Late last year, the Department of Labor (DOL) issued two final regulations that impose significant new requirements on employee benefit plans. The first bears on the procedures that plans providing health and disability benefits must follow in processing claims for benefits. The second relates to the information that must be disclosed in the summary of the plan that is provided to participants (the SPD). The regulations generally become effective in 2002, although it is believed that the DOL may push back the effective date, depending on the progress of legislation on a new Patient’s Bill of Rights. Presumably, human resources personnel are at work to ensure compliance with the new regulations. However, corporate counsel should be involved in this process as well. Assuming they become effective, the regulations will impose significant new costs and other burdens on plan sponsors. They almost certainly also will lead to increased—and more costly—litigation.

Even though the most onerous provisions apply only to employer-sponsored health and disability benefit plans, the proposed regulations published in 1998 covered pension plans as well. Hence, the regulations are likely to be extended in the future to apply to pension plans, so employers sponsoring pension plans have a significant interest in the new requirements. As they stand, the regulations will affect more than 130 million enrollees in ERISA employer-sponsored plans.

The regulations will govern the procedures by which individuals submit claims for coverage and appeal adverse claim decisions. While not mirroring the proposed “Patient Bill of Rights,” the regulations, passed in the waning days of the Clinton administration, put into law many of the requirements of the proposed legislation—albeit without congressional approval. The new regulations impose more stringent requirements on the time and manner in which plans must respond to claims, impose more elaborate procedures governing appeals of an adverse claim decision and require plans to make additional disclosures to claimants. Some of the details of these new requirements are as follows:

1. **Expedited Decision Making**

   - The time frame for notifying claimants of adverse benefit determinations (up to 90 days with a 90-day extension) is modified as follows:
     - for “urgent” health claims (involving threats to the patient’s life or health), no more than 72 hours
     - for “pre-service” health claims (services requiring pre-approvals), no more than 15 days
     - for other health claims (“post-service” claims), no more than 30 days
     - for disability claims, no more than 45 days.
• The minimum period for allowing claimants to file appeals for health and disability claims (60 days) is lengthened to 180 days.

• The time frame for notifying claimants of appeals decisions (up to 60 days with a 60-day extension) is modified as follows:
  ♦ for “urgent” health claims, no more than 72 hours (with plans having to accept oral or written appeals and transmit information expeditiously, such as by telephone or fax)
  ♦ for “pre-service” health claims, no more than 30 days
  ♦ for “post service” health claims, no more than 60 days
  ♦ for disability claims, no more than 45 days.

• The rules require decisions to be made even more quickly if, for example, it is necessary due to a patient’s medical condition. Conversely, limited extensions may be available in certain cases. For example, two extensions of up to 30 days each are available for a disability claim. However, there must be a valid reason for the extension that is beyond the control of the plan, and the claimant must be informed of the reason. Also, the stated periods are maximums, not entitlements. In other words, if a specific claim presents no difficulty, a claimant could assert that it was unreasonable to delay the decision until the end of the maximum period.

• Any physician with knowledge of the claimant’s medical condition can decide that the claimant’s situation is “urgent” and thereby require the plan to meet the extremely short time frames for processing such claim (and any appeal).

• Patients must be notified and given the opportunity to appeal a plan’s decision to terminate previously approved ongoing treatments before coverage ends.

• These new requirements will be particularly burdensome with respect to claims for disability benefits. Disability claims are often very complex, and thus will be difficult to resolve within the new time frames.

2. Expanded Right to Information

• Plan must notify a claimant of failure properly to file a pre-service claim within five days (24 hours in the case of an urgent care claim).

• Notice of an adverse benefit determination must specifically identify any internal rules, guidelines, protocols, etc. that served as a basis for the determination and offer to provide the material at no cost.

• Notice of an adverse benefit determination based on medical necessity, experimental treatment, or other similar exclusion or limit must either explain the scientific or clinical judgment of the plan in applying the terms of the plan to the claimant’s medical circumstances, or provide an explanation free of charge.

• Regulations make express the fiduciary duty to build into a plan’s procedures administrative safeguards and processes that are designed to ensure and verify that plan provisions have been followed and consistently applied to similarly situated...
claimants. Plan must make available to the affected participant evidence that the plan has generated or obtained to ensure compliance with this requirement.

- Claimants must have access to all “relevant” information in the claims record, which includes any information that was generated, submitted or considered by the plan in denying the claim, even if it was not relied on.

3. New Standards for Appeals Process

- A fiduciary who is independent of the person or group that decided the initial claim must decide the appeal and may not give any deference to the initial decision.
- If the denial rests on a medical determination, an independent healthcare professional, who was not involved in the initial decision, must be utilized in the appeal process.
- Plan may require arbitration, but claimant may not be required to pay or be precluded from challenging the arbitrator’s decision in court.

4. Miscellaneous Issues

- Regulation generally does not preempt stricter state laws providing patients with external review rights. The vagueness of this provision will lead to increased litigation. Also, it means that employers with operations in multiple states may be subject to different and possibly conflicting requirements.
- A failure to meet any requirement, even a minor one, will give participants increased leverage against the plan in litigation, because the decision by the plan will not be entitled to deferential review by a court under the *Bruch* standard. Furthermore, the failure excuses the claimant from the generally applicable requirement of exhausting the plan’s review procedures before going to court.
- SPDs must be reviewed, and presumably expanded to include additional information, which will be a costly exercise.

Compliance with these new regulations will be costly for employers to implement and to comply with on an ongoing basis. The initial costs will be incurred in revising SPDs to reflect the new provisions, hiring third party administrators or new personnel to process claims within the shortened time frames, and installing new software and scanning systems to comply with the added specificity required for denials and to provide the necessary information on similar claims. The ongoing costs will be incurred in maintaining this expanded workforce and responding to claimants’ demands.

The DOL has estimated that the total start-up costs for complying with the new regulations through the first year (2002) will be $518 million. This figure and the cost of compliance in the future appear to be a pittance when compared to the incalculable but significant costs related to new causes of action. The provisions of these new regulations allowing states to enact stricter requirements and, as the DOL believes, permitting trial *de novo* in the event of a failure to comply with even a minor requirement of the new regulations are the new Plaintiff Attorney Relief Act—especially in light of the fact that perfect compliance with all of the provisions of these regulations will be extremely difficult if not impossible to accomplish.
Since the new regulations do not take effect until January 1, 2002, Congress can still revoke them. In fact, several members of Congress—including John Boehner (R-OH), chairman of the House Education and the Workforce Committee—have questioned the cost/benefit of these new regulations. The DOL is also considering a repeal of the regulations. Barring any such action, however, employers must take steps to ensure their plans comply with the regulations or be faced with lawsuits by the government and individuals for failing to administer properly their health and disability plans.

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