealth Group, we thank you for your thoughtful consideration of our comments. Please do not hesitate to contact me if you have any questions regarding our recommendations.

Sincerely,



Gail K. Boudreaux  
Executive Vice President  
and President,  
UnitedHealthcare

---

<sup>1</sup> Technical Release 2010-01 appears to implicitly recognize this in its discussion of external review for self-insured group health plans in discussing the types of documents the IRO may consider in its review of adverse benefit determinations, which mainly include medical records, attending health care professional’s recommendations, reports from appropriate health care professionals, practice guidelines, evidence based standards, applicable clinical review criteria, etc. Page 5, Technical Release 2010-01.