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HEALTH CARE REFORM: EXTERNAL REVIEW PROCESS

In March, President Obama signed the Patient Protection and Affordable Health Care Act (PPACA) and the Health Care and Education Reconciliation Act of 2010 (HCERA), together referred to as the Act. This e-alert is the latest in a series of e-alerts on health care reform and provides additional information about the external review process required by PPACA.

PPACA adds section 2719 to the Public Health Safety Act (PHSA)¹, providing new internal claims and appeals and external review processes. This section applies to non-grandfathered health plans as of the first day of the first plan year beginning on or after September 23, 2010.

On July 23, 2010, the Department of Health and Human Services (HHS), Department of Labor (DOL), and Department of the Treasury (the Departments) jointly issued regulations regarding the new internal claims and appeals and external review processes. These regulations state that plans not subject to a state external review process (for example, self-funded ERISA plans) must comply with a federal external review process. The Departments did not describe a federal review process until August 23, 2010, when they published interim procedures for a federal external review process and model notices regarding internal claims and appeals and external reviews.

The Departments announced the availability of Employee Benefit Security Administration (ESBA) Technical Release 2010-01, which provides an interim enforcement safe harbor for compliance with the PPACA external review process. The interim enforcement safe harbor applies to plan years beginning on or after September 23, 2010, and is in effect until superseded by future guidance on the federal external review process. This guidance also states that the DOL and the Internal Revenue Service (IRS) will not take enforcement action against a self-insured group health plan that complies with one of the following:

- The procedures outlined in Technical Release 2010-01.
- A state external review process. This option applies in states choosing to allow self-insured plans access to their state external review process.

Reinhart Comment: At this point, it is unclear how many states will grant self-insured plans access to their external review process. Most self-funded plans subject to the new external review process may need to comply with the process described in the Technical Release. Technical Release 2010-01 describes procedures for standard external reviews and expedited external reviews.

Standard External Review

The following procedures apply to standard external reviews.

1. **Request for external review.** A plan must allow a claimant to file a request for external

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¹PPACA adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of Part A of Title XXVII of PHSA into ERISA and the Code and make them applicable to group health plans and health insurance issuers providing insurance coverage to group health plans. PHSA section 2719 is included in the effective sections.

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review within four months after receiving a notice of adverse benefit determination or final internal adverse benefit determination.

2. Preliminary review. Within five business days of receiving an external review request, the plan must complete a preliminary review of the request. The preliminary review must determine all of the following:
 - Whether the claimant was covered under the plan at the time the health care item or service was requested or provided.
 - Whether the adverse benefit determination relates to a failure to meet the requirements for eligibility under the plan.
 - Whether the claimant exhausted the plan's internal appeal process or is not required to exhaust the internal appeals process.
 - Whether the claimant provided all information necessary to process an external review.

The plan must notify a claimant in writing about the preliminary review results within one business day of completing the preliminary review. If the request is complete, but not eligible for external review (for example, because the claim relates to eligibility under the plan), the notice must describe the reason for ineligibility and provide EBSA contact information to allow the claimant to discuss the issue with EBSA. If the request is not complete, the notice must describe the information needed for completion. The plan must then allow the claimant to finish the request within the later of the four-month filing period or a 48-hour period following the claimant's receipt of the notice.

3. Referral to Independent Review Organization (IRO). The plan must assign external reviews to an accredited IRO. To ensure independence from the plan, plans must contract with at least three IROs for assignment and rotate claims assignments among them, or provide for random selection. IROs must not be eligible for financial incentives based on the likelihood of supporting a denial of benefits.

The plan and IRO must enter a contract that reflects the following:

- The IRO will use legal experts where appropriate to make coverage determinations.
- The IRO will notify the claimant in writing of the request eligibility and acceptance for external review. The notice must state that the claimant may submit in writing any additional information within ten business days of the claimant's receipt of the notice. The IRO may, but is not required to, accept and consider information submitted after ten business days.
- The plan must provide the IRO any documents and information considered in making the adverse benefit determination within five days of the assignment to the IRO. If the plan fails to timely provide the documents, the IRO may terminate the external review and reverse the adverse benefit determination. Within one business day of making this decision, the IRO must notify the claimant and the plan.
- The IRO must forward to the plan information received from the claimant within one business day of receipt. The plan may reconsider its adverse benefit determination, but reconsideration will not delay the IRO external review. The plan may choose to reverse its adverse benefit determination and terminate the external review. The plan must notify the claimant and the IRO of a decision to reverse the adverse benefit determination within one business day of making the decision. The IRO must terminate the external review upon receiving that notice.

- The IRO will review the claim on a *de novo* basis and not be bound by the conclusions reached during the plan's internal claims and appeals process. In addition to documents provided, the IRO will consider, if appropriate, all the following items:
 - The claimant's medical records.
 - The attending health care professional's recommendation.
 - Reports from appropriate health care professionals.
 - Plan terms.
 - Appropriate medical practice guidelines.
 - Applicable clinical review criteria developed and used by the plan.
 - The opinion of the IRO's clinical reviewer after considering information provided.
 - The IRO must provide written notice of the final external review decision within 45 days of receiving the request for external review. The IRO must provide the notice to the claimant and the plan.
 - The IRO's decision notice must contain all the following:
 - The general description of the request for external review, including information sufficient to identify the claim (for example, the date of service, the health care provider, the claim amount, the diagnosis code and its meaning, the treatment code and its meaning, and the reason for the prior denial).
 - The date the IRO received the assignment to conduct the external review and the date of the decision.
 - References to the evidence, including the specific coverage provisions and evidence-based standards, considered in reaching the decision.
 - The principal reason for the IRO's decision, including any evidence-based standards relied on in making the decision.
 - A statement that the determination is binding, except to the extent that other remedies may be available under law to either the plan or the claimant.
 - A statement that judicial review may be available to the claimant.
 - Current contact information for any applicable office of health insurance consumer assistance or ombudsman.
 - The IRO must maintain records of all claims and notices associated with the external review for six years. The IRO must make the records available for examination by the claimant, the plan, or a state or federal oversight agency upon request, except where disclosure would violate privacy laws.
4. Reversal of decision. The plan must immediately provide coverage or payment for a claim upon receipt of an IRO decision reversing the adverse benefit determination.

Expedited External Review

The following procedures apply to expedited external reviews.

1. Request for expedited external review. The plan must allow a claimant to request an expedited external review if the claimant receives one of the following:
 - An adverse benefit determination involving a medical condition for which the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the claimant.
 - A final internal adverse benefit determination, if the claimant has a medical condition with a time frame for completing the standard external review that would

seriously jeopardize the life or health of the claimant, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay or health care item, or service for which the claimant received emergency services, but has not been discharged from the facility.

2. Preliminary review. Immediately upon receiving a request for expedited external review, the plan must determine whether the request meets the reviewability requirements for standard external review. The plan must immediately send the claimant a notice meeting the requirements for standard external review.

Reinhart Comment: The Technical Release does not define "immediately."

3. Referral to IRO. Upon determining that a request is eligible for external review, the plan must assign an IRO pursuant to the same requirements used for standard external review. The plan must transmit all necessary documents and information to the IRO electronically or by any other available expeditious method. The IRO must consider the information or documents described under the procedures for standard external review. Again, the IRO must review the claim on a *de novo* basis.
4. Notice of final external review decision. The plan's contract with the IRO must require the IRO to provide notice of a final expedited external review decision as expeditiously as the claimant's medical condition requires, but not more than 72 hours after the IRO receives the request for an expedited external review. If the notice of final decision is not in writing, the IRO must provide the claimant and the plan written confirmation of the decision within 48 hours of providing the notice of final decision.

Consideration Items for Self-Funded Plan Sponsors

1. The Technical Release requires plans to contract with at least three IROs to conduct external reviews. These requirements will soon be effective for plans that lose or have already lost grandfathered status. Therefore, some plans must move very quickly to identify and select IROs to comply with this requirement. Plans will then need to finalize contracts with the selected IROs that include all of the elements listed above.
2. Neither the regulations nor the Technical Release indicate whether self-funded plans will have the ability to challenge decisions made by IROs in court or otherwise. The Technical Release indicates that the determination is binding except to the extent that the plan or the claimant may have other remedies available. Historically, however, plans have not had the practical need or the corresponding methodology to challenge a determination made in favor of the claimant. The self-funded plan itself typically controlled the process and served as the final arbiter of the benefit determination. It is unclear whether plans will choose to challenge IRO determinations and whether plans have the ability to institute a challenge.
3. The regulations and Technical Release also did not describe the impact of the external review process on plan fiduciary responsibilities. In most instances, a committee of the plan sponsor or the plan sponsor itself has served as the final arbiter of claims and the ERISA fiduciary. If an IRO decision is final and binding on the plan and claimant, subject to a potential lawsuit, the IRO would appear to fill the role of plan fiduciary. However, the guidance fails to address the accuracy of this conclusion. Plans may be required to contract the delegation of fiduciary status with IROs.