HUNTON& WILLIAMS

CLIENT ALERT

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Health Care Reform — Regulations Issued on Expanded Internal/External Claims Review Process For Nongrandfathered Group Health Plans

On July 19, 2010, the United States Departments of Health and Human Services, Labor and Treasury issued interim final regulations covering the mandates under the Patient Protection and Affordable Care Act, as amended (the "Health Care Reform Act"), relating to the internal and external claims review process. These requirements, which do *not* apply to grandfathered group health plans, substantially expand the claims review and appeals processes that group health plans must follow in administering claims. Because the new requirements apply as of the beginning of the first plan year on or after September 23, 2010, all group health plans, especially self-funded plans that administer claims internally, must begin taking action now to update their claims review processes and plan documentation to comply with the new rules.

This is one in a series of alerts that address important aspects of the Health Care Reform Act and the government guidance issued to date. For our related alerts, see "Health Care Reform - What Employers Need to Know Now," issued in April 2010; "Health Care Reform - Grandfathered Plan Regulations Issued," issued in June 2010; and "Health Care Reform - Regulations on Patient Protections Issued," issued in July 2010.

The following is a summary of the key aspects of the internal claims and appeals and external review processes regulations.

Internal Claims and Appeals Processes

Under the Employee Retirement Income Security Act of 1974 ("ERISA"), as amended, group health plans are generally required to adopt internal claims review procedures that provide claimants with a full and fair review of their benefit claims. These claims review requirements, which are set forth in the Department of Labor regulations 29 C.F.R. § 2560.503-1, will now apply to (i) non-ERISA covered group health plans (such as plans sponsored by churches and state and local governments) and (ii) insurance carriers offering individual health insurance coverage to the same extent that the requirements apply to a group health plan.

In addition, the new regulations also significantly expand the current ERISA claims review requirements for covered plans, by adding the following six new requirements:

- **Expansion of "Adverse Benefit Determination."** For purposes of a plan's internal claims review procedure, an adverse benefit

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determination[1] must now include a rescission of coverage.[2]

- **Expedited Notifications for Urgent Care**. For claims involving urgent care, the new regulations reduce the timeframe for notifying a claimant of the benefit determination from 72 hours to 24 hours after receipt of the claim, unless the claimant fails to provide sufficient information to make the determination.

- **Expanded Requirements for Full and Fair Review; New Information or Rationale**. In addition to ERISA's current requirements regarding a "full and fair" review, a plan or issuer must now provide the claimant — free of charge, as soon as possible and sufficiently in advance of the final determination — with (i) any new or additional evidence considered, relied upon or generated by the plan or the issuer in connection with the claim and (ii) any new or additional rationale relied upon by the plan or issuer in denying the claim.[3]

- **Avoiding Conflicts of Interest**. Plans must ensure the independence and impartiality of the persons involved in making claims decisions. In this regard, the regulations prohibit plans from hiring, promoting or terminating a claims adjudicator, medical expert or anyone providing similar services on the basis that the individual will deny, or support the denial of, benefits.

- **Expanded Notice Requirements for Claims Denials**. In addition to ERISA's current notice requirements for claims denials, plans must now provide the notice in a "culturally and linguistically appropriate manner" (described below), and must also meet the following additional notice requirements:

  - Adverse benefit determinations must include sufficient information identifying the claim. This means that adverse benefit determinations must now include the date of service, the health care provider, the claim amount, the diagnosis code (and its meaning) and the treatment code (and its meaning).[4]

  - Adverse benefit determinations must include the plan's or insurer's "denial code" and its meaning.[5] Final decisions must also include a discussion of the applicable standards and the basis for the denial.

  - Adverse benefit determinations and final internal adverse benefit determinations must include an explanation of internal and external appeals processes and how to initiate an appeal.

  - Contact information for any office, health insurance consumer assistance or ombudsmen under the Health Care Reform Act must also be provided.

- **Deemed Exhaustion of Internal Claims Review Procedure**. If the plan fails to *strictly* adhere to the claims review requirements, the claimant will be deemed to have exhausted administrative remedies and may proceed directly to the applicable external appeals process (discussed below) or to litigation.[6] In such litigation, the plan will be deemed to have denied the claim on appeal without the exercise of discretion by the plan fiduciary.[7]

Finally, note that while the plan is generally required to continue coverage during the internal claims review process, the regulations clarify that it must only do so for an ongoing course of treatment.

[1] Under ERISA, an "adverse benefit determination" generally includes a denial, reduction or termination of, or a failure to provide or make a payment (in whole or in part) for, a benefit.

[2] In general, a coverage rescission is a retroactive cancellation or discontinuation of coverage (unless it is due to a failure to timely pay required premiums or contributions). The Health Care Reform Act generally prohibits rescissions except in the case of an act, practice or omission that constitutes fraud, or an intentional misrepresentation of a material fact.

[3] The preamble to the new regulation emphasizes that the intent of these notification requirements is, in part, to permit claimants to respond to any new or additional information or rationale.

[4] It would appear that requiring this additional detail in claims denial notices will, particularly for plan sponsors who administer claims internally (e.g., through an administrative committee), significantly increase the time and expense involved in responding to benefit claims with very little real benefit to affected plan participants.

[5] It is unclear whether self-funded plans that do not currently include denial codes must now create them to comply with this requirement.

[6] This is without regard to whether the plan "substantially" complied or the failure was *de minimis*. This new provision is directly contrary to current ERISA case law.

[7] Although not entirely clear, it would appear that such cases may be heard by courts on a *de novo* basis without regard to plan language reserving discretion to review claims, or the actual conduct of the plan fiduciaries in the claims process. Again, if this is the result of the regulation, it is directly contrary to current ERISA case law precedent here as well.

Form and Manner of Notice Requirements

As described above, the regulations require that benefit denial notices be provided in a culturally and linguistically appropriate manner. Generally, the plan or issuer must provide the notice in a non-English language upon request if: (a) for plans with fewer than 100 participants, at least 25 percent of the participants are literate only in the non-English language and (b) for plans with 100 or more participants, the lesser of 500 participants or 10 percent of participants are literate only in the non-English language. Additionally, the notices written in English must state, prominently and in the non-English language, that the notice is available in the non-English language. Once a request has been made by a participant to provide the notice in a non-English language, all subsequent notices to that participant must be in the non-English language. Finally, if the plan or issuer maintains an employee service center, or the like, to assist participants with claims and appeals, assistance must be available in the applicable non-English language.

External Review Processes

In addition to the internal claims review processes described above, nongrandfathered group health plans must also comply with, and make available to participants, either a state external review process or a federal external review process. The external review process provides participants, at the cost of the plan or issuer, with an independent review of their claim from an accredited independent review organization (IRO). The determination of the IRO is generally binding on all parties; however, it does not preclude the participant from initiating litigation under ERISA if the IRO confirms the benefit denial.

Generally, if the health care coverage is provided through insurance (i.e., an insured group health plan or an individual insurance policy) or under a non-ERISA covered self-insured group health plan,[8] the insurer or plan must comply with any applicable state external review process (provided such process meets the NAIC Uniform Model Act's minimum consumer protections).[9] If the applicable state external review process does not meet the minimum required consumer protections, or if there is no compliant state process in place, the federal external review process will apply. Self-funded group health plans that are subject to ERISA will be required to comply with the federal external review process.

- **Minimum Standards for State External Review Processes**. The Department of Health and Human Services has been given broad authority to determine whether a state external review process meets the minimum consumer protections. The regulations provide that, in order to meet the minimum requirements, the state external review process must:
  - Provide for the external review of adverse benefit determinations that are based on medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit.
  - Require the issuer or plan to provide effective written notice to participants of their rights with respect to the external review process.
  - Permit participants to request a review even though they have not exhausted the plan's internal claims review procedure if the issuer or plan has failed to meet *any* of the internal claims review requirements (discussed above) or has waived the exhaustion requirement, or if the participant has applied for an expedited review concurrently with the internal review.
  - Require the issuer or plan to pay the cost of the IRO conducting the review. The state process may charge the participant a nominal fee (up to $25 and no more than $75 per plan year); however, this fee must be waived if it will cause undue financial hardship for the participant.
  - Not impose a minimum dollar claim amount to be eligible for external review.
  - Allow the participant at least four months after receiving the final internal adverse benefit determination to request an external review.
  - Assign IROs on a random basis (or some other basis that assures independence and impartiality). In no event

[8] In general, these are, as mentioned above, self-insured group health plans that are not subject to ERISA, such as nonfederal governmental and church plans.

[9] To give states an opportunity to bring their external review laws into compliance and, at the same time, ease the initial administration of these requirements for covered group health plans, the regulations establish a transition period during which all state external review processes will be deemed to be compliant. This transition relief will apply throughout any plan year beginning *before* July 1, 2011.

can the IRO be selected by the plan or issuer.

- Maintain a list of IROs qualified by the types of health care service at issue; IROs must also be accredited by a nationally recognized private accounting organization.
- Require that IROs have no conflicts of interest that will influence their independence.[10]
- Provide the participant with at least five business days to submit written materials to the IRO. Participants must be notified in writing of their right to submit such information, and the IRO must forward any such submitted information to the issuer or plan.
- Provide that the IRO's decision is binding on the issuer or plan, as well as the participant, except to the extent that other legal remedies are available.[11]
- Require the IRO to provide written notice of its decision within 45 days after receipt of the request for review.
- Provide for expedited external review under certain circumstances, including (a) where the adverse benefit determination involves emergency care and the participant has not been discharged from a facility or (b) the claim involves a medical condition that would seriously jeopardize the life or health of the participant if the normal process were followed. In the case of an expedited request, the IRO must make its decision within 72 hours of its receipt of the request.
- Require issuers or plans to include, in their SPD, policy, certificate or other description of the coverage, a description of the external review process.
- Require IROs to maintain written records and make them available to the state upon request.
- Meet certain requirements relating to experimental or investigational treatment.
- **Federal External Review Process**. If a group health plan or issuer is not subject to a state external review process,[12] the issuer or plan must make available to participants the federal external review process. The federal external review process will be similar to the process set forth in the NAIC Uniform Model Act, and it will apply to all adverse benefit determinations, or final internal adverse benefit determinations, except those based on eligibility to participate in a group health plan. The regulations describe particular requirements for the federal external review process, which are similar to the minimum requirements for a state external review process described above.

Lastly, note that unlike under the new internal claims review process, there is currently *no* requirement to provide continued coverage during an external review process.

Immediate Action Required

The Health Care Reform Act's requirements regarding internal claims and appeals and external review processes require nongrandfathered group health plans to analyze and make appropriate changes to their claims review processes and plan documentation. Additionally, plan sponsors should consider the risk management elements of these new and expanded claims review requirements, as it appears likely that they will result in additional arguments for the plaintiff's bar to bring more ERISA litigation. We welcome the opportunity to assist you in dealing with these requirements.

[10] Neither the IRO nor the individual clinical reviewer assigned to review the benefit denial may have a material professional, familial or financial conflict of interest with the issuer or group health plan.

[11] For example, if the IRO upholds the plan's denial, the participant could file a lawsuit under ERISA.

[12] For example, the federal external review process would apply if there were not an applicable state process, the state process fails to meet the minimum consumer protections, or if the group health plan at issue is a self-funded plan subject to ERISA.