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ISSUE	H.R. 2990 – Senate Passed Amendment Patients Bill of Rights Plus Act, 10/14/99 (originally S. 1344)	H.R. 2990 – House Passed Version Division B—Bipartisan Consensus Managed Care Improvement Act of 1999, 10/14/99	COMMENTS
Health Plan Liability	No provision	Permits a plan participant/beneficiary (or the estate of either) to bring a cause of action in state court to recover damages resulting from personal injury or wrongful death against any person in connection w/ the provision of insurance, administrative services or medical services, or that arises out of the arrangement of such services, to or for a group health plan. Personal injury is defined as a "physical injury and includes injury arising out of the treatment (or failure to treat) a mental illness or disease." §1302(a)/ ERISA §514(f) No person is liable for punitive, exemplary, or similar damages if cause of action under state law relates to an external appeal decision and the plan/issuer complied with external appeal requirements and the determination of the external appeal entity in a timely fashion. §1302(a)/ ERISA §514(f) Subjects group health plan, employers, or other plan sponsors maintaining a group health plan, or employees of such employer acting w/in scope of employment, to liability if they exercise "discretionary authority to make a decision on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and the exercise . . . of such authority resulted in personal injury or death." §1302(a)/ ERISA §514(f) Exercise of discretionary authority <u>not</u> construed to include: a decision to include/exclude any specific benefit from the plan; any decision to provide extra-contractual benefits; or any decision not to consider the provision of a benefit while internal or external review is being conducted. §302(a)/ ERISA §514(e) Individuals are not required to exhaust administrative remedies (internal or external appeals) when injury or death has occurred before completion of such processes. §1302(a)/ ERISA §514(f)	**In General:** The House bill provisions will discourage plan sponsors – employers and unions – from voluntarily providing health benefits to employees. This is because the bill inappropriately expands state tort liability to all "group health plans" and treats health plan administration as if it were the same as medical practice. Any activity by any person that involves the provision or arrangement of insurance, administrative services, or medical services may give rise to a medical liability lawsuit. **Meaningless Employer Exception:** The House bill, for the first time in federal law, explicitly imposes tort liability directly on any "employer" that exercises discretion (i.e., makes a choice or decision regarding a health benefit plan) on a claim for benefits. This meaningless exception would not bar a lawsuit against an employer. In the separate role as a plan sponsor, an employer is always a "fiduciary" (defined by law as a person who exercises discretion). This exception merely offers a defense, and an employer would have to expend time and costs to prove in court that discretion was not exercised. Only by relinquishing control of employer-provided benefits would an employer be able to raise successful defenses to liability. **Illusory Punitive Damages Limit:** The House bill includes a meaningless "safe harbor" and preempts state law punitive damages in very limited circumstances. Such a "safe harbor" would apply only where the group health plan approves coverage in accordance with the determination of an independent external review entity. In fact, plans would provide the care ordered by such a review without the "safe harbor" language, and so the provision has no real impact. This will, ironically, discourage plaintiffs from seeking external review – a means to a quicker, more direct solution – because if they do not, they can then go directly to court. The trial bar, preferring actions where punitive damages are available, will encourage this approach.

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Medical Necessity	No provision	Provisions do not contain a specific definition for medical necessity, but do provide that a qualified external appeal entity (QEAE) shall determine whether the decision of the plan/issuer is in accordance with the medical needs of the patient, based upon specified evidence at the time of the external review entity's decision. The QEAE would not be bound by plan's definition of medical necessity. Among the evidence that a QEAE could take into consideration in evaluating denials of claims involving "medical judgment," questions of medical necessity or appropriateness, or the investigational or experimental nature of a course of treatment are "[c]ommunity standard of care and generally accepted principles of professional medical practice" and "government-issued coverage and treatment policies." §1103/ ERISA §514(f)	**In General:** The House bill permits an independent external review panel of providers to substitute fundamental provisions in an insurance or health plan contract for standards manufactured in the appeals process by the provider panel. This could render a private contract negotiated between health plans and plan sponsors meaningless, and the obligations of the health plan would become uncertain, and this uncertainty would result in higher premiums. **Sanctity of Contracts:** A plan could become obligated to pay for items and services based upon standards outside the contract. This would have the effect of destroying the ability of the parties to negotiate terms and conditions of contractual agreements. The "reasonableness" of the plan's determination would be replaced by the external provider panel's own standard, which would vary with each panel that reviews each case, and the obligation of the health plan would become uncertain, leaving the plan and plan sponsor open to being sued for inequitable treatment of similar claims. **Quality and Solvency**: As a result of such concerns, plans may decide to pay many claims that they otherwise would not, regardless of their "medical necessity" and the outcome for the patient, in order to avoid abrogation of the contract by the external review panel. The use of ad hoc standards imposes costs for unanticipated treatments not reflected in the actuarial data used to price the health plan's premium. This could well lead to health plan insolvency or, at a minimum, would introduce pricing factors that will increase the cost of coverage.

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Scope: **Inter-relationship of federal and state laws**	**Application of federal and state laws:** **Grievance/Appeals/Disclosure:** provisions apply to all ERISA group health plans; states may not enact provisions that "relate to" ERISA plan. **Breast Cancer Treatment:** provisions apply to all group health and individual health plans; states may not enact provisions that prevent application of federal law with respect to insured plans (HIPAA model) or that "relate to" ERISA plan.	**Application of federal and state laws:** **Grievance/Appeals/Disclosure/ Liability:** provisions apply to all group health and individual plans; states may not enact provisions that "relate to" ERISA plans; provides for non-preemption of "actions" under state law to recover damages for personal injury or wrongful death in connection with, or arising from, provision of insurance, administrative, or medical services; includes "actions" based on group health plan, employer/plan sponsor exercise of discretion. Grants states the ability to select external appeal entities for issuers. **Quality/Provider Protections:** provisions apply to all group health and individual health plans; states may not enact provisions that prevent application of federal law with respect to insured plans (HIPAA model) or that "relate to" ERISA plan.	**In General:** These bills do not assure national uniformity in the application of plan standards. Both bills assure dual regulation of group health plans.
Utilization Review	Requires every employee benefit plan conducting utilization review (UR) to provide adequate written notice of denial to plan participants/beneficiaries and to provide for a full and fair review. UR is defined as "a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review." §121(a)/ERISA §503(a),(b),(g) Requires group health plan or health insurance issuer conducting UR to make eligibility, copayment determinations; notify plan participants/beneficiaries and treating health care professionals; and respond to oral/ written requests from the plan participant/beneficiary or treating health care professional (with consent of plan participant/beneficiary).	Requires group health plans (plans) and group and individual health insurance issuers (issuers) providing health insurance coverage and any outside agents to conduct utilization review (UR) only in accordance with specified requirements. UR defined as "procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review." §1101(a)/ ERISA §714 Requires UR to be conducted consistent with written policies and procedures, utilizing clinical review criteria developed with input from a range of health care professionals (directed to meet needs of at-risk populations and individuals with severe illnesses/chronic conditions using gender-specific and pediatric-specific criteria where available). §1101(b)/ ERISA §714 Prohibits revision/modification of specific standards, criteria, or procedures during retrospective review if service was specifically pre-authorized/approved during the same course of treatment. Requires a program to evaluate clinical appropriateness of at least a sample of claims denials. §1101(b)/ERISA §714 Requires UR program be administered by appropriately trained, qualified, independent personnel. Prohibits any form of compensation to employees, agents, or contractors that encourages denial of claims. Prohibits health care professional providing services to individual from performing UR in connection with those services. §1101(c)/ERISA §714 Requires UR personnel be "reasonably accessible by toll-free telephone during normal business hours" with appropriate provision for prompt response during other hours. UR shall not be furnished more frequently than reasonably required to assess medical necessity. §1101(c)/ERISA §714	**In General:** Both bills define "utilization review" as involving a "clinical" decision making process, thus wrongly transforming an administrative procedure for coverage and payment decisions into a medical procedure. This overturns consistent federal court decisions determining "utilization review" to be an administrative procedure and could subject coverage and payment determinations to state tort liability as "medical" decisions. **Overly Broad Definition**: Both bills cast a wide net over the types of "techniques" that would be classified as "utilization review." For example, by including second opinions in the definition, many fee-for-service arrangements would become subject to full UR standards. Another effect would be to eliminate plan/issuer flexibility by "freezing" current techniques in statute, preventing the evolutionary development of new quality enhancing tools. **Micromanagement Concerns:** The House bill imposes over 70 new requirements for "utilization review" procedures that would micromanage health plans. The bill would impose shortened and ambiguous time deadline standards for "group health plans" to meet in making claims determinations. **Timeframes:** These are overly rigid, ambiguous, and much shorter than reasonable requirements that are defined on a case-by-case basis. Timelines do not distinguish between preauthorization of a service and claim payment for an already delivered medical service. This would create opportunities for mistakes due to hurried

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Utilization Review (continued)	**Time limits:** Sets prior authorization review decision time periods (non-emergency services, 30 days; expedited, 72 hrs). Plan participant/beneficiary may request that plan determine need for "expedited" review. Permits treating health care professional to document need for "expedited" review. **Notice:** Sets requirements for notice of determination to the plan participant/ beneficiary and treating health care professional (routine: written notice within 2 working days of determination; expedited: within the 72 hr. review period; concurrent: one day; retrospective: within 5 working days of determination). Notice to include reasons for denial, instructions on how to obtain additional information, and the right to appeal with instructions as to how to do so. §121(a)/ERISA §503(b)	**Time limits**: Requires UR determination be made w/in 14 days. Can be extended for 14 days if a request for necessary information is provided no later than 5 business days after receipt. Requires medical exigency (not defined) consideration. Expedited decision w/in 72 hours. Concurrent determination as soon as possible as needed, w/ sufficient time for appeal. Requires retrospective review of previously provided services w/in 30 days of receipt of information, and in no case later than 60 days. [Reference to special rules for emergency services, maintenance of care, post-stabilization care in §1113(a), (b).] Treats failure to meet deadline as a denial of the claim. §1101(d)/ ERISA §503(b) **Notice:** Requires notice of benefit claim denial to be in printed, easily understandable form for the participant, beneficiary or enrollee; contain reasons (clinical rationale) for denial, information on how to appeal, availability of clinical review criteria (upon request), and any additional information to make a decision on appeal. §101(e)/ERISA §714. Notice for concurrent review shall also include number of ongoing approved services, new total of approved services, next review date (if any). §101(d)/ERISA §714	decision-making. In effect, all claims payment determinations would have to be made within 5 days of claim receipt in order to determine whether any additional information would be needed to pay a claim. This would apply the 5 day rule to literally billions of claims reviewed annually and currently paid within a 30 day period. Pressure to comply with this requirement would harm consumers by forcing needless claims denials for insufficient information. **Medical Exigency:** Both bills condition timelines on "medical exigency." The actual timelines imposing duties and penalties for failure to meet the deadlines would be defined on an ad hoc basis by individual circumstances in each case. The meaning of "medical exigency" is not clear; but, a provider could shorten the "standard" deadline of 14 days to 1 day or 1 hour for any "sudden"/"urgent" medical problem. Industry compliance would be difficult and costly. **Fraud**: These standards would make health plan/insurer detection of fraud/abuse more difficult as claims payment decisions would be made not on the basis of the facts of a claim, but on the basis of meeting artificial time deadlines.
Claim Definition And Payment	**Definition:** A coverage determination is defined as, with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract. §121(a)/ERISA §503(g) **Prompt payment:** No provision.	**Definition:** A claim for benefits is defined as "any request for coverage (including authorization), for eligibility, or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage." A denial is defined as "a denial, or a failure to act on a timely basis upon, in whole or in part, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under this title." §1101(f)/ERISA § 714 **Prompt payment:** Requires prompt payment of claims for health care services or supplies with respect to benefits covered by the plan/issuer in a manner consistent with the Social Security Act. §1134/ERISA §714	**In General:** The bills do not clearly distinguish between coverage determinations and payment decisions. They would apply the standards established for coverage determinations to claim payment decisions. This is particularly inappropriate for payment decisions because the provider has already delivered the treatment or service.
Appeals and Grievance Procedures **Grievances**	Requires group health plan or health insurance issuer to have written grievance procedures to deal with complaints by participant/beneficiary that do not involve a coverage determination; determinations to be nonappealable. §121(a)/ERISA §503(c)	Requires group health plan and health insurance issuer in connection w/ health insurance coverage to establish/maintain a system to provide for presentation or resolution of oral/written grievances (not a claim for benefits). § 1104(a)/ERISA §714 Requires grievance process to include: written notification to individuals/providers w/ phone numbers, business addresses of personnel responsible for grievance resolution; system to record/document grievances for at least 3 years; process for timely processing/follow-up action with notification of resolution. Grievances are not subject to appeal. §1104(b)/ ERISA §714	**In General:** The use of the phrase "grievance" is easily confused with appeals for coverage denials. The types of issues under the "grievance" provisions are more clearly "complaints."
Appeals and Grievance Procedures **Internal Review**	Requires group health plan or health insurance issuer conducting UR to permit plan participants or beneficiaries to appeal an adverse coverage determination for up to 180 days of date of denial. §121(a)/ ERISA §503(d) Requires review of an adverse coverage determination be conducted by an individual with appropriate expertise not directly involved in initial determination. Requires review related to medical necessity and appropriateness, or based on experimental or investigational treatment, be conducted by physician with appropriate expertise, including age-appropriate expertise, who was not involved in initial decision. §121(a)/ERISA §503(d)	Requires group health plans and health insurance issuers offering health insurance coverage to provide adequate notice in writing to plan participants/beneficiaries whose claim has been denied with reasons for denial/rights to appeal, in manner to be understood by participant, beneficiary, enrollee, or representative. Requires full and fair review w/in 180 days. Request for review may be made orally (must be followed up in writing, no time specified). §1102 (a)/ ERISA §714	**In General:** These bills would impose over 100 new requirements in relation to internal and external appeals. Both bills would inappropriately broaden the scope of matters that are subject to review due to the definition of "claims." As previously noted, payment decisions may be subject to these rules. The provision of 180 days in which to request an appeal in both bills is unreasonably long. The current 60 day rule under ERISA has worked well and is consistent with state law and the NAIC model.

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Internal Review (continued)	**Time limits:** Sets same timelines as for initial determination for initial appeal. Sets requirements for notice of determination to the plan participant/beneficiary and treating health care professional (routine: written notice within 2 working days of completion of review; expedited: within the 72 hr. review period). §121(a)/ ERISA §503(d) Failure to respond within guidelines shall be treated as an adverse determination. **Notice:** must include reasons for determination, including clinical or scientific-evidence based rationale, procedures for obtaining additional information and notice of right to independent external review. Plans must maintain appeal records for 6 yrs. §121(a)/ ERISA §503(d)	Requires review of denial of claim involving medical judgment by physician, or by an appropriate specialist in the case of limited scope coverage, who did not make initial denial. §1102(b)/ ERISA §714. Defines limited scope coverage as coverage of only dental or vision benefits (or other coverage defined in regulation). (Does not include long-term care in definition of limited scope benefits.) §1102(b)/ERISA §714 **Time limits:** Review to be completed w/in 14 days (in accordance with the medical exigencies). Failure to make determination in timeframe treated as claim denial. If request for additional information is sent w/in 5 business days of receipt of review request, period extended for 14 days. §1102(b)/ERISA §714 **Expedited review**: (1) w/in 72 hrs or before the end of approved period of care for on-going care, (2) when normal timeframe could seriously jeopardize life or health or ability to regain maximum function or continuation of coverage. **Notice:** Requires plan/issuer to provide basis for decision/appeal rights in notice of denial. Permits information to be transmitted by telephone, fax, or other similarly expeditious method. §1102(c)/ ERISA §714 Permits plan/issuer to waive requirement of internal review and proceed directly to external appeals process. §1102(d)/ ERISA §714 Requires system to record/document appeals for at least 3 years §1104(b)/ ERISA §714.	Required review by a physician or a specialist could increase plan costs for internal review needlessly in cases in which additional information is provided, enabling claim payment and making the appeal no longer necessary. **Time Limits**: By requiring that all requests for information must be made within 5 days of the filing of the claim, both bills effectively require plans to complete reviews within that time. This is unrealistic as it would effectively require all plans to make claim payment determinations within 5 days, since that is the process in which the adequacy of information submitted is evaluated. This requirement would only encourage mistakes in a hurried review. As noted previously, the use of the ambiguous "medical exigency" rule would create an unworkable standard as well and would unreasonably expose plans to liability. The bills do not impose any obligation to provide information requested in a timely fashion on health care professionals or patients.
Appeals and Grievance Procedures **External Review**	Requires group health plan/health insurance issuer in connection w/ a group health plan to have external appeals process for adverse coverage determinations regarding (1) medically necessary and appropriate services if (a) service exceeds a significant financial threshold or (b) patient's life/health is in jeopardy; OR (2) services are experimental or investigational; AND (3) plan participant/beneficiary has completed internal appeals process. Requires group health plan/health insurance issuer to permit plan participants to file written request for independent external review of adverse coverage determination within up to 30 days of denial date. §121(a)/ERISA §503(e) Failure of group health plan/health insurance issuer to meet timeline requirements would be treated as adverse determination. **Timeframes for selection of a qualified external appeals entity (QEAE), and for submission of information to QEAE:** Routine: 5 working days or less; for parties (plan, issuer, participant/beneficiary, or physician) to forward necessary information to QEAE: 5 working days or less after notice by plan or issuer. Requires follow-up written notice to plan participant/beneficiary and plan administrator from plan or issuer. §121(a)/ERISA §503(e) **Qualifications for QEAE**: Must be licensed or credentialed by a state; state agency established to conduct independent external reviews; an entity under contract with the federal government to provide such services; an entity accredited as such by an accrediting body recognized by the Secretary; or an entity recognized as meeting criteria established by the Secretary. Requires QEAE to designate one or more independent external reviewers (IERs) within 30 days or less of notification by plan or issuer. §121(a)/ERISA §503(e) **Qualifications for IER**: Must be appropriately licensed/credentialed in a state; have no material, professional, familial, or financial affiliation with case under review or parties to it; have appropriate expertise (including age-appropriate) in diagnosis, treatment under review; be of the same specialty as treating health care professional; compensation not tied to decision rendered. IER would only be liable for arbitrary and capricious medical determinations. §121(a)/ERISA §503(e)	Requires plan/issuer provide for external appeal/review process meeting specified requirements, including those to be promulgated by Secretary. Externally appealable decision means a denial of claim for benefits based in whole or in part on decision that the item/service is not medically necessary or appropriate, is investigational/ experimental, is a medical judgment, or that plan/issuer failed to meet deadline regarding such a decision. Requires procedure to permit appeal by participant, beneficiary, enrollee, or a representative (e.g., provider) under certain conditions. §1103(a)/ ERISA §714 Permits plan to require exhaustion of internal appeal process before going to external appeal; permits filing fee not to exceed $25 (refundable if plan reversed), may not require filing fee for certified indigent individual. §1103(a)/ ERISA §714. Requires plan to contract with one or more QEAEs; use procedures to assure unbiased decisions; provide for audit to assure decisions unbiased. Requires contract terms meet standards set by Secretary; external review process cost to be paid by plan/issuer. Provides that a state may establish external review procedures for health insurance issuers. §1103(b)/ ERISA §714 **Qualifications of QEAE:** Requires plan contract only with a QEAE. QEAE required to: (1) meet independence requirements; (2) use panel of 3 or more clinical peers (among qualifications actively practicing, same specialty/sub-specialty); (3) possess sufficient medical, legal, and other expertise for timely review; and (4) meet other requirements of the Secretary. §1103(c)/ ERISA §714. QEAE must be certified/recertified as meeting requirements of Secretary, under process recognized by Secretary, or by qualified private standard-setting organization meeting standards set by Secretary. §1103(c) QEAE or peer reviewer may not have familial, financial, professional relationship with any related party; compensation must be reasonable, cannot be contingent on decision. §1103(c). Requires QEAE to determine, based on evidence submitted by each party, whether denial of claim is externally appealable; whether claim is expedited; and if internal process completed. §1103(b)/ERISA §714 Requires plan/issuer to provide QEAE w/ timely access to information, provisions of plan/coverage relating to matter being appealed. §1103(b)/ERISA §714	**In General**: The House bill inappropriately references "medical judgment" decisions of a plan; this wrongly characterizes coverage and payment decisions as medical decisions. Also, use of a plan's "failure to timely act" on a review request must be applied only when a plan has all of the information needed to make a decision. The concerns cited above about the timeframes required for the plan also apply, particularly with respect to the use of "medical exigency." This would establish a case-by-case standard that would be impossible to meet and would only create opportunities for the trial bar. **Qualifications of Reviewers**: The bills establish requirements that may be impossible to meet and could needlessly disqualify some of the nation's most qualified expert medical reviewers. The independence requirements establish conflict-of-interest standards that are so overly broad that no one may be able to qualify as a reviewer. Certain professional relationships (e.g., reviewer affiliation w/ a hospital that participates in the health plan's network) would be inappropriately characterized as a conflict under this broad standard.

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External Review (continued)	**Standard of IER review:** Requires IER to (1) make an independent determination based on valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; (2) take into consideration appropriate, available information including (a) any evidenced-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; (b) timely evidence or information submitted by the plan, issuer, patient or patient's physician; (c) the patient's medical record; (d) expert consensus including: (i) literature as defined in section 556(5) of the Federal Food, Drug, and Cosmetic Act; (ii) the following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information; and (iii) findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Agency for Healthcare Research and Quality, National Institutes of Health, National Academy of Sciences, Health Care Financing Administration, and any national board recognized by the National Institutes of Health for the purposes of evaluating the medical value of health services. §121(a)/ERISA §503(e) **Notice:** Requires plan or issuer to ensure that participant/beneficiary receives notice within 30 days of determination by IER. **Timeframes for IER review:** Determined by medical exigencies of the case: expedited: no longer than 72 hrs; routine: 30 working days/less after later of: date assigned or date when all necessary information received. §121(a)/ERISA §503(e) **Other:** Requires GAO to study completed independent external reviews and report to Congress within 2 yrs. §121(a)/ERISA §503(e) Nothing in this section shall be construed as modifying section 514 of ERISA (preemption) with respect to a group health plan. §121(a)/ ERISA §503(f) **Binding determination/reimbursement:** Proper decision of IER is binding on plan or issuer. Requires IER to set timeframe in which plan or issuer must provide coverage. If plan/issuer does not comply, participant/beneficiary may obtain items or services from any provider, and plan/issuer must reimburse for the total costs regardless of plan limitations as long as the services would have been covered and are provided consistent with the IER's determination. Plan/issuer can be sued for unpaid costs and any necessary legal expenses. §121(a)/ERISA §503(e) **Rule of construction:** Nothing shall prohibit a plan administrator, plan fiduciary, or health plan medical director from requesting an independent external review by an IER without first completing the internal review process. §121(a)/ERISA §503(f) **Enforcement:** Civil Penalties: $10,000 assessment on the plan by the Secretary to be paid to participant/beneficiary if treatment was not started as determined by IER; up to $10,000 may be imposed by the Secretary for failure to meet any other determination or timelines under §121(a)/ERISA §502(e). §121(b)/ERISA §502(c)	**Standard of Review:** External appeal process shall include a fair, *de novo* determination; QEAE shall determine whether decision is in accord w/needs of patient based on patient's medical condition and relevant, reliable evidence. QEAE may consider (but is not bound by) plan definitions of medical necessity, experimental, investigational or related terms. QEAE shall consider decision made by plan/issuer and guidelines used in decision, personal health/medical information, and the opinion of the treating professional. QEAE *may* also take into consideration, but is not limited to, results of studies/peer-review journals, government agency-sponsored professional conferences, practice guidelines, "government-issued coverage and treatment policies," "community standard of care and generally accepted principles of professional medical practice," opinions of qualified experts, results of peer reviews conducted by plan. §1103(b)/ ERISA §714. **Timeframes for review:** QEAE to give oral decision (confirmed in writing as soon as possible) or in writing w/in 21 days; w/in 72 hours for expedited decision. QEAE shall state determination basis in layperson language, provide appeal rights notice. If QEAE reverses/modifies decision, plan shall authorize benefits, take timely actions consistent with decision, submit compliance documentation to QEAE. §1103(b)/ ERISA §714 **QEAE/Peer Reviewer Protection**: QEAE/peer reviewer not subject to recourse by plan/issuer if no conflict of interest exists under regulations of Secretary. QEAE/ peer reviewer immune from civil or criminal liability if due care was exercised in performance of duty and no actual malice or gross misconduct. §1103(c)/ERISA §714 **Binding determination:** QEAE decision would only be binding on plan/issuer. §1103(d)/ ERISA §714 **Enforcement:** Any person acting in capacity of authorizing benefit is subject to civil monetary penalties of $1,000/day for failure to follow QEAE determination from date determination received until corrected. Such person shall be subject to cease and desist order, attorney's fees, and costs for noncompliance, as well as additional penalties (lesser of 25% of benefits or $500,000) for pattern or practice of refusal to authorize benefits as determined by QEAE or repeated violations. Standard of proof: clear and convincing. Any person acting in capacity of authorizing benefit subject to removal/disqualification. §1103(e)/ ERISA §714 Such person shall be subject to other causes of action/remedies under state or federal law. §1103(f)/ ERISA §714	**Standard of Review:** The use of a case-by-case standard for "medical necessity" is arbitrary and would permit different reviewers to apply a different standard to each case, even for persons covered under the same plan. Because reviewers are 'not bound by' the language of the plan document, the reviewers are empowered to stand in the place of the contracting parties rather than in the place of the previous reviewing parties. The standard of review will be inconsistent and will vary from case-to-case depending on the make-up of each separate reviewing panel and the combination of evidence employed by the panel. In addition, reviewers will make their determination based upon the "medical needs" of the patient, irrespective of the contractual coverage obligations of the plan. The use of "de novo" review would wrongly ignore any reasonableness of the plan's previous decision as well as the receipt of new information. The review should not encourage "gaming" by giving providers an opportunity to continually present evidence that may not have been available at a prior review. **Binding Determination:** The concept that an external review determination would only be binding on the plan raises legal and possible Constitutional questions. Binding arbitration is generally upheld where **both** parties contractually agree to be bound by such a decision.

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Information Disclosure	Requires a group health plan and a health insurance issuer that provides coverage in connection with a group health plan to provide comparative plan information on: covered items and services, in-network/out-of-network features/ restrictions, cost-sharing, optional supplemental benefits, PCP selection, definition of "medical necessity", appeals and grievances, access to OB/GYN or pediatricians, formularies/requests for off-formulary medications, continuity of care, access to medical records, compensation information and UR procedures. Requires Secretary of HHS to conduct a study relating to provider competencies. §112/ERISA §714	Requires that plans/issuers provide in printed form, at the time of initial coverage, and at least annually thereafter, information on: service area, covered benefits (limits/exclusions), cost-sharing (deductibles/coinsurance/liability/limitations), nonparticipating providers, experimental coverage, drug formularies, providers, POS options, referrals, accommodations for non-English speakers, emergency coverage, loss ratios, prior authorization rules, appeals, QA, information on issuer. §§1121(a), (b) Requires individuals be notified in writing before any <u>significant changes</u> are made concerning information listed above. §§1121(a), (b)/ ERISA §714 Requires that, upon request, information be made available concerning UR activities, grievance and appeals, physician compensation, credentials/list of participating providers, and formulary restrictions. §§1121(a), (b), (c)/ ERISA §714	**In General:** Much of the information requiring disclosure should already be provided under current ERISA Summary Plan Description requirements. The provisions assume that inundating individuals with more information is better for consumers, without an assessment of its actual value to individuals. Some of the proposed requirements may unintentionally cause compulsory disclosure of otherwise proprietary information to ease the discovery process for the trial bar. This provision would impose over 70 new requirements on health benefit plans and would increase administrative costs, which will have to be reflected in premiums.
Emergency Medical Services	Requires a group health plan, "other than a fully insured group health plan," to use a "prudent layperson" standard for medical evaluation, necessary emergency care services, "emergency ambulance services" including additional emergency care to stabilize an emergency medical condition following an emergency medical screening. §101/ERISA §721 Requires maintenance of medical stability. When a non-participating provider provides care to maintain stability, health plans must reimburse if: (1) coverage for services of the type furnished is provided under the group health plan and (2) the provider has contacted the plan regarding approval. If the group health plan fails to respond within one hour of being contacted, the plan is liable for the cost of stability maintenance care. Plan participant cost sharing is limited to in-network amounts. §101/ERISA §721	Requires plan/ issuer providing <u>any</u> benefits for services "in an emergency department of a hospital" to provide coverage w/out prior authorization, whether or not furnished by a participating provider; a plan participant/beneficiary would be liable only for copayments incurred as if services were provided in-network, without regard to any other term or condition of coverage (other than an exclusion, coordination of benefits, affiliation, waiting period, or applicable cost-sharing). §1113/ ERISA §714 Requires use of a prudent layperson standard; defines emergency services to include medical screening, further medical examination, and treatment to stabilize (treatment necessary to assure no material deterioration of the condition to result from the transfer). Requires reimbursement for maintenance care or post-stabilization care if such benefits are available under the plan. §1113/ ERISA §714	**In General:** The mandate for payment of all emergency medical services provided to a patient by a non-network provider must be limited to ensure that the covered medical services are directly related to the emergency medical condition for which the patient has sought care. **Balance Billing:** These provisions would limit the patient's copayments to the level that would have been required if care had been received in-network, but they do not provide any comparable capping mechanism for health plan payments to non-network providers.
Medical Communica-tions ("gag clauses")	Prohibits a group health plan, "other than a fully insured group health plan," from restricting or prohibiting providers in communications with patients regarding health status of the participant or medical care/treatment for the condition/disease. §101/ERISA §727	Prohibits the provisions of any contract or agreement or the <u>operation of any contract or agreement</u> from restricting the ability of a health care professional to advise his/her patient regarding health status, medical care, or treatment regardless of whether such benefits are covered under the plan, if the professional is acting within the lawful scope of practice. § 1131/ ERISA §714 Renders null and void any contract or agreement restricting medical communication. §1131/ ERISA §714	**In General:** The GAO has been unable to find any evidence of the existence of gag clauses in health plan provider contracts. But both bills, as drafted, would require review of every sentence in each network agreement, involving hundreds of complex clauses. For example, these provisions would establish a very subjective standard under which a provider might assert that a phrase or clause has the effect of prohibiting or restricting the provider's ability to give desired advice. This ambiguous standard favors providers and will be used to challenge many contract provisions, such as those relating to quality of care, and render otherwise valid terms and conditions null and void. This approach would be used by the trial bar to bring frivolous lawsuits.

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Access to Specialty Services	Requires a group health plan "other than a fully insured group health plan" to allow female participants whose PCP is not an OB/GYN direct access to OB/GYNs for pregnancy, routine and preventive women's health care services. Requires plans to treat the ordering of other routine care by an OB/GYN as if the patient's PCP authorized it. §101/ERISA §723 Requires group health plans "other than a fully insured group health plan" to allow child participants whose PCP is not a pediatrician direct access to pediatricians for routine care. Requires plans to treat the ordering of other routine care by a pediatrician as if authorized by patient's PCP. §101/ERISA §724 Requires a group health plan, "other than a fully insured group health plan" to ensure participants have timely access to primary and specialty health care professionals as needed for covered services. Coverage may be provided through network providers or, if necessary, contractual arrangements with out-of-network providers. Does not prohibit a plan from including providers only to the extent necessary to meet the needs of the participant. Plan may require that specialty care be provided pursuant to a treatment plan developed by specialist in consultation with the PCP or case manager and the participant, approved by the plan, and in accordance with plan QA and UR standards. §101/ERISA §725	Requires plans/issuers that provide for designation of primary care provider (PCP) to permit each participant, beneficiary and enrollee to designate any participating PCP who is available. §1112(a)/ ERISA §714 Requires plans/issuers to provide <u>medically necessary or appropriate specialty care</u> from any qualified participating health care professional available. Rule of construction provides that such requirement is inapplicable if plan/issuer clearly informs individuals of limitations of choice of professionals w/ respect to such care. §1112(b)/ ERISA §714 Requires plans/issuers to make available or provide for referral to a specialist for an individual with a 1) condition or disease of sufficient seriousness and complexity; and 2) where benefits for such treatment are provided under the plan or coverage. A specialist may be a health care practitioner, facility, or center that has adequate expertise through training/experience. Plan/Issuer may require that care be provided pursuant to a treatment plan (developed by the specialist, approved by plan in consultation with PCP, in accordance with applicable QA and UR standards). Plan not required to provide for referral to nonparticipating specialist, unless no participating specialist with appropriate expertise is available. §1114(a)/ ERISA §714 If plan refers individual to a nonparticipating provider, costs shall not exceed in-network amounts. Requires plan to maintain procedures to coordinate care for individuals with "ongoing special conditions" (disease that is life threatening, degenerative or disabling and requires care over a long period) to request/receive referrals to specialists. Specialists above shall be permitted to treat w/out a referral from PCP. Requires procedure for individuals who require ongoing specialty care to receive standing referral. §1114(b)/ ERISA §714 Prohibits plan from requiring authorization or referral for coverage of gynecological care and pregnancy related services of participating OB/GYNs. Provides care ordered by participating professional as authorized by PCP. §1115/ERISA §714 Permits designation of pediatric specialist as a child's PCP. §1116/ ERISA §714 If plan refers individual to a nonparticipating provider, costs shall not exceed in network amounts. Requires plan to maintain procedures to coordinate care for individuals with "ongoing special conditions" (disease that is life threatening, degenerative or disabling and requires care over a long period) to request/receive referrals to specialists. Specialists above shall be permitted to treat w/out a referral from PCP. Requires procedure for individuals who require ongoing specialty care to receive standing referral. §1114(b)/ ERISA §714 Prohibits plan from requiring authorization or referral for coverage of gynecological care and pregnancy related services of participating OB/GYNs. Provides care ordered by participating professional as authorized by PCP. §1115/ERISA §714 Permits designation of pediatric specialist as a child's PCP. §1116/ ERISA §714	**In General:** The bills would allow individuals to seek specialty care from non-participating providers. Application of the ambiguous "medical exigency" standard will require a case-by-case review of each of these requirements. Current law imposes strict duties upon plan fiduciaries to make decisions about the expenditure of limited plan assets in the best interests of each individual covered; however, plan fiduciaries also are required to balance individual needs against the needs of all plan participants. Fiduciaries can be held liable for inappropriately spending plan assets on a few individuals when reviewed in the context of the group's needs. **Effect on Plans Requiring PCPs:** Particularly in health plans requiring the designation of a PCP, this provision will undermine the ability of health plans to coordinate care for the majority of health plan enrollees. **Imprecise language:** The vagueness of the term "appropriate specialist" will invariably lead to extensive legal challenges to – and external appeals of – health plan participating provider requirements. This requirement would have a negative impact on health care costs and, therefore, on the numbers of people without health care coverage. More importantly, it would have a negative effect on attempts by health plans to implement managed care mechanisms designed to coordinate and improve the quality for care for plan participants.
Continuity of Care/ Transi-tional Care	Requires a group health plan, "other than a fully insured group health plan," to notify plan participants on a timely basis of coverage termination/changes, provide participant with opportunity to notify plan of need for transitional care, and allow participant to receive care from that provider for 90 days from date that plan provides notice of termination, or through: post-partum care for enrollees in 2nd trimester of pregnancy, end of a period of institutionalization for persons so confined, or end of life for terminally ill persons. Requires provider to accept plan payment, adhere to plan standards, policies and procedures. §101/ERISA §726 Requires MedPAC to prepare and submit a report on costs, patterns of care for persons with serious, complex conditions and possibilities of improving upon that	Requires plan/issuer to notify individual with ongoing special condition on a timely basis of the right to elect continuation of coverage of treatment by their provider and permit individual to elect to continue to be covered during transitional period (90 days). The term "ongoing special condition" includes a condition that is life threatening, degenerative, or disabling; that requires specialized medical care over a prolonged period of time; and pregnancy. "Termination" includes non-renewal and expiration, but does not include termination because of fraud or failure to meet quality standards. §1117 Provides for continuation of care beyond 90 days and until discharge for scheduled	**In General:** Continuity of care provisions should focus on the continuity and quality of care provided to the individual in transition, not on the continuity of care delivered by the provider. The granting of an independent right of transition to plan participants would not encourage them to work with their health plans during the transitional period to select another provider when and as appropriate. The "notice" requirements of the proposals would create a tremendous administrative burden that would result in attendant significant cost increases. Depending on the type of coverage plan involved, health plans are in many cases not

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Continuity of Care/ Trans-itional Care (continued)	care (within 12 months upon date of enactment). §101/ERISA §726 Requires AHCPR to conduct studies on possible thresholds for major conditions causing serious and complex illnesses, impact on costs, quality (within 12 months upon date of enactment). §101/ERISA §726 Requires HCFA to conduct studies on merits of applying similar thresholds in M+C programs, including adapting risk adjustment (within 12 months upon date of enactment). §101/ERISA §72	surgery or organ transplant, or if on established waiting list. Continuation provided if pregnant at time of termination or if terminally ill for remainder of life. §1117 Permits conditioning coverage on provider acceptance of reimbursement, quality standards, cost sharing, polices/procedures, and prior authorization. §1117/ ERISA §714	aware of enrollee-physician relationships. These bills place no obligation on providers requiring them to identify which of their patients are covered by the health plan. It is not clear under the bills whether a mere voluntary change of provider by an individual would be considered a "termination"; providers do not appear to have any responsibilities to health plans or to patients when they voluntarily leave a network or an area It is unclear how these requirements apply to arrangements such as preferred provider organizations. To some extent this mandate would apply unevenly; the type of continued access that a patient would have to a health care professional whose contract with a health plan was being terminated would depend – at least in part – on the type of plan covering the individual (e.g., closed panel HMO, an HMO with a POS option, a PPO, etc.) This provision could encourage health care providers to "game" the system, canceling contracts as a negotiating ploy.
Point-of-Service (POS) Option	Requires a group health plan, "other than a fully insured group health plan," providing coverage through a defined set of participating health care professionals to offer participants the option to purchase POS coverage at the time of enrollment/ other times the plan offers participants a choice of coverage options. §101/ERISA §722 Does not apply to plans to which a POS coverage option is not available or accessible within reasonable promptness. Exempts self-insured small employers (at least 2, but not more than 50 employees). Does not include coverage of providers that the plan excludes because of fraud or quality of care. Allows plans to impose higher premiums/cost sharing, but does not require an employer to pay additional costs or to make additional contributions with respect to POS option. §101/ERISA §722	Requires a health insurance issuer who offers enrollees health insurance coverage in connection with a group health plan that only provides for coverage of in-network services to also offer enrollees, at the time of enrollment and annually (during open season) thereafter, the option of non-network coverage through another group health plan or other health insurance issuer in the group market. §1111/ERISA §714 Enrollees responsible for additional premiums and cost sharing unless paid by sponsor through arrangement with issuer. §1111/ERISA §714	**In General:** This provision would eliminate the consumer and employer choice of a network-only arrangement. A mandatory POS would compel network-based plans to pay for services provided by non-network providers. The provision would also conflict with quality standards because network plans cannot require non-network providers to meet standards or to monitor care for outcomes reporting. Exceptions to this requirement, while well intended, would require extensive micromanagement to ensure that a POS arrangement is not available with reasonable promptness, or that another plan or issuer has arranged coverage.
Provider Nondis-crimination/ Retaliation	Prohibits a group health plan, "other than a fully insured group health plan," from discriminating against a provider acting within the scope of his/her license/certification solely on the basis of such license/certification. Does not require a plan to offer coverage that includes participation of every willing provider or health professional that meets the plan's terms/conditions. Does not restrict plan from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan. §101/ERISA §730A	Prohibits plans/issuers from discriminating with respect to participation or indemnification of providers, solely on the basis of a provider's license or certification. §1132/ ERISA §714 Does not require coverage of particular benefits/services; does not prohibit plans from establishing quality measures; does not prohibit inclusion of providers only to the extent necessary to meet needs of participants, enrollees, or beneficiaries. Does not override state licensure, scope-of-practice law, or require plan/issuer to include every willing provider who meets conditions of the plan. §1132/ ERISA §714 Prohibits plans/issuers from retaliating against an individual or health care provider based on their participation in an UR/grievance process. §1135(a)/ ERISA §714 Prohibits retaliation/discrimination against a protected health care professional because the professional: disclosed information in good faith information to public regulatory agency, private accreditation body, or management personnel of the plan/issuer; or cooperated in an agency investigation. §1135(b)/ ERISA §714 **Notice:** Requires posting a notice of this information. §1135(b)/ ERISA §714	**In General:** This provision would give providers statutory leverage over health plans in both the network selection process and termination process. Even though certain rules of construction are included with respect to quality and patient needs, providers would use the general rules to challenge their exclusion or contract termination by a health plan. This will increase administrative costs and discourage rigorous quality standards for network participation.

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Access to Clinical Trials	Requires a group health plan, "other than a fully insured group health plan," to pay for the routine costs of approved cancer clinical trials. Routine payment costs do not include the cost of tests or measurements conducted primarily for the purpose of the clinical trial involved. §101/ERISA §730(a) Establishes a committee to develop standards for "routine costs." §101/ERISA §730(a)	Prohibits plans from denying qualified individuals from participation in clinical trials; imposing additional conditions; failing to pay for routine patient costs; discriminating on basis of participation in such trial. Plan may require use of participating provider who is participating in the clinical trial. §1119(a)/ ERISA §714 Qualified individuals are those covered under the plan with life-threatening/serious illness, no effective standard treatment, and meaningful potential for significant benefit. §1119(b)/ ERISA §714 Requires payment of routine patient costs, but not those reasonably expected to be borne by sponsors. Approved clinical trials: clinical research study/investigation funded by one or more federal agencies (NIH, DVA, DOD). §§119(c) and (d)/ ERISA §714	**In General:** This mandate broadly includes certain procedures that have not been proven to be effective in cancer treatment, and which are more characteristic of basic research (Phases I and II). The requirement is open-ended and will prove to be costly. These provisions and those dealing with the requirements for external review of experimental or investigational treatment are redundant. If both were to be enacted, which one of these requirements would prevail? In addition, the mandate lacks appropriate patient safety standards and, as drafted, could expose patients to harm and plans to liability if a patient were to die as a result of a problematic trial. This mandate would raise the same concerns regarding plan fiduciary responsibility as cited above.
Prescription Drugs	Requires a group health plan, "other than a fully insured group health plan," that provides coverage for prescription drug benefits and limits the coverage to drugs in formularies, to ensure that physicians, pharmacists participate in formulary development, review. §101/ERISA §728 Requires plan coverage for non-formulary alternatives considered medically necessary and appropriate. §101/ERISA §728	Requires plan/issuers that limit drugs to those in formulary to ensure: 1) participation of participating physicians/pharmacists in development of the formulary; 2) disclose the nature of formulary restrictions to individuals and providers; and 3) provide for exceptions from formulary when non-formulary is medically indicated. §1118/ ERISA §714	**In General:** This mandate would broadly apply to plan benefit designs beyond a closed formulary. Prescription drug coverage can be more affordable under benefit designs that include variations in copayment structure. The proposed mandate would prohibit such "tiered" copays; this would increase premiums or require a reduction in benefits for consumers because plans would have to cover non-formulary drugs as preferred drugs. This provision would also limit the effectiveness of PBMs to control costs that have on average increased 10 percent to 20 percent annually in recent years.
Mental Health	Prohibits a group health plan, "other than a fully insured group health plan," from discouraging or prohibiting participants from self-paying for behavioral health care services, once the plan has denied coverage of such services. §101/ERISA §729(a) Prohibits such plans from terminating provider for accepting self-payment from participants for non-covered behavioral services/those with limited coverage. Does not prohibit termination if the provider fails to meet quality standards or for fraud. §101/ERISA §729(a)	No provision	**In general:** The provisions with respect to self-pay will complicate the administration of privacy protections. While individuals should have the discretion to spend their own money on personal health care as they choose to, allowing mental health providers to simply charge individuals for treatment that the health plan does not consider medically necessary or appropriate would effectively undercut one of the tools that health plans use to influence providers to use "best practices."

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Physician Incentives	No provision	Prohibits any physician incentive plan unless requirements under the Social Security Act are met; applies requirements of the Social Security Act (relating to incentive plans) as if the appropriate Secretary imposes requirements. §§1133 (a), (b)/ ERISA §714	**In general:** The imposition of Medicare rules on the private health plan market would seriously impair the ability of plans to encourage quality care delivery. It is critical when, in light of the recently released Institute of Medicine study, up to 98,000 individuals have died because of medical mistakes, that health care quality incentives be applied appropriately. The provision assumes that "improper" provider incentives only exist in managed care, ignoring various arrangements that exist between providers that create incentives to over treat patients regardless of medical need. Providers are not required to even disclose such financial relationships with each other (i.e., physician hospital privileges, purchase of practices, joint ventures, provision of management services) or malpractice and disciplinary histories.
Services related to Mastec-tomies	Requires group health plans/health insurance issuers that provide coverage in connection with a group health plan that provides medical and surgical benefits to ensure inpatient coverage for treatment of breast cancer determined by attending physician to be medically necessary, in consultation with the patient following a mastectomy, a lumpectomy, or a lymph node dissection. §201/ERISA §715 Prohibits group health plans/health insurance issuers providing health insurance coverage in connection with a group heath plan from providing financial or other incentives to reduce length of inpatient stays or limit referrals for secondary consultations. §201/ERISA §715 Requires coverage for secondary consultations regardless of outcome of initial consultation. If the recommended specialist is not in the plan's network, but the attending physician has certified the secondary consultation to be necessary, then the health plan must cover the services as if the specialist were a provider participating in the plan's network. §201/ERISA §715	No provision	**In General:** These provisions would grant providers complete freedom from any utilization review requirements for the specific aspects of breast cancer treatment outlined and would attempt to obligate plans to reimburse providers for any treatment that they chose regardless of the merits of the course of treatment. Most importantly, it would prevent health plans from implementing managed care mechanisms designed to coordinate and improve the quality for care for consumers/plan participants. It continues the practice of mandating coverage by "body part."