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Department of Labor Issues Final Claims Regulations

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SERVICES

On November 21, 2000, the Department of Labor (DOL) issued its final regulation governing claims procedures for employee benefit plans. 65 Fed. Reg. 70246, to be codified at 29 C.F.R. part 2560. The final regulation applies to all claims filed on or after January 1, 2002.

The proposed regulation was issued on September 9, 1998, 63 Fed. Reg. 48390, and grew out of the 1997 report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The proposed rule represented a significant change from the existing claims regulations that were issued by DOL in 1977. DOL received over 700 comments on the controversial proposed regulation, and held three days of hearings related to the rule.

The final rule does contain some significant improvements compared with the proposed rule. For example, it distinguishes between prior authorization claims and retrospective review claims and has different time frames for both. (The proposed rules treated all non-urgent claims the same.) The final regulation also eliminates the requirement that plans have five days to determine whether a claimant has submitted sufficient information to make a determination, a provision plans vigorously argued was tantamount to requiring them to make the entire determination within 5 days. The final rule also has a more reasonable effective date than the proposed rule, allowing plans more time to prepare for compliance.

Even so, the final regulation is a major departure from the current rule. In addition, DOL included several new requirements that were not found in the proposed regulation. We discuss below a summary of the final regulation, focusing on group health plans, and highlight areas that are likely to cause significant compliance burdens.

Summary of Final Regulation

A. Initial Determinations

The final regulations divide claims into four categories – urgent, pre-service, post-service, and concurrent.

Urgent Care Claims – The plan administrator must provide claimants with notice of the initial determination as soon as possible, taking into account the medical exigencies of the case, but no later than 72 hours after receiving the claim. The notice may be provided orally, as long as the plan provides a written notice within 3 days after the oral notice is provided. Notices must be provided whether adverse or not. 29 C.F.R. ¤ 2560.503-1(f)(2)(i).

If an urgent claim is incomplete or not properly filed, the plan must notify the claimant within 24 hours. The claimant will have 48 hours to provide the necessary information, and the administrator must notify the claimant of its decision within 48 hours of receiving additional information, or from the time the information was due.

Prior Authorization or "Pre-Service" Claims – The plan administrator must provide claimants with notice of the initial determination within a reasonable time period, but no longer than 15 days from receiving the claim. 29 C.F.R. ¤ 2560.503-1(f)(2)(iii)(A). Notices must be provided whether adverse or not. The time period may be extended 15 days for reasons beyond the plan's control, as long as the appropriate extension notice is provided. If an extension is needed due to lack of information, the claimant has 45 days to provide the additional information, and the time period is tolled when the extension notice is sent. 29 C.F.R. ¤ 2560.503-1(f)(4). If the claim is improperly filed, the plan must provide notice of the failure within 5 days (24 hours for urgent care). 29 C.F.R. ¤ 2560.503-1(c)(1)(i).

Retrospective Review or "Post-Service" Claims – The plan must provide notice within 30 days, and a 15-day extension is available. Only adverse benefit determinations are subject to this rule. 29 C.F.R. ¤ 2560.503-1(f)(2)(iii)(B).

Concurrent care – A reduction or termination of ongoing care is treated as an adverse benefit determination (other than a reduction by plan amendment or plan termination). The claimant must be notified sufficiently in advance to allow an appeal before the benefit is reduced or terminated. Any request to extend an urgent care course of treatment beyond the initially prescribed period of time must be decided within 24 hours, provided that the claim is made at least 24 hours prior to the expiration of the initially prescribed period. 29 C.F.R. ¤ 2560.503-1(f)(2)(ii).

Contents of Notice – For all plans, the plan administrator must provide written or electronic notice of an adverse benefit determination that must: (i) state the specific reason for the denial; (ii) reference specific plan provisions; (iii) describe additional information necessary to perfect the claim and why such information is necessary; and (iv) describe plan procedures, time limits and the claimant's right to sue. 29 C.F.R. ¤ 2560.503-1(g).

For group health plans and disability plans, the notice must also disclose any internal rule, guideline, or protocol relied on in making an adverse determination (or state that such information is available free of charge). In addition, if a claim is denied based on medical necessity or an experimental care exclusion, the notice must explain the scientific or clinical basis of the determination (or state that such information is available free of charge).

B. Appeals

For group health plans, claimants have 180 days to file an appeal of an adverse benefit determination, and every plan must have procedures to provide "full and fair review" of the initial decision. 29 C.F.R. ¤ 2560.503-1(h)(3)(i).

"Full and Fair Review" – The review must be conducted by an independent named fiduciary who is neither the original decisionmaker nor his subordinate. The claimant may submit additional information, which must be taken into account on review, and no deference is to be given to the original decision. The plan must provide the claimant access to all "relevant" documents (defined below). Where the appeal involves medical necessity or experimental claims, the named fiduciary must consult with a health care professional with appropriate training, who was neither the medical professional consulted in the initial determination, nor his subordinate. 29 C.F.R. ¤ 2560.503-1(h)(2)&(3). Plans are permitted to require two levels of review, provided that both may be conducted within the applicable time frames. 29 C.F.R. ¤ 2560.503-1(c)(2).

Urgent Care Claims – The plan must notify the claimant of its appeal determination as soon as possible, taking into account medical exigencies, but no later than 72 hours after receiving the request for review. The plan procedures must allow for oral requests for urgent appeals, and the plan must accept materials by phone or fax. 29 C.F.R. ¤ 2560.503-1(i)(2)(i).

Pre-Service Claims – If the plan provides one level of appeal, it must notify the claimant of a determination within a reasonable time, but no later than 30 days from the receipt of the appeal request. If the plan provides two levels of appeal, it must notify the claimant of the first appeal decision within 15 days of the appeal request. 29 C.F.R. ¤ 2560.503-1(i)(2)(ii).

Post-Service Claims — If the plan provides one level of appeal, it must notify the claimant of a determination within a reasonable time, but no later than 60 days from the receipt of the appeal request. If the plan provides two levels of appeal, it must notify the claimant of the first appeal decision within 30 days of the appeal request. 29 C.F.R. ¤ 2560.503-1(i)(2)(iii).

Notice of Appeal Determination – The plan administrator must provide written or electronic notice of an adverse benefit determination that must include the same information as notices for initial determination. In addition, the notice on appeal must include a statement that claimants are entitled to receive, upon request and free of charge, copies of all documents "relevant" to their claim, whether or not relied upon making a determination. The notice also must provide a description of any voluntary appeal or alternative dispute resolution procedures. 29 C.F.R. ¤ 2560.503-1(j).

"Relevant" – Relevant is defined as a document, record, or other information that (i) was relied on; (ii) was submitted, considered, or generated in the course making the determination, without regard to whether it was relied on; (iii) demonstrates compliance with the plan's procedures to ensure that claims are treated consistently; or (iv) in the case of a group health plan or disability plan, constitutes a statement of policy or guidance concerning the denied treatment option or benefit, regardless of whether relied on. 29 C.F.R. ¤ 2560.503-1(m)(8).

C. Key Compliance Issues

Procedures may not unduly inhibit claims processing. The final rule includes a new provision applicable to all plans requiring that procedures not unduly inhibit or hamper the initiation or processing of claims. 29 C.F.R. ¤ 2560.503-1(b)(3). The regulation offers the example of requiring prior approval in cases where the approval is impossible or could seriously jeopardize the life or health of a claimant (e.g., a medical emergency where the claimant is unconscious). This provision could provide a basis for (1) challenging preauthorization for emergency room visits or (2) general challenges to preauthorization requirements. For example, this provision might provide an additional basis for the Connecticut Attorney General's recent suit against Physicians Health Services alleging that the medical necessity/preauthorization provisions applicable to prescription drug benefits violated section 404. Connecticut v. Physicians Health Services of Conn., Inc., 103 F. Supp.2d 495 (D. Conn. 2000) (dismissed for lack of standing).

Required disclosure of prior similar cases. The preamble to the proposed regulation indicated that the Department was considering requiring plan administrators to disclose up to 50 similar prior cases as part of the adverse appeal notice. This provision was very controversial, and the Department decided not to include it in the final regulation. In lieu of the proposed disclosure, the Department included a new general requirement, which requires that plan provisions be applied consistently for similarly situated claimants. 29 C.F.R. ¤ 2560.503-1(b)(5). The regulation then requires administrators to make available documents and records necessary to establish compliance with this requirement as part of the "relevant" documents claimants may request. 29 C.F.R. ¤ 2560.503-1(h)(2)(iii), (j)(3). Thus, on appeal, administrators may have an affirmative duty to disclose records of prior similar benefit determinations.

Time periods are not safe harbors. The time periods established under the regulation for handling claims are maximums. Claims must be handled in shorter timeframes if "reasonable." For urgent care and concurrent care, the claims must be handled "as soon as possible" consistent with "medical exigencies."

Urgent care claims. The regulation provides for a very broad definition of urgent care, including any claim that "could" seriously jeopardize the life or health of the claimant or his or her ability to regain "maximum function." It seems possible that many claims could involve the claimant's ability to regain "maximum function." Importantly, whether a claim involves "urgent care" is determined by a representative of the plan applying a "prudent layperson" standard. Plans are not permitted to require that physicians must certify whether a claim is urgent, but if a physician does represent a claim is urgent, the physician's determination is binding on the plan. 29 C.F.R. ¤ 2560.503-1(m)(i).

Preemption: Somewhat surprisingly, the regulation includes a special preemption rule providing that the claims regulation preempts state insurance laws only to the extent that such laws "prevent the application of" the regulation. 29 C.F.R. ¤ 2560.503-1(k). This provision mirrors the narrower preemption standard in ERISA section 731, established by HIPAA for state insurance laws that regulate preexisting conditions. However, the Department does not attempt to reconcile how the narrow preemption rule in section 731 can supplant the well-established test for preemption and the insurance savings clause in ERISA section 514.

The regulation goes further and provides that state insurance laws allowing external appeals are not preempted. However, claimants cannot be required to exhaust state law external review before proceeding to court under section 502.

Taken together, the preemption provisions could be the most far-reaching and legally questionable in the entire regulation. While no appeals court has determined whether state laws regulating internal appeals are preempted, the Seventh and Fifth Circuits have split on whether state insurance laws mandating external review are preempted. Both courts found that the state external review law "related to" ERISA plans and was thus saved under the insurance savings clause. However, the Fifth Circuit found that the law was nonetheless preempted, applying a traditional federal conflicts preemption analysis. Corporate Health Ins., Inc. v. Texas Dept. of Ins., 2000 WL 792345 (5th Cir. 2000) (external review clearly augments the ERISA claim for benefits provisions under section 502(a)(1)(B)). In

contrast, the Seventh Circuit found state law did not conflict with ERISA's remedial scheme. Moran v. Rush Prudential HMO, Inc., 2000 WL 1551659 (7th Cir. 2000) (state external review law deemed part of insurance contract; participant was merely exercising rights under the plan).

Exhaustion of administrative remedies. The regulation broadly changes the settled rule that participants must exhaust administrative remedies, absent a showing of futility or irreparable harm. Diaz v. United Agric., 50 F.3d 1478 (9th Cir. 1995) (futility exception when participant shows it is certain that claim will be denied); Henderson v. Bodine, 70 F.3d 958 (8th Cir. 1995) (participant in immediate need of medical treatment). Specifically, the regulations provide that claimants will be deemed to have exhausted their administrative remedies and may proceed directly to court if a plan fails to establish or follow procedures consistent with the regulation. 29 C.F.R. ¤ 2560.503-1(l).

D. Looking Ahead

Many of the requirements in the final claims rule are also included in the various versions of the Patients' Bill of Rights, so the new rule must be evaluated against the provisions that may finally emerge from Congress rather than just the existing regulations. It seems likely that Congress will pass, and the President will sign – whether Gore or Bush – patients' rights legislation in 2001.

Managed care legislation is likely to be more sweeping than the DOL regulations and may affect the DOL regulations in a number of ways. Congress may adopt its own version of internal review that expressly trumps the DOL regulations and may direct DOL to issue new regulations consistent with the legislation. More importantly, if the new patients' rights legislation contains a general negligence standard for liability, plans would face significant risks under DOL's final rule. It might be argued that any violation of the claims regulation would become a per se negligence violation, exposing the plan to the liability rules. In addition, the availability of new damages could create incentives for participants to go straight to court and not exhaust the plan's administrative remedies.