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#### Managed Care and State External Review Statutes

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Abstract. This report discusses ERISA's existing procedure for reviewing the adverse coverage determinations of participants in employer-sponsored group health plans. The report also reviews decisions of the U.S. Courts of Appeals for the Fifth and Seventh Circuits involving the preemption of state external review statutes and legislative proposals in the 107th Congress to amend ERISA to require external review.



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# Managed Care and State External Review Statutes

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#### Summary

This report discusses ERISA's existing procedure for reviewing the adverse coverage determinations of participants in employer-sponsored group health plans. The report also reviews the recent decision by the Supreme Court involving the preemption of state external review statutes and legislative proposals in the 107<sup>th</sup> Congress to amend ERISA to require external review. This report will be updated in response to relevant legislative and judicial activity.

Currently, forty-two states and the District of Columbia have either legislation or regulations in place concerning an independent review process for enrollees in health plans.<sup>1</sup> In *Rush Prudential HMO v. Moran*, the Supreme Court concluded that an Illinois statute requiring health maintenance organizations ("HMOs") to provide for review by an unaffiliated physician when there is disagreement about the medical necessity of a covered service was not preempted by the Employee Retirement Income Security Act ("ERISA").<sup>2</sup> The Court's decision appears to have resolved a split of authority over the validity of state statutes that require HMOs to provide some form of external review for adverse coverage determinations.

This report will discuss ERISA's existing procedure for reviewing adverse coverage determinations, the recent decision of the Supreme Court, and legislative proposals to amend ERISA to require external review.

**Existing Claims Procedure.** Section 503 of ERISA requires a plan to provide "a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the

<sup>2</sup> 536 U.S. \_\_\_ (2002).

<sup>&</sup>lt;sup>1</sup> See *Consumer Grievance Procedures: Internal and Independent Appeals*, Health Policy Tracking Service, National Conference of State Legislatures (April 2002).

claim."<sup>3</sup> In regulations issued pursuant to section 503, the Pension and Welfare Benefits Administration has identified when a plan's review procedures shall be deemed "reasonable."<sup>4</sup> In general, a plan must meet specified timing requirements when making initial coverage determinations and when reviewing adverse coverage determinations. Pre-service claims, that is claims for benefits that require approval prior to obtaining medical care, must be distinguished from post-service claims or those that seek reimbursement for services rendered. The manner in which plan participants are notified of benefit determinations, as well as the content of such notifications, are also defined by the regulations.

Although the regulations do not provide for the availability of external review following the internal review of adverse coverage determinations, they do allow a group health plan to maintain two levels of mandatory review for such determinations.<sup>5</sup> Many private health plans, including Aetna U.S. Healthcare and Pacificare Health Systems, have announced that they will voluntarily provide access to external review when care is denied.<sup>6</sup> Thus, participants in such plans will have to exhaust both levels of review before they may seek relief under ERISA's civil enforcement provisions.

Interpretive guidance on the relationship between the regulations and state external review requirements is also included in the regulations. Section 2560.503-1(k)(2)(i) states:

... a State law regulating insurance shall not be considered to prevent the application of a requirement of this section merely because such State law establishes a review procedure to evaluate and resolve disputes involving adverse benefit determinations under group health plans so long as the review procedure is conducted by a person or entity other than the insurer, the plan, plan fiduciaries, the employer, or any employee or agent of any of the foregoing.

However, the regulations state that external review, albeit mandated by state law, is "not part of the full and fair review required by section 503 of [ERISA]."<sup>7</sup> Thus, the regulations indicate that participants do not have to exhaust such state law procedures before they may bring suit under the civil enforcement provisions of ERISA.<sup>8</sup>

<sup>&</sup>lt;sup>3</sup> 29 U.S.C. § 1133.

<sup>&</sup>lt;sup>4</sup> See 29 C.F.R. § 2560.503-1.

<sup>&</sup>lt;sup>5</sup> See 29 C.F.R. § 2560.503-1(c)(2).

<sup>&</sup>lt;sup>6</sup> Geraldine Dallek and Karen Pollitz, Henry J. Kaiser Family Foundation, External Review of Health Plan Decisions: An Update 2 (2000).

<sup>&</sup>lt;sup>7</sup> See 29 C.F.R. § 2560.503-1(k)(2)(ii).

<sup>&</sup>lt;sup>8</sup> *Id.* See also 65 Fed. Reg. 70,254 n.33 (Nov. 21, 2000) ("It is the view of the Department that claimants would be entitled to have a claim dispute adjudicated in court pursuant to section 502(a) of the Act after exhausting the plan's claims procedures, but without regard to State law procedures described in subparagraph (k)(2), regardless of whether such State law procedures are mandatory pursuant to State law.")

**Preemption and Corporate Health Insurance v. Texas Department of** *Insurance.* Section 514(a) of ERISA expressly preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan . . ."<sup>9</sup> The U.S. Supreme Court has interpreted this language as applying to any state law that "has a connection with or reference to such a plan."<sup>10</sup> The Court has also stated that "[u]nder this 'broad common sense meaning,' a state law may 'relate to' a benefit plan, and thereby be preempted, even if the law is not specifically designed to affect such plans, or the effect is only indirect."<sup>11</sup>

A state law that "relates to" an ERISA plan may avoid preemption if it regulates insurance within the meaning of ERISA's "saving clause." Section 514(b)(2)(A) qualifies section 514(a) by excepting from preemption "any law of any State which regulates insurance, banking, or securities."<sup>12</sup> However, an additional clause serves as an exception to ERISA's saving clause. Section 514(b)(2)(B), ERISA's "deemer clause," indicates that a state law that "purport[s] to regulate insurance" cannot deem an employee benefit plan to be an insurance company for purposes of regulation.<sup>13</sup>

Interest in ERISA's preemptive effect on state patient protection statutes has increased steadily since Aetna first indicated that it would challenge Texas' Health Care Liability Act. The Act, Senate Bill 286, became effective on May 22, 1997. Aetna promptly challenged it on the grounds that it was preempted by section 514(a) of ERISA.

The Act sought to regulate managed care in three ways. First, it provided a statutory cause of action against managed care entities that failed to meet an ordinary care standard when making healthcare treatment decisions. Second, it established an independent review procedure to determine whether treatment is appropriate and medically necessary. Third, it protected physicians from HMO-imposed indemnity clauses and from retaliation by HMOs for advocating medically necessary care for their patients.

The Fifth Circuit concluded that the liability, anti-indemnification, and antiretaliation provisions of the Act were not preempted by ERISA.<sup>14</sup> However, the Fifth Circuit found that the independent review provisions were preempted. The Fifth Circuit maintained that because the independent review provisions "attempt to impose a state administrative regime" on coverage determinations they are preempted by ERISA.<sup>15</sup>

<sup>14</sup> See also Welborn, *supra* note 10 at 15.

<sup>&</sup>lt;sup>9</sup> 29 U.S.C. § 1144. For additional discussion of ERISA's preemption provisions, see CRS Report 98-286, *ERISA's Impact on Medical Malpractice and Negligence Claims Against Managed Care Plans*.

<sup>&</sup>lt;sup>10</sup> Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 97 (1982).

<sup>&</sup>lt;sup>11</sup> Ingersoll-Rand v. McClendon, 498 U.S. 133, 139 (1990).

<sup>&</sup>lt;sup>12</sup> 29 U.S.C. § 1144(b)(2)(A).

<sup>&</sup>lt;sup>13</sup> 29 U.S.C. § 1144(b)(2)(B). See also *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 45 (1987).

<sup>&</sup>lt;sup>15</sup> Corporate Health Insurance, 215 F.3d at 537. Despite its general finding of preemption, the Fifth Circuit concluded that additional independent review language accompanying the liability (continued...)

While the court conceded that the independent review provisions did "regulate insurance" in the manner contemplated by ERISA's saving clause, it found that the provisions are preempted because they conflict with a substantive provision of ERISA.<sup>16</sup> Following the Supreme Court's determination that the saving clause must be interpreted in light of the legislative intent concerning ERISA's civil enforcement provisions, the Fifth Circuit recognized that ERISA's enforcement scheme "preempts not only directly conflicting remedial schemes, but also supplemental state law remedies."<sup>17</sup> In this case, the independent review provisions created an alternative remedy for obtaining benefits. Because a plan would be bound by the decision of the independent review organization, a participant could obtain a benefit even if he did not follow ERISA's civil enforcement procedures.

**Moran v. Rush Prudential HMO.** In *Moran v. Rush Prudential HMO*, the Seventh Circuit concluded that an Illinois external review statute did not conflict with ERISA's civil enforcement scheme and was saved from preemption by ERISA. Like the Fifth Circuit, the court determined that the statute "related to" an employee benefit plan. The court also found that the statute regulated insurance, and thus was protected by ERISA's saving clause. Further, the court maintained that ERISA's deemer clause was not applicable because the plan at issue was an insured plan, that is offered by an HMO and not self-funded by an employer.<sup>18</sup> The court relied on the Supreme Court's interpretation of the deemer clause in *FMC Corp. v. Holliday.*<sup>19</sup> In that case, the Court found that the deemer clause "makes clear that if a plan is insured, a State may regulate it indirectly through regulation of its insurer and its insurer's insurance contracts."<sup>20</sup> In this case, the plan was offered by Rush Prudential HMO.

Unlike the Fifth Circuit, the Seventh Circuit found that the Illinois external review statute does not create an "alternative remedy scheme" that conflicts with section 502(a) of ERISA.<sup>21</sup> Although the statute requires an HMO to provide a covered service if an independent reviewing physician determines that the service is medically necessary, the court found that the procedure created by the statute is "not tantamount to the relief offered" under section 502(a).<sup>22</sup> The court explained that because the provisions of the statute were incorporated into the plaintiff's insurance contract, they did not operate as an alternative remedy for recovering benefits. Rather, the provisions established an additional internal mechanism for making decisions about when a service is medically necessary. The court appears to have distinguished external review that becomes a part

<sup>&</sup>lt;sup>15</sup> (...continued)

provisions and making review voluntary on the entity's part were not preempted.

<sup>&</sup>lt;sup>16</sup> Corporate Health Insurance, 215 F.3d at 538.

<sup>&</sup>lt;sup>17</sup> Corporate Health Insurance, 215 F.3d at 538-39 (citing Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 (1987)).

<sup>&</sup>lt;sup>18</sup> *Moran*, 230 F.3d at 970.

<sup>&</sup>lt;sup>19</sup> 498 U.S. 52 (1990).

<sup>&</sup>lt;sup>20</sup> *FMC Corp.*, 498 U.S. at 64.

<sup>&</sup>lt;sup>21</sup> Moran, 230 F.3d at 971.

<sup>&</sup>lt;sup>22</sup> *Id*.

of a plan because of a state statute from external review that is simply mandated by state law.

**Supreme Court's Decision.** On appeal, the Supreme Court affirmed the judgement of the Seventh Circuit.<sup>23</sup> The Court determined that section 4-10 of the Illinois statute was a regulation of the business of insurance, and thus saved from preemption pursuant to ERISA's savings clause and the McCarran-Ferguson Act.<sup>24</sup> The Court reviewed section 4-10 against a multi-factor test used to determine whether a state law regulates the business of insurance.<sup>25</sup> Under the multi-factor test, the Court first asked whether, "with a common-sense view," the law was specifically directed toward the insurance industry.<sup>26</sup>

With regard to the Illinois statute, the Court found that, despite Rush's contrary assertions, the statute was directed at the insurance industry and did not apply to any other industry.<sup>27</sup> The Court then considered three factors established under McCarran-Ferguson to determine whether the Illinois statute should be saved from preemption. A state law would not be subject to preemption if it (1) has the effect of transferring or spreading risk; (2) if it is an integral part of the policy relationship between the insurer and the insured; or (3) if it is limited to entities within the insurance industry.<sup>28</sup> The Court noted that the factors were guideposts, and that a state law is not required to satisfy all three to survive preemption.<sup>29</sup> Applying the three factors to the Illinois statute, the Court determined that the second and third factors were clearly satisfied.

Recognizing that the statute could likely be saved from preemption under McCarran-Ferguson, Rush also argued that preemption was appropriate because Congressional intent should override ERISA's savings clause. In making this argument, Rush compared the provisions in the Illinois statute to the claims for damages which the Court found to be preempted in *Pilot Life Ins. Co. v. Dedeaux.*<sup>30</sup> In *Pilot Life*, the Court found that ERISA preempted a participant's claim for damages because the claim constituted an alternative remedy outside the limited scope of remedies Congress provided for in ERISA.<sup>31</sup> The

<sup>25</sup> See Metropolitan Life Ins. v. Massachusetts, 471 U.S. 724 (1985).

<sup>26</sup> 536 U.S. \_\_\_\_, slip op. at 8 (2002).

<sup>27</sup> Slip op. at 13.

 $^{31}$  *Id* at 57.

<sup>&</sup>lt;sup>23</sup> In its opinion, the Supreme Court acknowledged that it granted certiorari to resolve the conflict between the Fifth and Seventh Circuits. While this opinion does not directly address the Fifth Circuit's opinion regarding preemption of the Texas statute, it is likely that the independent review provisions of the Texas statute will be recognized as permissible in light of this opinion.

<sup>&</sup>lt;sup>24</sup> The McCarran-Ferguson Act requires that the business of insurance be subject to state regulation. The statute provides, with certain exceptions, that "[n]o Act of Congress shall be construed to invalidate . . . any law enacted by any State for the purpose of regulating the business of insurance . . . ." 15 U.S.C. 1012(b).

<sup>&</sup>lt;sup>28</sup> Slip op. at 16 (citing Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119, 129 (1982)).

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987).

Court distinguished the Illinois statute from the remedy sought in *Pilot Life* and other cases, finding that the Illinois statute merely prescribes "a state regulatory scheme that provides no new cause of action under state law and authorizes no new form of ultimate relief."<sup>32</sup> The Court also rejected Rush's argument that independent review was an "alternative scheme of arbitral adjudication," and thus in conflict with Congress' intent to confine dispute resolution under ERISA to the courts.<sup>33</sup> In dismissing Rush's argument, the Court noted that the state scheme was significantly different from arbitration, and was actually closer to a "mandate for [a] second opinion" rather than arbitration.<sup>34</sup>

**External Review and Patient Protection Legislation in the 107**<sup>th</sup> **Congress.** The patient protection bills passed by the House, **H.R. 2563**, and Senate, **S. 1052**, would each amend ERISA to require group health plans and health insurance issuers to provide participant and beneficiaries with the opportunity for an independent external review of claim denials.<sup>35</sup> Under both bills, first, a qualified external review entity would review the request for external review to determine whether the claim is appropriate for an independent medical review. To be eligible for such review, the claim denial must involve a "medically reviewable decision"; that is, the denial must involve a question of medical necessity, the use of an experimental or investigational item or service, or otherwise require an evaluation of medical facts. If the qualified external review, then an independent medical review will make its determination.

During its review, the independent medical reviewer would consider all appropriate and available evidence and information, including the internal review decision, the recommendation of the treating health professional, and the plan or coverage document. The determination of the independent medical reviewer would be based on the medical condition of the participant or beneficiary and valid or relevant scientific and clinical evidence. The independent medical reviewer would have to meet specified independence, licensure, and expertise requirements. Further, the independent medical reviewer would be permitted only a reasonable level of compensation. The decision of the independent medical reviewer would be binding on the plan or issuer. A determination that the plan or issuer should provide the benefit could not be appealed.

<sup>&</sup>lt;sup>32</sup> Slip op. at 23.

<sup>&</sup>lt;sup>33</sup> Slip op. at 25.

<sup>&</sup>lt;sup>34</sup> Slip op. at 27.

<sup>&</sup>lt;sup>35</sup> For more information on both bills, see CRS Report RL30978, *Patient Protection During the* 107<sup>th</sup> Congress: Side-by-Side Comparison of House and Senate Bills.