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DOL, HHS, and Treasury Issue Amended Guidance on Health Care Reform's Internal and External Claims Process Rules

In response to comments on prior guidance, the Departments issued new guidance relating to health care reform's internal and external claims process rules applicable to non-grandfathered health plans.

Background

Section 2719 of the Public Health Service Act (PHSA), as added by the Patient Protection and Affordable Care Act, requires non-grandfathered health plans (generally, health plans that are modified or established after March 23, 2010) to incorporate an internal appeals process that satisfies the claims regulations under the Employee Retirement Income Security Act (ERISA). In addition, all non-grandfathered plans must include an external review process that complies with state or federal law, depending on the type of plan.

In July 2010, the Departments of Health and Human Services (HHS), the Treasury, and Labor (DOL) (collectively the Departments) released interim final regulations (2010 regulations) addressing the internal claims and appeals process rules and external review rules. (See our August 11, 2010 *For Your Information*.) Those regulations generally required compliance for plan years beginning on or after September 23, 2010.

After the Departments issued the 2010 regulations, commenters identified a number of implementation challenges. Subsequently, the DOL, on behalf of all of the Departments, issued two technical releases that ultimately delayed enforcement of certain provisions until plan years beginning on and after July 1, 2011 or January 1, 2012, depending on the provision. (See our October 1, 2010 and April 12, 2011 *For Your Information* publications.) The delayed provisions relate to the time frame for urgent care determinations, the content of adverse benefit determination notices, the application of the strict adherence standards, and the requirement to provide notice in a culturally and linguistically appropriate manner.

Revised Internal Claims and Appeals Rules

In June 2011, the DOL and HHS issued Technical Release (TR) 2011-02 on behalf of the Departments, and HHS issued additional guidance relating to nonfederal governmental plans. TR 2011-02 amends the earlier technical releases to provide temporary standards for consumer protections during a transition period and other relief. It also included revised model notices. At the same time, the Departments issued amendments to the 2010 regulations (2011 amendments) addressing a number of the comments that the Departments had received. The

2011 amendments were effective July 22, 2011. Neither TR 2011-02 nor the 2011 amendments affect the enforcement grace periods.

The 2011 amendments modify the requirements that are subject to the previously announced delayed enforcement policy. The modifications include the following:

Time Frame for Urgent Care Determinations

Existing ERISA rules call for plans to rule on urgent care claims as soon as possible, and in no event later than 72 hours after receipt. The 2010 regulations reduced this time frame to no later than 24 hours. The 2011 amendments go back to the 72 hours maximum standard. However, the 2011 amendments require that plans give deference to a determination by an attending provider as to whether the claim is in fact urgent.

Information Included in Notices of Adverse Benefit Determinations

The 2010 regulations required a number of items to be included with any notice of an initial or final "adverse benefit determination," including the diagnosis and treatment codes involved in the claim and their corresponding meanings. Many commenters thought this presented privacy challenges because claim determination notices often go to the covered employee rather than the patient. The 2011 amendments eliminate the requirement to include the diagnosis and treatment codes. Instead, they only require a statement that the diagnosis and treatment codes and their meanings are available upon request. If an individual then requests this information, the plan must provide it as soon as is practicable. The plan may not treat the request as a request for an appeal or external review.

Strict Adherence Standard

One of the most controversial aspects of the 2010 regulations was a rule that if a plan failed to comply with each and every aspect of the regulations, the claimant would automatically be deemed to have exhausted the internal claims and appeals process. Even minor violations allowed the participant to seek immediate external review or file a lawsuit without exhausting the plan's administrative remedies. The 2011 amendments relax this standard to provide that errors in plan procedures will not result in application of the strict adherence standard if the errors were:

- De minimis;
- Non-prejudicial or non-harmful;
- For good cause or because of matters beyond the plan's control;
- In the context of an on-going, good-faith exchange of information; and

- Not a pattern or practice of non-compliance.

If a plan asserts that it meets these criteria, it will be required to provide an explanation in response to a written request from the claimant.

Culturally and Linguistically Appropriate Notices

Section 2719 of the PHSA requires that plans provide various communications related to appeals and external review in a "culturally and linguistically appropriate" manner. The 2010 regulations required that notices be provided in a non-English language based on threshold counts of the number of participants who are literate in the same non-English language. Plan sponsors particularly objected to the requirement that once a participant requested notices in another language, all future notices to that person would need to be in that same language.

The 2011 amendments simplify the notification process by requiring communications in a non-English language to be provided only to individuals who reside in counties that have been identified by the Census Bureau as having 10% or more of their population literate only in the same non-English language. A plan that has participants who reside in one of these counties must have a customer assistance process (such as a telephone hotline) with oral language services available in the relevant non-English language and must provide notices in that language upon request. The 2011 amendments require notices of adverse benefit determinations and final external review decisions addressed to individuals who reside in such a county to contain a one-sentence notice in the non-English language about the availability of language assistance. The required languages are:

- Chinese (required only in San Francisco County, California);
- Tagalog (required only in two portions of Alaska);
- Navajo (required for Apache County, Arizona; McKinley County, New Mexico; and San Juan County, Utah); and
- Spanish (required in portions of 22 states and Puerto Rico).

Plan sponsors have the option of including the non-English notices in all appeals/external review communications or only those directed to individuals who reside in the specified counties.

> ***BUCK COMMENT***. *In the preamble to the 2011 regulations, the Departments indicate that the list of counties will be updated annually. Hopefully, the Departments will give plan sponsors adequate notice of any changes. Many plan sponsors will likely need to include the one sentence notice in Spanish in their notices.*

Changes to External Review Rules

Section 2719 of the PHSA provides for state and federal external review. Generally, state external review processes apply to health insurance issuers and self-funded plans (such as non-federal, governmental plans, church plans, and multiemployer welfare arrangements) that may be subject to state insurance laws. If applicable state law does not provide for an external review process or if the state process fails to meet certain minimum standards, health insurance issuers, insured plans, and self-funded non-ERISA plans are required to comply with the federal external review process. Self-funded ERISA plans must have external review processes that comply with federal requirements. The new guidance makes changes to these rules.

State External Review Processes

Under the earlier guidance**,** existing state external review processes were treated as meeting the minimum external review standards required by health care reform during a transition period that applied to plan years beginning before July 1, 2011. The new guidance modifies the transition period so that it now ends on December 31, 2011. Generally, the HHS-administered federal external review will apply to the internal adverse benefit determinations provided on or after January 1, 2012 unless HHS determines that a state's external review process: (1) meets the minimum standards set out in the 2010 regulations; or (2) meets the temporary standards set out in TR 2011-02. The temporary standards apply until January 1, 2014.

> ***BUCK COMMENT***. *The change in dates will shorten the transition period for plans with plan years beginning after January 1, 2012 and before July 1, 2012.*

Election of a Federal Review Process

A self-funded, nonfederal governmental plan or health issuer that is subject to the federal external review process because the state external review process is inadequate or non-existent may elect to comply with: (1) an HHS-administered external review process; or (2) the private accredited independent review organization (IRO) process that applies to ERISA plans. HHS guidance describes how a plan or issuer makes this election. Generally, the plan or issuer must submit the election by email to HHS by the earlier of January 1, 2012 or the date by which the plan or issuer first uses the federal external review process.

Scope of Federal External Review

The 2010 regulations allowed claimants subject to the federal external review process to request external review of any adverse benefit determination for any reason other than whether the individual met the plan's eligibility requirements. Commenters objected to giving an IRO authority over legal and contractual questions and requested that the external reviews be limited to questions involving medical judgments (such as whether a treatment is experimental in nature).

The 2011 amendments temporarily suspend the 2010 regulations regarding the scope of claims eligible for any external review requests that are initiated on or after September 20, 2011. IROs still have authority to rule on the broad array of non-eligibility appeals for any external review requests filed before that date. The Departments indicate that they intend the temporary suspension of an IRO's ability to rule over other matters to end by January 1, 2014.

During this suspension period, an IRO's authority is only over appeals involving either medical judgment or rescissions of coverage. The 2011 amendments provide that medical judgment includes, but is not limited to, adverse benefit determinations based on the plan's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit, or its determination that a treatment is experimental or investigational. In the preamble to the 2011 amendments, the Departments provide examples of adverse benefit determinations that they believe would involve medical judgment. Such determinations include whether:

- The treatment setting is appropriate;
- Treatment by a specialist is medically necessary or appropriate;
- The treatment involved emergency or urgent care;
- A preexisting condition exists;
- An item or service generally is excluded, but it is allowed in certain circumstances based on a medical condition (for example, where speech therapy is generally excluded, but would be allowed to aid in the restoration of speech lost due to a medical condition);
- A participant is entitled to an alternative standard to obtain a wellness reward;
- The frequency, method, treatment, or setting for a preventive service is covered where such details are not already set out in federal guidance; and
- The plan is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act.

***BUCK COMMENT**. Although the list from the preamble is not binding, it shows what determinations the Departments believe would involve medical judgment.*

Clarification of Binding Review Requirement

The 2010 regulations require that an external review decision by an IRO be binding on all the parties involved except to the extent that other remedies are available under state or federal law. The 2011 amendments provide that when an IRO makes a determination that the plan must provide a benefit or pay a claim, the plan must do so immediately, regardless of whether it intends to seek review of the IRO's decision in court. The 2011

amendments also clarify that the requirement that the IRO's decision be binding does not preclude a plan from paying a claim or providing a benefit at any time, even if the IRO's determination was adverse to the claimant.

Modification of Enforcement Safe Harbor for Self-funded Plans

TR 2011-02 further modifies the enforcement safe harbor for self-funded plans that was previously set out in Technical Release 2010-01 and FAQ-8 of the Affordable Care Act Implementation FAQs, Part I. The safe harbor in TR 2010-01 required plans to contract with at least three IROs and rotate assignments among them. FAQ-8 provides that where a plan does not strictly comply with TR 2010-01, compliance is determined on a case-by-case basis.

TR 2011-02 provides that to be eligible for the revised enforcement safe harbor, a self-insured plan must contract with at least two IROs by January 1, 2012 and with at least three IROs by July 1, 2012 and must rotate assignments among them. A plan is subject to an enforcement action if it does not have a contract in place. A plan may use a process other than rotational assignment and still be in compliance with the 2010 regulations, but failure to use rotational assignments will result in closer scrutiny by the Departments. Nothing in the new guidance changes the ability of plan sponsors to contract with IROs via global contracts obtained by their third-party administrator.

Conclusion

Sponsors of non-grandfathered health plans and those considering changes that would cause the loss of grandfathered status should carefully review the 2011 amendments and TR 2011-02 in light of their current administrative practices. While overall this guidance is positive and likely to ease administrative burdens for affected plans, the appeals and external review standards are likely to result in additional plan costs for non-grandfathered plans.

Buck's consultants would be pleased to discuss the latest pieces of guidance and how they may impact your health plan.

This FYI is intended to provide general information. It does not offer legal advice or purport to treat all the issues surrounding any one topic.