# Employee Benefits & Executive Compensation ADVISORY

August 23, 2011

## So What Are My Internal and External Claim Review Requirements? A Question Every Group Health Plan Is Asking.

Recently, the U.S. Departments of Treasury, Labor (DOL) and Health and Human Services (HHS) (collectively, the "Agencies") jointly issued new interim final regulations ("New Final Regulations") and new related technical guidance[1] ("New Technical Guidance") regarding the internal and external claim review requirements set forth in new Public Health Service Act Section 2719 ("Claim Review Rules"), as added by Section 1001 of the Patient Protection and Affordable Care Act of 2010 (ACA). The Final Regulations amend interim final regulations related to the Claim Review Rules issued by the Agencies on July 23, 2010 ("Original Regulations"), and the New Technical Guidance comes on the heels of technical guidance issued earlier in 2011 and in 2010.

Although the New Final Regulations and the New Technical Guidance provide much needed clarification around the Claims Review Rules, the flurry of guidance regarding the Claims Review Rules has left group health plan sponsors, administrators and insurers with many questions relating to their new responsibilities. We summarize below the recent clarifications and revisions with the hope of providing an integrated roadmap for these new legal requirements.

**Practice Pointer: The new Claims Review Rules added by the ACA incorporate by reference the claims review regulations set forth in ERISA ("ERISA Claims Regulations").[2] Thus, if your group health plan is subject to ERISA, and your group health plan is not a grandfathered plan as defined by the ACA, you are responsible for complying with both ERISA's claims procedure rules and the new Claims Review Rules set forth in the ACA. More importantly, a failure to comply with the ERISA Claims Regulations may now result in imposition of the $100 per day excise tax under the Internal Revenue Code (Section 4980D) imposed on failures to comply with the various health insurance reforms added by Sections 1001 and 1201 of the ACA, including but not limited to new Section 2719.**

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1 The guidance includes the Final Regulations, Technical Release 2011-22 (Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage, and Guidance for States on State External Review Processes) and model notices of adverse benefit determinations, all of which are available on the DOL EBSA website at http://www.dol.gov/ebsa/healthreform/.

2 *See* 29 C.F.R. 2560.503-1, as amended from time to time.

The New Final Regulations address both the internal and external review requirements of the Claims Review Rules. We address each in turn below.

## I. Requirements Relating to Internal Claims and Appeals

***Up to 72 hours now allowed for benefit determinations relating to urgent care***

The Final Regulations generally return the maximum determination period for claims involving urgent care from 24 hours to the pre-ACA rule in the ERISA claims regulations of 72 hours. However, the plan or insurer must defer to the provider's determination as to whether a claim involves urgent care. Consistent with the ERISA Claim Regulations, the Agencies emphasize in the preamble to the New Final Regulations that 72 hours is a maximum time period (as opposed to a safe harbor) and that medical exigencies may require a more rapid determination.

***Diagnosis and treatment codes now only required upon request***

The New Final Regulations eliminate the requirement that notices of adverse benefit determinations (ABDs) automatically include diagnosis and treatment codes and their meanings. Instead, plans and insurers must provide such codes and their meanings as soon as practicable following a request from a plan participant or beneficiary. Importantly, the notice of an ABD must inform participants and beneficiaries of their right to obtain such codes.

***Requirement that notices be provided in a culturally and linguistically appropriate manner ("CLA requirements")***

The New Final Regulations significantly simplify the requirement imposed by the Original Regulations that notices of adverse benefit determinations be provided in a culturally linguistic and appropriate (CLA) manner. Under the Original Regulations, if the plan covers less than 100 participants at the beginning of the plan year, the plan is considered to comply with the CLA requirement if it provides notices, upon request, in a language in which 25 percent or more of its participants are literate (only in the same non-English language). If the plan covers 100 or more participants at the beginning of the plan year, the plan is considered to comply with this requirement if it provides notices, upon request, in a language in which the lesser of 500 or more participants or 10 percent of all participants are literate (only in the same non-English language). If the threshold is satisfied, all notices must state in the relevant non-English language indicating that the notice will be provided upon request in the non-English language. The New Final Regulations replace the somewhat complex, plan-by-plan determination imposed by the Original Regulations with a single standard based on the county to which the recipient of the notice resides.

Under the new standard, if at least 10 percent of the population in the county are literate only in a particular non-English language and speak English less than "very well," as determined by the American Community Survey data published by the United States Census Bureau, then each notice of an adverse benefit determination sent to a recipient with an address in that county must include a one sentence statement in that non-English language about the availability of language services

provided by the plan. The plan must also provide oral language services in the non-English language and provide written notices in the non-English language upon request.

**Practice Pointer: The preamble to the Final Regulations contains a current list of relevant counties and languages. There are 255 counties (78 of which are in Puerto Rico) that meet the threshold.[3] In the vast majority of cases, Spanish is the relevant non-English language; however, Chinese, Tagalog and Navajo are present in a few counties affecting just five states, Alaska, Arizona, California, New Mexico and Utah.**

The Final Regulations also eliminate the "tagging and tracking" requirement under which all subsequent notices to a claimant who requested a notice in an applicable non-English language had to be in that language. This requirement was challenging for many current systems. In lieu of this requirement, the Final Regulations require that the English versions of all notices include a prominently displayed statement in any applicable non-English language describing how to access the language services provided by the plan. Targeted notices are not required—i.e., the statements may be included in all notices. The Agencies have published model notices that contain sample statements in each of the relevant languages.[4] The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) in any applicable non-English language and, upon request, must provide a written translation of any notice in any applicable non-English language.

***The Final Regulations constrict the "strict adherence" standard for exhaustion of remedies***

The Original Regulations allow claimants to bypass the internal appeals process if the plan fails to strictly comply with the procedural requirements. The New Final Regulations provide an exception to this strict adherence requirement for errors that are minor and meet certain other requirements. In particular, claimants may be required to exhaust internal administrative remedies despite a failure of a plan or insurer to strictly comply with the applicable rules if the failure was *de minimis*; non-prejudicial to the claimant; attributable to good cause or matters beyond the control of the plan or insurer; in the context of an ongoing good-faith exchange of information; and not reflective of a pattern or practice of noncompliance.

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[3] The Department of Labor will update this guidance annually if there are changes to the list of counties determined to meet this 10 percent threshold.

[4] The model notices may be found on the DOL's EBSA website at http://www.dol.gov/ebsa/healthreform/.

**Practice Pointer: The DOL has followed a similar approach with respect to the ERISA Claims Review Regulations. According to the DOL, not every deviation by a plan from the requirements of the ERISA Claims Regulation permits a claimant to exhaust the plan's internal review procedures and file suit.[5] If the plan's procedures provide an opportunity to effectively remedy the inadvertent deviation without prejudice to the claimant, then there ordinarily will not have been a failure to establish or follow reasonable procedures as contemplated by the ERISA Claims Regulations. On the other hand, the DOL has viewed systematic deviations from the plan procedures, or deviations not susceptible to meaningful correction through plan procedures, such as the failure to include a description of the plan's review procedures in a notice of an adverse benefit determination, as justifying a bypass of the internal procedures.**

***Effective date of internal review changes***

Each of the changes and clarifications related to a plan's internal review process discussed above relate to provisions delayed by Technical Release 2011-01 until plan years beginning on or after January 1, 2012. Thus, the clarifications and changes set forth in the New Final Regulations related to a plan's internal review process are delayed until plan years beginning on or after January 1, 2012.

## II. Requirements Relating to External Reviews – In General

Plans and issuers must follow either a federal external review process or a state external review process. Ultimately, both the federal and state processes are to include, at a minimum, the consumer protection provisions of the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners (the "NAIC Model Act"). The process that applies depends on whether the plan is fully insured or self-insured.

### A. Requirements Relating to External Reviews – Self-Insured Plans Subject to ERISA or the Code

Self-insured plans subject to ERISA and/or the Code are generally required to comply with a federal external review process that uses independent reviewing organizations or IROs (the "private IRO process).[6] DOL Technical Release 2010-017 sets forth a safe harbor process for complying with the federal external review requirements. The Final Regulations make several key changes with respect to the federal external review process.

***Scope of the federal external review process***

The breadth of claims with respect to which the federal external review processes applied was the subject of great concern to many employers. Under the Claims Review Rules, all benefit denials, other than questions of eligibility, were subject to external reviews. In contrast, the NAIC Model Act

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5 *See* Q-F2 at http://www.dol.gov/ebsa/pdf/CAGHDP.pdf.

6 Plans may also voluntarily comply with a state process if state makes the process available to self-insured plans.

7 The release may be found at http://www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf.

is limited to claims relating to medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit.

The Final Regulations temporarily narrow the scope of the federal external claim review so that it more closely resembles the NAIC Model Act, although it is not identical. Under the Final Regulations, the scope of the federal review includes adverse benefit determinations by a plan that involve "medical judgment," as determined by the independent review organization, or "rescissions" (as set forth in new PHSA Section 2712). The New Final Regulations indicate that medical judgment includes, *but is not limited to*, claims based on the plan's requirements for medical necessity, appropriateness, health care setting, level of care, effectiveness of a covered benefit or a determination that a treatment is experimental. Claims involving medical judgment do not include claims that only involve contractual or legal interpretations. The regulations provide a couple of examples to illustrate a claim involving medical judgment. In one example, the plan covers 30 visits to a particular specialist, but will cover more in the event of an approved treatment plan submitted by the health care provider. The provider submits a treatment plan for a 31st treatment, which is denied due to lack of medical necessity. In this example, the claim involves a determination of medical judgment and would be subject to external review. On the other hand, if there is just a specified number of treatments, with no exception, the denial of the 31st visit would not involve medical judgment and would not be subject to external review. In the other example, the plan does not provide coverage for out-of-network services unless the service cannot be effectively provided in-network. Claimant seeks coverage for a procedure performed out of network. The plan denies coverage for the treatment on the basis that it is out-of-network (in other words, it can be effectively provided in-network). This claim involves medical judgment and is subject to the external review requirement.

The preamble lists a number of other examples of situations that involve medical judgment, including (to list a few) whether a participant is entitled to a reasonable alternative standard for a reward under a wellness program; the frequency, method, treatment or setting for a required preventive service where none is specified in the recommendations; and whether a plan is complying with the non-quantitative treatment limitations under the Mental Health Parity Act.

The narrowing of the scope of the federal external review is temporary, and will be revisited by the Agencies by January 1, 2014, when the remainder of the health reforms become effective. If the Agencies revert to a broader scope of review, they will provide some time for plans and issuers to adjust.

**Practice Pointer:** **Do HRA claims involve "medical judgment"? HRAs typically limit reimbursement to expenses that qualify as "medical care" as defined in Code Section 213(d) or, alternatively, the claimant's share of an expense that is covered by the employer's major medical plan but for a deductible or other financial limit (e.g., copayment or coinsurance). In either case, we believe there is a strong argument that HRA claims do not involve medical judgment as contemplated by the New Final Regulations. Instead, HRA claim determinations involve legal or contractual interpretations. For example, in the case of an HRA that reimburses any expenses that qualify as Code Section 213(d) medical care, the determination under the HRA is limited to whether the expense satisfies the legal definition of "medical care." Even claims for "dual purpose" services or treatments—services or treatments that qualify as "medical care" only if they would not be received but for a medical condition—do not constitute medical judgment because the plan or the claims administrator must simply determine whether a health care provider has recommended the service for a condition—not whether the service or treatment is medically necessary or appropriate.**

*Effective date of change:* The change in the scope of the federal external review is effective with respect to claims for external review initiated on or after September 20, 2011. This raises some question as to whether the narrower standard can be applied before the effective date.

**Practice Pointer:** **Unlike many of the internal review requirements set forth in the Claims Review Rules that were delayed, the obligation to make an external review available was not. Thus, group health plans are arguably obligated to comply with the broader-scope external review process with respect to requests for external review initiated prior to September 20, 2011.**

***IRO assignment process***

The original DOL safe harbor guidance on the external review process provided that, to be eligible for the safe harbor, the plan (or the plan's TPA) must contract with at least three IROs. The purpose of this requirement was to ensure an independent and impartial review process. In subsequent Frequently Asked Questions, the Agencies clarified that failure to contract with at least three IROs would not be a *per se* violation of the Claims Review Rules and that, instead, the plan could demonstrate other steps taken to ensure that its external review process was independent and without bias.

Under revised DOL guidance, a plan must contract with at least two IROs by January 1, 2012, and rotate assignments among them. As this is a safe harbor, a plan may use an alternative process to demonstrate that reviews are independent and unbiased. However, DOL and the Treasury Department will "look closely" at any alternative means. At a minimum, these agencies expect plans to document how any alternative process constitutes random assignment, as well as how it ensures that the process is not subject to undue influence by the plan and without bias.[8]

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[8] DOL Technical Release 2011-02 may be found at http://www.dol.gov/ebsa/newsroom/tr11-02.html.

**Practice Pointer: If an HRA involves no claims involving medical judgment, must it engage the services of two or more IROs? Technically, the IRO is responsible for making the determination as to whether a claim involves medical judgment—not the plan sponsor administrator—so the conservative answer is that an HRA must still engage two or more IROs. On the other hand, it seems misleading to offer claimants the opportunity to request an external review for claims that are not ever eligible for external review by plan design. Plan sponsors and administrators should discuss the issue with legal counsel.**

### B. Requirements Relating to External Reviews – Fully Insured Plans

In general, in the case of a fully insured plan, the issuer is responsible for complying with the external review requirements. If the state has a compliant external review process, then the issuer must comply with that process.[9] If the state does not have a compliant process, then a federal external review process applies. The original regulations provided a transition period to allow states to bring their laws into compliance with the NAIC Model Act. The Final Regulations end the transition rule for existing state processes on December 31, 2011, regardless of the plan year. A further transition period is provided until January 1, 2014, for state processes that are similar to the NAIC Model Act process. Beginning January 1, 2014, state processes must comply with the NAIC Model Act. In states without a qualifying state process, the insurer may elect either to follow an HHS process administered through the federal Office of Personnel Management or the IRO process that applies to self-funded plans.

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[9] Note that plans that are exempt from ERISA, such as nonfederal governmental plans, may be subject to state law because ERISA preemption does not apply.

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