UnitedHealth Group℠

December 8, 2010

Office of Consumer Information and Insurance Oversight
Department of Health & Human Services
Attention: OCIIO-9986-NC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted Via Federal Rulemaking Portal: http:www.regulations.gov

RE: Request for Information regarding the Affordable Care Act Federal External Review Process

Dear Sir or Madam:

UnitedHealth Group is pleased to provide the Departments of Health and Human Services and Labor (the "Agencies") our comments in response to the Request for Information (the "RFI") regarding Federal External Review Process established by the Patient Protection and Affordable Care Act ("PPACA" or the "Act"), 75 Fed. Reg. 70160 (November 17, 2010).

UnitedHealth Group is dedicated to making our nation's health care system work better. Our 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 to provide input on the new federal external review ("FER") process, based on our experience with state external review programs and their contract Independent Review Organizations ("IROs"), as well as our administration of a Voluntary External Review Program for self-funded customers. As the Agencies design the FER process and prepare a request for proposal, it will be important to conduct a procurement that fully recognizes the expertise, staff and costs required to meet the federal requirements. As we discuss below, we believe that the use of IROs to fulfill certain demands of the FER program is inappropriate (nor are IROs equipped to fulfill those demands), and believe that the Agencies

should revise the scope of this program to be consistent with state external review requirements and the Act.

Scope of Federal External Review

The RFI requests comments on "operational issues" in order "to ensure consistent and uniform processes for external review." Before responding to the particular issues (1) through (16) identified in the RFI, we want to address a threshold issue which impacts both the operations and consistent processes of external review overall.

The FER process established by the Interim Final Rule issued on July 23, 2010 ("IFR") applies "to ***any*** *adverse benefit determination* or *final internal adverse benefit* determination," except a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan. Adverse benefit determinations subject to FER appear to include denials for clinical reasons (e.g., medical necessity), denials for administrative reasons (e.g., benefit limitations) and rescissions.

The IFR creates a scope for FER which exceeds the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners ("NAIC Model Act"). Under the NAIC Model Act, the scope of external review is limited to decisions based on *medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit*. In contrast, FER will extend to **any** decision, other than one based on eligibility. Indeed, the broad scope of FER would extend to such categories as out-of-network payment amounts, coinsurance amounts, coordination of benefit information, timely filing denials, claims processing, prompt pay, provider coding, network, exhaustion of benefits or deductibles, out-of-pocket maximum thresholds, and nonclinical exclusions such as aromatherapy, hypnotism, personal care, comfort or convenience items and exercise equipment.

We request that the Agencies revise the scope of adverse decisions potentially subject to FER to be consistent with the NAIC Model Act and existing state programs. Expanding the scope of decisions subject to FER to include denials for both clinical and administrative reasons would have significant implications. While we recognize that rescission decisions are important to review through an independent process, extending FER to all administrative denials is inconsistent with PPACA for the following reasons:

- **The FER process is inconsistent with PPACA and the NAIC Model Act.**

While the Act requires the Secretary to develop a model "similar" to the NAIC Model Act, FER's scope and expansiveness is not similar. The NAIC Model Act is focused on a narrow class of the most controversial denials – those related to clinical issues. The clinical class of adverse benefit decisions is a relatively small universe of all denials, which we estimate at no more than 10 to 15 percent of all denials. The FER model will now extend to the remaining 85 to 90 percent, except for the small amount that concerns eligibility determinations.

This inconsistency will result in two vastly different external appeals processes. Plans and carriers subject to FER will bear costs and compliance issues much different than those subject

to state external review ("SER"). Enrollees in plans subject to SER will have different rights than those subject to FER. The IFR falls short of the Act's stated goals of reducing the cost of health care and extending the same rights to all Americans.

- **The economic assumptions used to support the IFR are flawed.**

The IFR estimated that the cost of FER would be $1.6 million dollars in 2011, based on data in a study by America's Health Insurance Plans ("AHIP") that estimated 1.3 external appeals per 10,000 participants which apparently led the Agencies to assume that there would be 2,600 FERs filed in 2011. However, the AHIP study was based solely on SER, and thus cannot serve as the basis for estimates regarding the much more expansive FER.

Medicare Parts C and D allow external review of more adverse decisions than contemplated by the NAIC Model Act and serves as a better source of expected external appeals. A Center for Medicare and Medicaid Services ("CMS") Fact Sheet about Medicare's expansive external review program indicates an appeal rate of 55.4 external appeals per 10,000 participants. (See http://www.cms.gov/MMCAG/05_IRE.asp.) Using the CMS data and the IFR methodology, the cost of the FER would be in excess of $148 million in year 2011 alone.

- **The IFR failed to account for all costs associated with FER, which impairs the ability of prospective IROs to fully recognize the administrative costs associated with entering into an agreement with the federal government.**

While the IFR estimated payment to external review agents to average $605 per review, it failed to recognize the new costs it has added to the administration of all health insurance coverage and group health plans. The expansion adds significant new costs related to identification, record gathering and transmittal of all forms of internal policy and operational documentation to the external review vendors. In reviewing administrative denials, IROs will need a broad range of information that will take time and effort to gather and provide. Existing IROs performing SERs have no experience with administering these new requirements and the associated costs that will mount under an expansive FER.

For instance, with regard to an appeal as to whether a subscriber has exhausted his or her deductible, the reviewer will need the plan benefit and claims information for all prior claims in that plan year. For network utilization (i.e., whether the provider is in-network or not), plans will be required to submit provider contracts (if in-network), which are not often stored electronically, or will need records which demonstrate that the doctor is out-of-network. Because the cost of FER will be borne by the plan, FER unnecessarily drives up cost and creates many scenarios – unlike under the NAIC Model Act – where the amount in dispute will frequently be dwarfed by the cost of FER compliance.

Moreover, the section of the IFR discussing economic impact notes that the average overturned claim under the NAIC Model Act is $12,400. The kinds of claims now subject to FER – denials for duplicate submissions, timely filing issues, benefit limitations, coverage exclusions, deductible disputes – will be a fraction of that average. Indeed, our average commercial claim on our largest claims processing platform is less than the average $605 IRO cost estimated in the IFR.

- **IROs do not have the expertise to review administrative denials and the RFI fails to make clear the new duties IROs must perform under FER.**

Many of the disputes subject to FER differ from those contemplated by the NAIC Model Act, where clinical records and medical professional expertise drives the external review. The DOL Technical Release 2010-01 (August 23, 2010), providing further instructions related to the IFR, indicates that IROs must be accredited by URAC or a similar nationally recognized accrediting organization.

URAC accredits IROs only on the basis of the ability to review determinations related to medical necessity, appropriateness of medical services, or experimental/investigational services. (See http://www.urac.org/programs/prog_accred_iro_ss.aspx?navid=accreditation&pagename=prog_accred_IRO). Indeed, the agents have no expertise in administrative denials and there is no way to validate competence in the required areas. However, FER gives those agents authority to make decisions vested in carriers and plan fiduciaries. In reality, FER seems to stand in stark contrast to ERISA's governing principles as it removes from ERISA fiduciaries their granted right to exercise expertise over a plan and gives it to unlicensed entities with no noted competence in complicated areas.

We urge the Agencies to consider these issues carefully and prioritize operational readiness and national consistency when designing the FER process. If the determinations subject to FER were to include denials for administrative reasons, clear, consistent and objective review standards and defined qualifications for individuals retained by IROs to review these types of decisions would be necessary. The Agencies will also have to consider the cost and administrative impact of managing a significantly greater volume of decisions, as compared to state experiences with external review limited to clinical issues.

Comments on Specific RFI Questions

(2) What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?

While robust standards exist for medical professionals that conduct clinical reviews, there are not similarly defined credentialing standards for non-clinical reviewers. If FER encompasses more than clinical reviews, we recommend that the process ensure the development of standards for review of non-clinical determinations, including the composition of the review panel, credentialing standards for reviewers and decision support protocols.

Because the scope of additional administrative issues within the FER process could range from out-of-network reimbursement disputes to provider coding, it will be important to define standards that would be used to consider these appeals. Absent clarification that FER will be revised to be consistent with the NAIC Model Act and existing state processes, we request that the Agencies address the development of objective standards for review of administrative issues and ensure compliance by any contracting IROs.

One area of particular concern is the qualifications of reviewers for rescission appeals. In these cases, IROs will need to determine whether: 1) the applicant intentionally omitted information on the application in order to obtain coverage; and 2) the undisclosed information was material to the risk assumed by the insurer. Analyzing these appeals will further require evaluation of: a) the awareness the applicant had of the undisclosed condition; b) the significance that the symptoms/condition had for the applicant; c) whether the undisclosed history provided the motivation for the applicant to apply for coverage; d) whether the applicant had an appreciation that fully disclosing his/her health history may preclude an insurer from issuing coverage; and e) whether the omitted health history was material to the risk assumed by the insurer.

Prior to the appeals requirements imposed by the IFR, most IROs used clinical professionals almost exclusively for reviews. As a result, the current readiness of these organizations to consider rescission appeals is limited to a review of the applicant's knowledge and experience with his/her condition or symptoms. In order to ensure proper analysis of a rescission appeal, we request that the Agencies require that review panels for rescission determinations include an individual with training and experience in underwriting insurance coverage and an individual experienced in civil litigation. The underwriter's expertise supports the analysis of the materiality of the undisclosed health history, while the litigation attorney's training and experience lends itself to evaluating whether all the evidence reasonably leads to a conclusion that the applicant's omission of health history rises to the level of "fraud or an intentional misrepresentation of a material fact."

In addition, health insurance contract language varies greatly from plan to plan, market to market, and state to state. An issuer that administers those contracts is very familiar with the provisions in its own contracts, how they inter-relate to each other, and the scope, breadth and depth of coverage they provide. However, an IRO will be confronted with having to evaluate this for a wide range of health insurance contracts, each of which is constructed very differently. When considering that most IROs currently are focused on clinical decisions rather than contract language interpretation, FER will require a whole new skill set for qualified reviewers. Because health insurance contracts are complicated, legal documents, we request that the Agencies require review panels to include attorneys with insurance and contract law experience or individuals with training and experience in drafting, reviewing and interpreting insurance contracts.

(4) What are IROs' current capacity for performing reviews? Does staffing and the time necessary for performing a review differ based on the type of claim (e.g. medical necessity, experimental/investigational treatment, coverage issues, etc.)?

Because SER processes are generally limited to clinical or experimental/investigational determinations, IROs may be challenged to identify and retain sufficient numbers of credentialed personnel to review the broader scope of issues subject to FER. We urge the Agencies to consider the number and types of determinations that may be subject to FER and ensure that accredited IROs can retain sufficient, credentialed reviewers and have the capacity to render timely, accurate and consistent decisions.

(16) What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?

We believe that IROs should be required to meet several key objectives:

- IROs must establish a national network of credentialed medical specialists and subspecialists, as well as professionals with expertise in underwriting, contract law, litigation, benefit interpretation and other areas necessary to appropriately evaluate the broad scope of decisions that may be subject to FER;
- IROs must demonstrate the ability to consistently produce high quality reviews, based in part on meeting accreditation standards; and
- IROs must meet high service standards, including ease of interface with insurers and plans, recordkeeping, ease of document transmission, and compliance with turnaround times and other business requirements.

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

Sincerely,

Thad C. Johnson
General Counsel
UnitedHealthcare