MEMORANDUM TO CLIENTS

Re: Model Notices to Comply with PPACA's Claims and Appeals Regulation and Interim Guidance on the Federal External Review Process

On August 23, 2010, the Departments of Labor ("DOL"), Health and Human Services ("HHS"), and Treasury (collectively, the "Agencies") jointly released model notices that non-grandfathered plans and health insurance issuers may use to satisfy new requirements under the Patient Protection and Affordable Care Act ("PPACA") regarding adverse benefit determinations and appeals of adverse benefit determinations. The model notices are available at the DOL's website, www.dol.gov/ebsa, and at the website for the HHS Office of Consumer Information and Insurance Oversight, www.hhs.gov/ociio/.

Additionally, the Agencies released interim guidance establishing procedures for the "Federal external review process" established by PPACA, which contains a limited enforcement safe-harbor for self-funded group health plans. The interim guidance, titled Technical Release 2010-01 ("Technical Release"), is expected to be published in the Federal Register on August 26, 2010, and is also available at www.dol.gov/ebsa.

I. Background

On July 23, 2010, the Agencies published an Interim Final Rule (the "IFR") that implemented requirements imposed by PPACA with respect to benefit claims and appeals of denied claims. See 75 Fed. Reg. 43,330 (July 23, 2010). The IFR applies to group health plans, insurance issuers offering group health insurance coverage, and insurance issuers offering individual policies, but does not apply to grandfathered plans. The requirements of the IFR apply for plan years beginning on or after September 23, 2010 (January 1, 2011 for calendar year plans). A detailed discussion of the IFR's requirements is available in our memorandum to clients dated July 28, 2010, which is available at http://www.groom.com/resources-521.html.

A. The IFR's Disclosure Requirements for Adverse Benefit Determinations and Notices of a Plan's Decision on Appeal

Among other things, the IFR requires that any notice of adverse benefit determination or final internal adverse benefit determination must include: (1) the date of service; (2) the name of the health care provider; (3) the claim amount (if applicable); (4) the diagnosis code (such as an ICD code or DSM-IV code); (5) the treatment code (such as a CPT code); and (6) the corresponding meaning of such codes. The denial codes (such as a CARC and RARC) must also be included, along with a description of any plan or issuer's standard (such as medical necessity), used in denying the claim. This information must be provided in addition to the content already required to be included in a denial notice under the existing DOL claims regulation.
The IFR also provides that notices of final internal adverse benefit determinations (i.e., decisions denying a claimant's appeal) must include a discussion of the plan's decision, along with a description of available internal appeals and external review processes, including information detailing how the claimant may file an appeal with any applicable office of health insurance consumer assistance or ombudsman established to assist individuals with claim denials. In the Preamble to the IFR, the Agencies advised that they would issue model notices that plans and health insurance issuers could use to satisfy their disclosure obligations with respect to notices of adverse benefit determinations.

B. **The IFR's "Federal External Review Process"**

The IFR also provided guidance on the new, mandatory external review process required under PPACA, and established a new Federal external review process that is applicable to non-grandfathered plans that are not subject to a state external review process (such as self-funded ERISA plans).

Specifically, under the IFR, insured (individual and group coverage) and non-ERISA self-funded plans (such as state and local governmental plans and church plans) that are subject to a state external review program that meets the NAIC Uniform Model Act must comply with the State external review and not the Federal external review process. Self-funded ERISA plans, however, as well as insured plans that are not subject to a State external review process, must comply with the Federal external review process. The IFR explained that the Agencies would be issuing further guidance detailing the requirements of the Federal external review process.

II. **The Agencies' Model Notices and Interim Guidance**

A. **The Model Notices**

The Agencies have issued model notices of adverse benefit determinations, internal appeal determinations, and external review determinations that plans and health insurance issuers may use to satisfy the new disclosure requirements established by the IFR. As noted, the model notices are available at the DOL's website, [www.dol.gov/ebsa](http://www.dol.gov/ebsa), and at the website for the HHS Office of Consumer Information and Insurance Oversight, [www.hhs.gov/ociio/](http://www.hhs.gov/ociio/).

B. **The Federal External Review Process**

The Technical Release, published by the DOL's Employee Benefits Security Administration, provides an enforcement safe harbor for non-grandfathered, self-insured group health plans that are not subject to a state external review process – and which are therefore subject to the Federal external review process. The interim enforcement safe harbor applies to plan years beginning on or after September 23, 2010, until it is superseded by future guidance.

The Technical Release provides that the DOL and the Internal Revenue Service will not take enforcement action against a self-funded group health plan that does either of the following:

1. Voluntarily complies with a state external review process, if a state so permits; or
2. Complies with the external review procedures detailed in the Technical Release.
Where no state external review process applies, the enforcement safe harbor established by the Technical Release would impose a number of obligations and administrative requirements upon self-funded plans. Among other things, plans would be required to:

- Allow claimants to file a request for external review within *four months* after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination (*i.e.*, a final plan decision denying an appeal);

- Complete, within *five business days* of receiving a request for external review, a preliminary review of the request, to determine if:
  
  a. The claimant was covered by the plan at the time the service was provided or requested;
  
  b. Whether the claim is eligible for federal external review (*i.e.*, the claim does not relate to the claimant's failure to satisfy the plan's eligibility requirements);
  
  c. The claimant has exhausted the internal claims and appeals process (unless not required to do so under the IFR); and
  
  d. The claimant has provided all forms and information required to process the external review request.

- Issue written notice to the claimant, within *one business day* after completing the preliminary review, as to whether the claim is eligible for external review.
  
  - If the claim is complete but not eligible for external review, the plan's written notification must include the reasons for its ineligibility and contact information for the DOL's Employee Benefits Security Administration (including its toll-free telephone number);
  
  - If the plan determines the request for external review is not complete, the plan must notify the claimant of the materials needed to complete the request, and the plan must allow the claimant to submit the additional materials within the later of (a) the four-month filing period, or (b) the 48 hour period following the claimant's receipt of the notification.

- Contract with at least three independent review organizations ("IROs") accredited by URAC or other nationally-recognized accrediting organizations to which external reviews will be sent on a rotating basis (or assigned by another unbiased method for selecting the IRO, such as random selection);
  
  - The Technical Release provides that the IRO must not be eligible for any financial incentive based on the likelihood that the IRO will uphold the plan's denial of benefits.

- Enter into contracts with IROs which provide, among other things, that:
a. The assigned IRO will use legal experts where appropriate to make coverage determinations under the plan;

b. The plan will provide the assigned IRO, within *five business days* of the claim's assignment, all documents and information that the plan considered in making the adverse benefit determination or decision on appeal.

- If the plan fails to provide the documents within this five day period, the IRO may unilaterally terminate the external review and make a decision to reverse the plan's benefit denial.

c. The IRO will decide the claim *de novo*, and not be bound by any decisions or conclusions reached during the plan's internal claims and appeals process. In other words, the IRO will be contractually prohibited from affording any deference to the plan's decision on the claim or appeal;

d. The IRO may consider materials outside of the plan's claim file, including (i) the recommendation of the claimant's treating health care provider; (ii) any appropriate practice guidelines that include applicable evidenced-based standards, and any other practice guidelines developed by the federal government, national or professional medical societies, boards or associations; (iii) the opinion of the IRO's clinical reviewers; and (iv) the terms of the plan document, to ensure that the IRO's decision is not contrary to the terms of the plan, unless the plan's terms are inconsistent with applicable law; and

e. The IRO will provide written notice of its decision on external review to the claimant and the plan within 45 days of the IRO's receipt of the external review request. The IRO's written notification must include:

- A general description of the reason for the request for external review (including information sufficient to identify the claim at issue, such as the date of service, provider's name, diagnosis and treatment codes and their corresponding meanings, and the grounds for the plan's denial of the benefit);

- The date the IRO received the external review request and the date of its decision;

- References to the evidence and documents considered by the IRO, including specific coverage provisions of the plan and evidence-based standards that the IRO considered;

- A discussion of the principal reason for the IRO's decision, including the rationale for its decision and evidenced-based standards that the IRO relied upon;
A statement that the IRO's decision is binding, except to the extent that other remedies may be available under Federal or State law to either the plan or the claimant, and a statement that judicial review of the decision may be available to the claimant;

Contact information for any applicable office of health insurance consumer assistance or ombudsman.

If an IRO reverses the plan's denial of benefits, the plan "must immediately provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim." Technical Release at 6.

C. Expedited Federal External Review Process

The Technical Release also establishes procedures governing requests for "expedited external reviews." A claimant may file a request for an expedited external review with the plan at the time the claimant receives:

1. An adverse benefit determination and the claim at issue involves a medical condition for which the time for completing the plan's internal appeals process would seriously jeopardize the claimant's life or health, or ability to regain maximum function; or

2. A final internal adverse benefit determination, if the time for completing the standard external review process described above would seriously jeopardize the claimant's life, health, or ability to regain maximum function, or if the claim involves an admission, availability, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from a facility.

Upon receipt of a request for an expedited external review, the plan must "immediately" conduct the preliminary review described above (on page 3). The plan must then "immediately" provide a written notice to the claimant detailing whether the claim is eligible for external review, and, if it is not eligible, the plan must detail the reasons for its ineligibility, or any materials needed to complete the request.

If the preliminary review establishes that the request is eligible for external review, the plan must refer the request to an IRO. The plan must provide the IRO with all documents and other information considered by the plan in deciding the claim or appeal by email, facsimile, or telephone, "or [by] any other available expeditious method." Technical Release at 7. The IRO must decide the external review request as expeditiously as the claimant's medical condition requires, but in no event more than 72 hours after the IRO receives the request for expedited external review.

D. Safe Harbor for Insurers Subject to the Federal External Review Process

For health insurance issuers in the individual, small, and large group markets who are subject to the Federal external review process (because there is no binding state external review process), the guidance issued by the Agencies provides that HHS has established a temporary safe harbor which applies for plan years (in the individual market, policy years) beginning on or after September 23, 2010 and until superseded by future guidance. During this period, HHS will not take enforcement action against an issuer that complies with an interim compliance method
that will be established by HHS, which will involve either (1) use of a state external review process (if the state so permits), or (2) a temporary process that HHS will establish. HHS will publish future guidance on the interim compliance process on its website, at www.hhs.gov/ociio/.

III. Conclusion

The issuance of the model notices should provide helpful guidance to plans and issuers regarding the content of adverse benefit determinations and decisions on appeal, although plans and issuers will still face hurdles in modifying their claims processing systems to incorporate all of the additional elements that must be disclosed under the IFR, especially given the rapidly approaching compliance date.

Self-funded group health plans and health insurance issuers subject to the Federal external review process should examine their appeal procedures to determine what modifications are necessary to comply with either (a) any available state external review process with which the plan may want to voluntarily comply, or (b) the Federal external review procedures set forth in the Technical Release.

* * *

If you have any questions, please contact your regular Groom contact or any of the attorneys listed below:

Jon W. Breyfogle jbreyfogle@groom.com (202) 861-6641
Jenifer A. Cromwell jcromwell@groom.com (202) 861-6329
Elizabeth T. Dold edold@groom.com (202) 861-5406
Thomas F. Fitzgerald tfitzgerald@groom.com (202) 861-6617
Lonie A. Hassel lhassel@groom.com (202) 861-6634
Cheryl Risley Hughes chughes@groom.com (202) 861-0167
Christine L. Keller ckeller@groom.com (202) 861-9371
Tamara S. Killion tkillion@groom.com (202) 861-6328
Mark C. Nielsen mnielsen@groom.com (202) 861-5429
William F. Sweetnam, Jr. bsweetnam@groom.com (202) 861-5427
Christy A. Tinnes ctinnes@groom.com (202) 861-6603
Brigen L. Winters bwinters@groom.com (202) 861-6618